







Adapt



Avoidable Problems



Team Approach



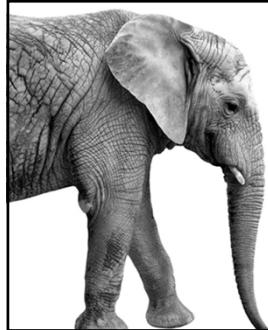


Data



Be on the lookout for...





Don't forget!
@oigathhs





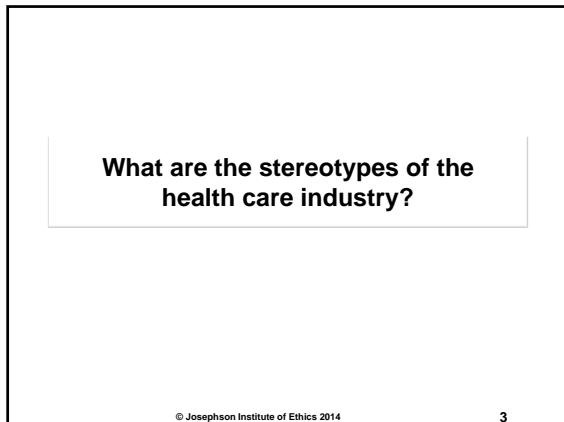
**ETHICS: THE FOUNDATION OF AN
EFFECTIVE COMPLIANCE PROGRAM**

Compliance and Ethics Institute

by Michael Josephson Josephson Institute of Ethics



How excited are you to find out that a lawyer will be talking to you about ethics and character?



**What are the stereotypes of the
health care industry?**

Stereotypes associated with hospitals

\$\$\$\$ – everything costs too much

Indifference – no one cares about the pain, discomfort or time of patient

Overly concerned with avoiding law suits

Inefficient

Bureaucratic maze – paperwork, paperwork

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Internal Perspective

Insurance companies have too much control

Lawyers are predators that increase costs and negatively affect medical decisions

Double standards for doctors and everyone else

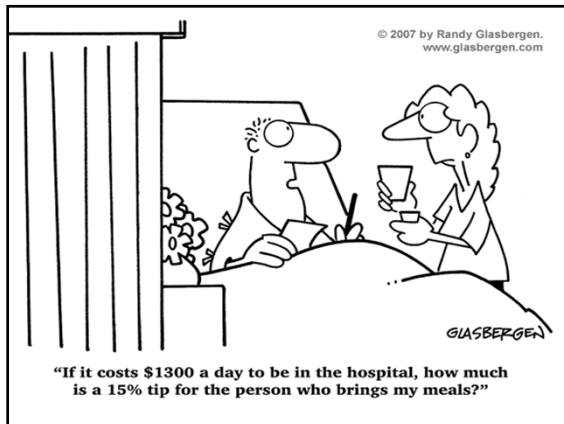
Indifference – no one cares about the employees

Bureaucratic maze – paperwork, paperwork

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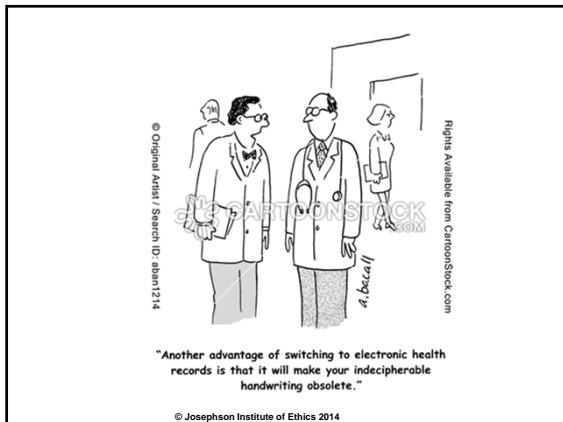




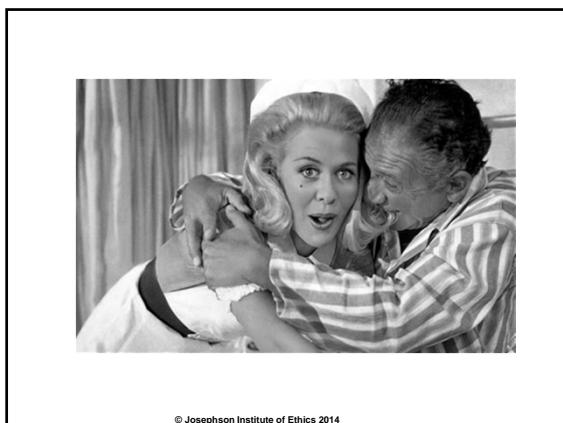












Nurse Ratched



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Major Challenges: People Issues

- 1 • Do you consistently hire service-oriented people with positive, can-do attitudes?
- 2 • Does management consistently addresses poor performance in a timely and constructive manner?
- 3 • Do you consistently reward and recognize people for their contributions and results, as opposed to allowing entitlement to drive results?
- 4 • Are reports on performance prepared and used within the company consistently give a fair and accurate view of employee performance?

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Excerpts of Alternative Version of Hippocratic Oath by Dr. Louis Lasagna (Dean of the School of Medicine at Tufts University) 1964

I will remember that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug.

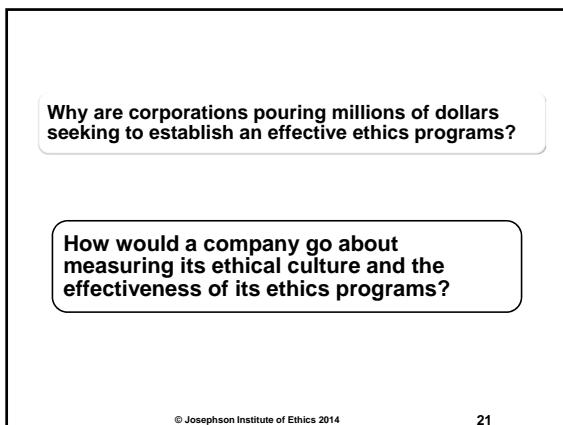
I will remember that I do not treat a fever chart, a cancerous growth, but a sick human being, whose illness may affect the person's family and economic stability. My responsibility includes these related problems, if I am to care adequately for the sick.

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The Compliance Mandate

In our current highly regulated and scrutinized business environment, corporations devote substantial resources to prevent resource-draining and reputation-damaging conduct that could result in criminal penalties or civil liability.

Because such conduct cuts profits, principles of prudence and self-interest impose a duty on management to take whatever steps are needed to assure that employees comply with laws and regulations

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Objective of a Compliance Program

The objective of a compliance program is to detect and prevent unlawful conduct within the corporation.

To achieve this a company must develop mechanisms to assure that employees know the law and increase the likelihood that they will obey it by establishing detection and reporting processes that create a credible likelihood that lawbreakers will be caught and disciplined.

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Compliance Centered Hierarchy of Objectives

- Promote Ethical Culture
- Prevent Ethically questionable conduct
- Prevent Unethical (lawful but awful) conduct
- Prevent Civil liability
- Prevent Regulatory violations
- Prevent Criminal conduct

Potential Impact of Illegal, Unethical or Questionably Unethical Conduct	Lost Profit & Growth
	Difficulties in Talent acquisition and retention
	Diminished Employee Pride and Morale
	Loss of Trust & Credibility
	Damaged Reputation

ETHICS: THE ROOT OF COMPLIANCE

HISTORY OF THE COMPLIANCE MOVEMENT

- Intensified focus on detecting and preventing illegal conduct began in the 1980s as a result of high profile business-government scandals including reports that millions of public dollars were being wasted on vastly overpriced components (e.g., \$600 hammers)
- President Reagan appointed a blue ribbon commission to study the problem resulting in the 1986 Packard Commission report.
- Led to Defense Industry Initiative on Business Ethics and Conduct with explicit goal to promote business ethics (the report was primarily about greed and waste - the criminal dimension of the misconduct was relatively small.)

Movement from Compliance to Ethics

In 1991 Federal Sentencing Guidelines for Organizations (FSGO) defined the elements of an effective compliance and ethics program and created a major incentive (i.e., sharply reduced penalties for violations) for companies to implement an effective compliance program.

The accounting scandals in the early 2000s demonstrated that too many companies had employed "window-dressing" compliance programs that met the letter of the law, but were essentially ineffective.

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FSGO – Carrot and Stick

The FSGO dramatically increased penalties for corporate violations (average fine imposed increased from under \$200,000 to more than \$3 million in 3 years) - a big stick to encourage companies to prevent misconduct.

The FSGO also offered a very large carrot by reducing penalties by as much as 90% if the company can demonstrate that at the time of the violation they had in place an effective compliance and ethics program.

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"Compliance is more than looking to the letter of the law. Indeed,...many organizations that have compliance programs already describe them as ethics and compliance programs and also employ 'ethics officers'.... [In fact] it is questionable whether a compliance program can be truly effective if it does not have an ethics component."

- Judge Diana E. Murphy,
Chair of the U.S. Sentencing Commission (2002)

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"Experience suggests that good ethics programs and good compliance programs are interdependent; each is incomplete without the other.

"A good compliance program must emphasize values and moral responsibility, because this increases the program's effectiveness among employees."

- Dawn-Marie Driscoll (cited by Judge Diana E. Murphy, Chair of the U.S. Sentencing Commission in 2002)

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Movement from Compliance to Ethics

In 2004 the Guidelines were amended with the explicit warning that "check the box" compliance programs would be insufficient to justify a sentencing reduction.

Under the revised guideline the judge must find that the program "promote[s] an organizational culture that encourages ethical conduct and a commitment to compliance with the law."

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2004 Amendments to FSGO require organizations to:

Identify areas of risk where criminal violations may occur

Train high level execs as well as employees in relevant legal standards

Give compliance /ethics officers sufficient authority and resources to carry out their responsibilities.

Demonstrate program is more than "check the box" re: each component - program could be reasonably expected to make real impact on organization's culture and behavior.

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2012 Amendments to FSGO

Require not only promoting compliance with laws, but promoting a "Culture of Compliance." The key elements:

1. A Compliance Officer with authority and operational responsibility for the program.
2. Establishing standards and procedures.
3. Communicating standards, procedures and other aspects of the program.
4. Board of Trustee oversight of program implementation and effectiveness.
5. Periodic reporting to high level personnel and the Board by the Compliance Officer.
6. Monitoring, auditing, and periodic evaluation of program effectiveness.
7. A confidential mechanism for reporting legal violations or seeking guidance without fear of retaliation.
8. Responding appropriately to criminal conduct with corrective action.

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"A parade of major scandals culminating in the most damaging and costly demonstration of wholesale corporate irresponsibility in history—the worldwide economic crisis created by the mortgage brokers and other financial institutions—should convince the folks in the C-suites and the boardrooms that no matter how good they look or expensive they are, internal control programs that focus almost entirely on compliance haven't and won't protect their organizations from reputation-damaging, resource-draining scandals. They also will not meet the new standards of federal prosecutors and regulatory agencies."

- Michael Josephson, "It's time to get serious about the ethics dimension of your compliance program" *Compliance & Ethical Professional April 2014*

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Evaluating a Program : Overall Design

Detect, deter and/or prevent conduct that subjects company to:

- Criminal prosecution and penalties
- Government regulatory actions and penalties
- Civil suits and liability
- Reputation damaging publicity
- Resource draining defensive action

Meet federal standards under Federal Sentencing Guidelines

Create a sustainable ethical culture that generates trust, credibility, and employee morale.

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BOLD ASSERTION #1

If we create a positive ethical culture that nurtures and demands a high level of integrity, respect, fairness and kindness the likelihood of major incidents damaging your institution's reputation and draining its resources is sharply reduced.

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BOLD ASSERTION #2

We can identify culturally accepted attitudes and behaviors that subject the institution to financial and reputational risks.

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BOLD ASSERTION #3

No matter how culturally entrenched, we can sharply reduce dangerous and damaging conduct almost immediately and eventually convert it to a minor concern if we devise and implement an effective detection and enforcement system.

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BOLD ASSERTION #4

Once behavioral norms change, the culture will follow.

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BOLD ASSERTION #5

Someone with the authority to reduce unacceptable risks already knows about but accepts or looks the other way at conduct that should be eliminated.

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**Which is the bigger problem:
Compliance or Ethics**

Compliance

Ethics

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If we solved all compliance problems would we also solve all or most of our ethical problems?

If we solved all ethical problems would we also solve all or most of our compliance problems?

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Ethics Is Bigger Than Compliance

Compliance is about doing what you are required to do by laws or rules.

Ethics is about doing what you should do because it is right.

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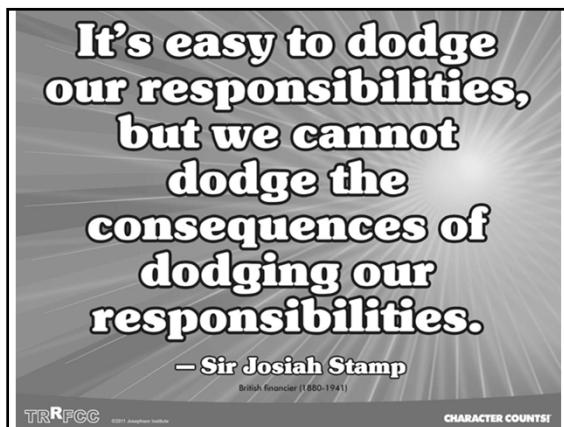
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Ethics is more than rhetoric...

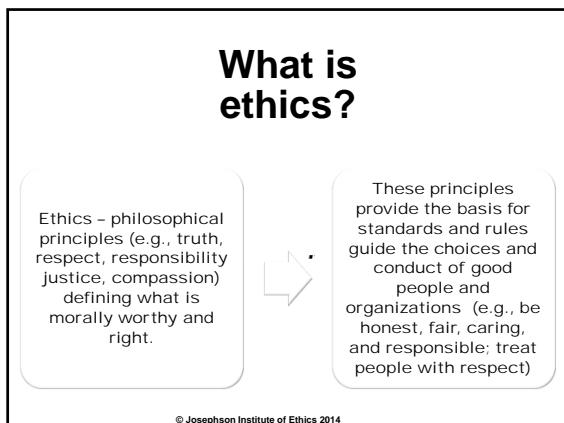
A Venn diagram consisting of three overlapping circles. The top circle contains the text: "It is not about what we say, or what we intend. It is not a written code or a framed credo." The bottom-left circle contains the text: "It's about what we DO". The bottom-right circle contains the text: "Ethics is about ACTIONS."

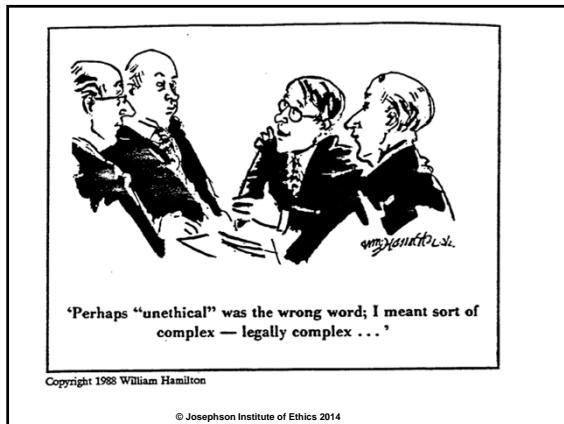
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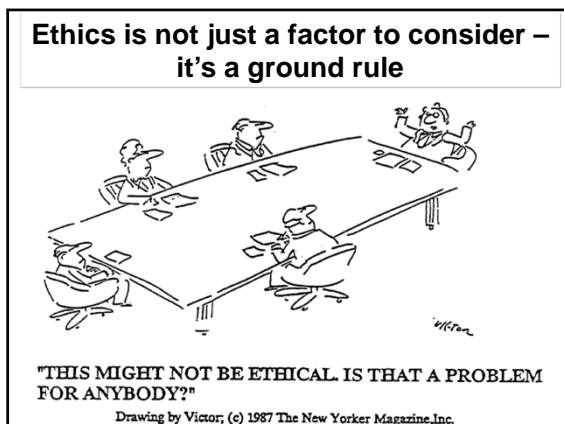
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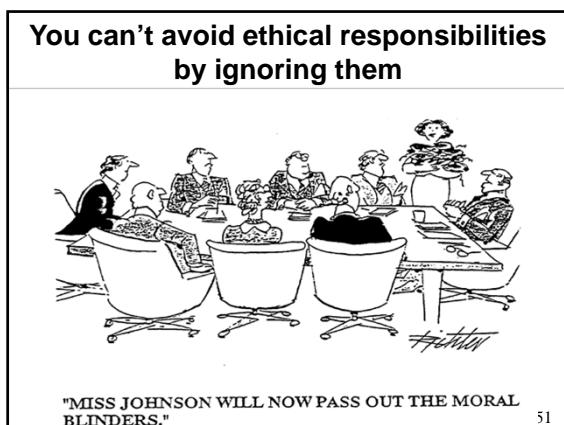












Big E ethics

- core principles about moral right and wrong; what it is to be a good and worthy person/institution

Little E ethics

- laws and rules (compliance ethics); gifts, conflicts of interest, etc. The Professional Code of Conduct

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Perceptions and Mindsets

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What is a Mindset

A habitual or characteristic mental attitude or an inclination or disposition that influences or determines a person's responses to and interpretations of situations.

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Do you see the arrow?



The FedEx logo is displayed in its signature bold, sans-serif font. The letter 'E' is stylized to contain a white arrow pointing to the right. A registered trademark symbol (®) is located to the right of the 'x'.

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Do you see the arrow?



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Do you see the arrow?

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Valuable Insights

Once you realize that messages and images are often embodied in negative space (the white space) you will look for such messages and often find them.

This is an example of a strategy that can open up your mind

Look for messages in the white space

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WHAT DOES YOUR ARROW SAY ABOUT YOU?

What values are critical to you personally?

What values are critical to your firm?

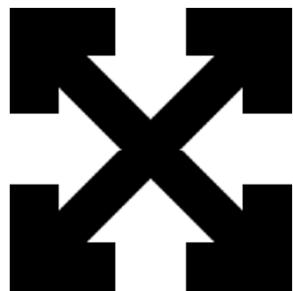
How do you assure that everyone in your firm upholds your values?

What is your responsibility to your clients to assure that they conduct business ethically as well as legally?

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How many arrows are there?



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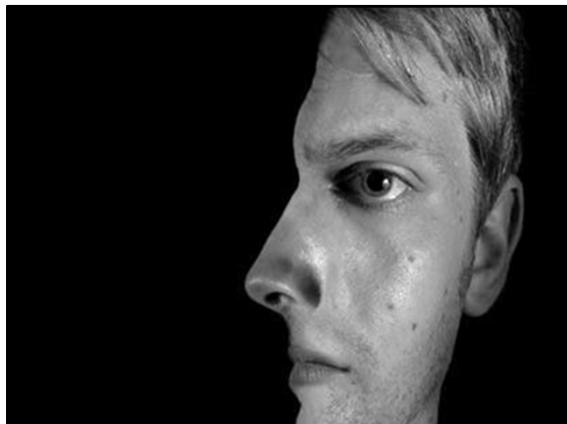
What do you see?

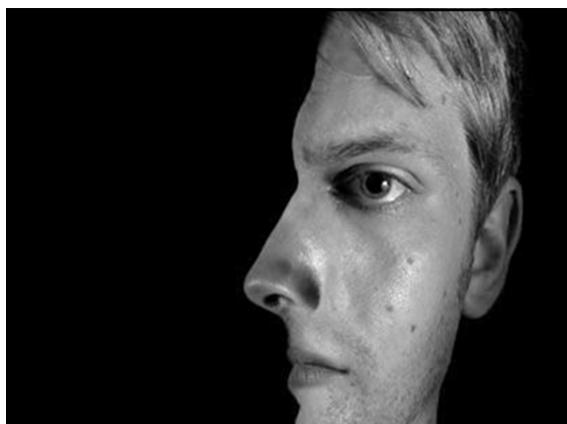


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An illustration showing three stonecutters working on a large brick structure, which appears to be a cathedral under construction. One cutter is at the top, another in the middle, and a third is at the base.

Three stonecutters were asked what they were doing.

- The first man replied: "I am making bricks from this stone."
- The second said: "I am making the foundation for a building."
- The third answered: "I'm building a cathedral."

So what? What difference does it make how a person looks at his work?

If you change your perspective you change the way you experience the world.

The Parable of the Master Carpenter



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Bagger Vance

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Ethics is about right and wrong and how an honorable person should behave.

Values refers to all important beliefs. Ethics refers only to beliefs about moral right and wrong.

← Values Are Different Than Ethics →

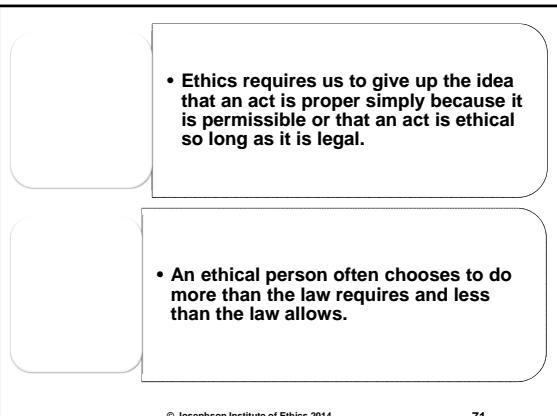
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There's a big difference between what you have a right to do and what is right to do.

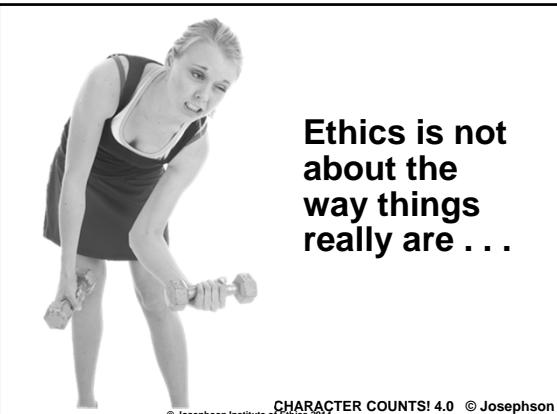
Justice Potter Stewart, U.S. Supreme Court



• Ethics requires us to give up the idea that an act is proper simply because it is permissible or that an act is ethical so long as it is legal.

• An ethical person often chooses to do more than the law requires and less than the law allows.

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Ethics is not about the way things really are . . .

CHARACTER COUNTS! 4.0 © Josephson Institute of Ethics 2014 72



Beyond Legalism

In today's environment, a narrow legalistic mentality will not only be inadequate, it can substantially increase risks.

Fueled by new laws and intense public cynicism, journalists, regulators, and prosecutors have become more creative and aggressive in bringing charges that can result in huge costs irrespective of technical legalities.

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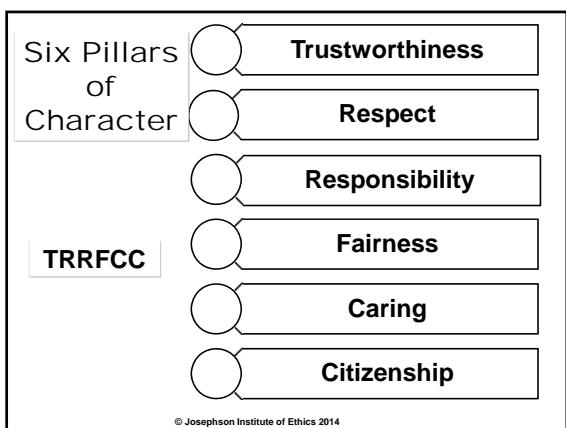
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If you could interview the people who would date and might marry your children, what qualities are essential to you?

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But what does this have to do with the ethics in your organization

What does management want from employees?

What do employees want from their managers?

What does the public want and expect from your company?

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Sometimes a warning is enough
to avoid unnecessary risk



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Sometimes it's wise to warn
even about obvious risks



Don't drive off the dock

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Risk Factor:
People sometimes do really dumb things



The antidote:
training, supervision
and discipline

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Warren Buffet:

"I look for three things in a new hire: energy, creativity and integrity.

But if you don't get the last thing, the first two will kill you."

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Find people with a moral compass and you won't have to emphasize compliance.

Everybody thinks it can't happen here...



Until it does.

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How many employees have the power to make decisions that can create legal liability or damage the reputation of your institution?



The Law of Big Numbers

In every organization of size there are bound to be some people with bad judgment or weak character – and they may be working for you



Risks are created or eliminated by the choices and conduct of individuals



When the "I" isn't straight, it can make a big difference in the end

What can be done to increase ethics?

Ethics training – online and classes

Assessments

Establishing and ethical culture

- HR policies – hire for character train for skills
- TEAM – teach, enforce, advocate, model
- Best possible result decision making

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Establishing an Ethical Culture

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How does a healthy body deal with an infection (an antigen)?

Our immune system consists of white blood cells which produce antibodies which attack, surround and consume the antigen.

In a healthy organization detrimental attitudes and behavior are surrounded and overcome by values-driven employees who act as anti-bodies.

In a healthy organization most forms of misconduct are prevented or limited without any need to report the activity.

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An ethical culture is a pervasive organizational climate that promotes ethical conduct and discourages unethical conduct.

ethical values are in the DNA of the organization

it's easier and more rewarding to do the right thing than the wrong thing.

everyone is expected to be concerned with discerning, doing, and requiring others to do the right thing.

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An ethical culture exists when formal and informal incentives:

Nourish and promote ethical conduct such as honesty, moral courage, respectfulness, responsibility, fairness, caring and good citizenship and

Discourage and prevent unethical conduct such as deceit, disrespect, unaccountability, unfairness, selfishness and lawlessness.

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Our immune system consists of white blood cells which produce antibodies which attack, surround and consume the antigen.

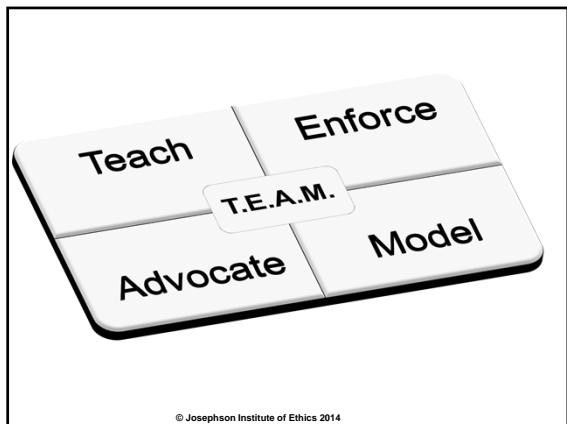
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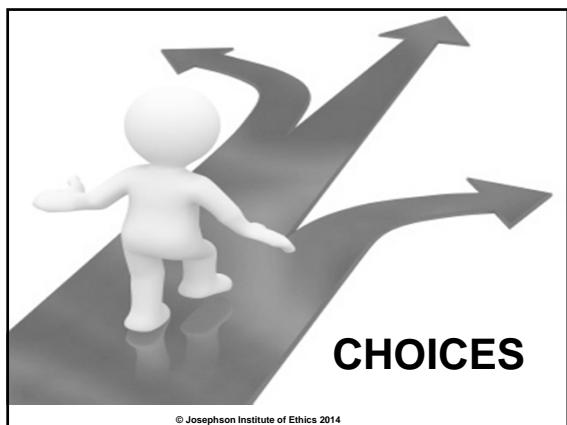
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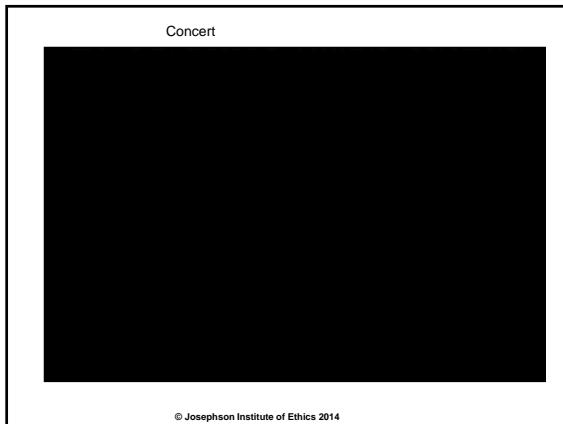
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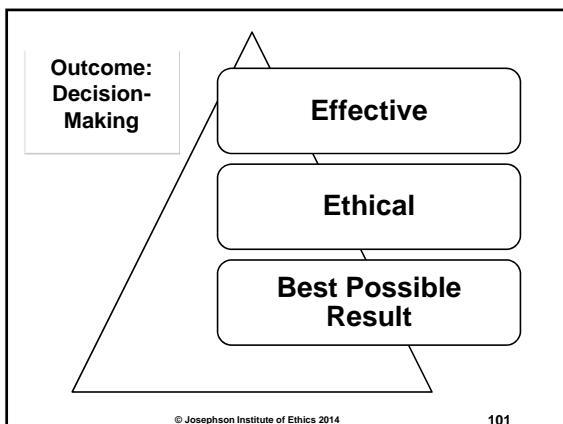
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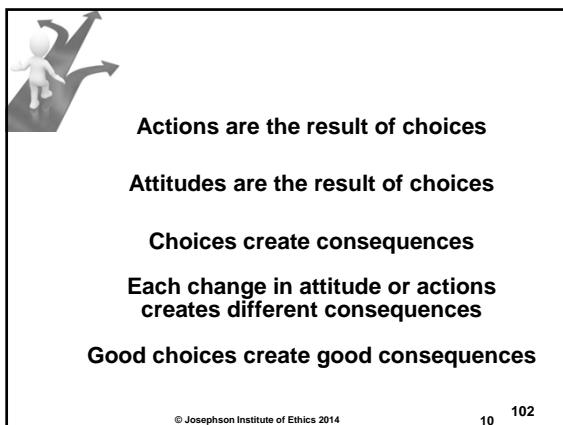












**Good choices produce
good results.**
**Better choices create
better results.**
**The best choices produce
the best possible result**

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Rational Decision-Making Versus Rationalizations

The difference between a rational decision and a rationalization is based on when the reasoning process takes place.

In a rational decision one reasons first in order to reach a conclusion.

In a rationalization the reasoning process is used to justify a conclusion or decision.

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When confronted by an approaching bear



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***If you want to
know how to live
your life, think
about what you'd
like people to say
about you after
you die – and live
backwards.***

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"Our souls are not hungry for fame, comfort, wealth or power. Our souls are hungry for meaning, for the sense that we have figured out how to live so that our lives matter, so that the world will be at least a little bit different from our having passed through it." - Harold Kushner

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What you're doing won't
make a difference



It does to this
starfish

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WHAT WILL MATTER

By Michael Josephson © 2003

Ready or not, some day it will all come to an end.
 All the things you collected, whether treasured or forgotten will pass to someone else.
 Your wealth, fame and temporal power will shrivel to irrelevance.
 It will not matter what you owned or what you were owed.
 Your grudges, resentments, frustrations and jealousies will finally disappear.
 So too, your hopes, ambitions, plans and to do lists will expire.
 The wins and losses that once seemed so important will fade away.
 It won't matter where you came from or what side of the tracks you lived on at the end.
 It won't matter whether you were beautiful or brilliant.
 Even your gender and skin color will be irrelevant.
 So what will matter? How will the value of your days be measured?
 What will matter is not what you bought but what you built, not what you got but what you gave.
 What will matter is not your success but your significance.
 What will matter is not what you learned but what you taught.
 What will matter is every act of integrity, compassion, courage, or sacrifice that enriched,
 empowered or encouraged others to emulate your example.
 What will matter is not your competence but your character.
 What will matter is not how many people you knew,
 but how many will feel a lasting loss when you gone.
 What will matter is not your memories but the memories that live in those who loved you.
 What will matter is how long you will be remembered, by whom and for what.
 Living a life that matters doesn't happen by accident.
 It's not a matter of circumstance but of choice.
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Creating and Maintaining an Exemplary Ethics & Compliance Program

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Building a Healthy ACO Compliance Program

HCCA 2014 Compliance Institute

Mary C. Malone, Esq.

Mary S. Malone, Esq.
Hancock, Daniel, Johnson & Nagle, P.C.

HDJN

The health law solution.

Disclaimer: The content of this presentation does not constitute legal advice.

Accountable Care Organizations

- In CMS's words:

ACOs are voluntary groups of physicians, hospitals, and other health care providers that are willing to assume responsibility for the care of a clearly defined population of Medicare beneficiaries attributed to them on the basis of patients' use of primary care services.

Donald Berwick, Administrator of CMS
New England Journal of Medicine
Making Good on ACOs' Promise

Accountable Care Organizations

- Private Payer Model:
 - Insurance carriers have a history of offering ACO-type models of care to private insurance markets
 - Medicare Model:
 - Pioneer
 - The first experimental model that placed participants at higher financial risk if Medicare savings goals were not realized.
 - MSSP
 - Reduces the amount of financial risk for ACOs.
 - Many providers that started in the Pioneer program are switching to the MSSP.
 - Advanced Payment
 - Selected MSSP ACOs can apply for this special payment program that pays ACOs for "projected" savings to help with fixed and variable start-up costs.

3

The MSSP

- The Centers for Medicare & Medicaid Services (CMS) established the Medicare Shared Savings Program to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce unnecessary costs.
- The Shared Savings Program will reward ACOs that lower their growth in health care costs while meeting performance standards on quality of care and putting patients first by sharing a portion of the savings.

4

Legal Backdrop

MSSP Accountable Care Organizations

Affordable Care Act – Section 3022

- Enacts Section 1899 of the Social Security Act establishing the Medicare Shared Savings Program.

Code of Federal Regulations

- Part 425 outlines the regulations implementing the requirements for ACOs participating in the Medicare Shared Savings Program.

Other Laws Applicable to ACOs

- Anti-Trust Statutes;
- Anti-Kickback Statute;
- Stark Law;
- Civil Monetary Penalties;
- False Claims Act; and
- State Specific Laws.

See Attachment 1:Checklist of MSSP ACO Requirements

The Triple Aim

Successful ACOs will be rewarded with a slice of the shared savings pie.



ACO Program Integrity

- Although not specifically required by the ACA, CMS enacted several program integrity requirements for MSSP ACOs.
- For example:
 - ACO must have a compliance plan and official.
 - ACO must maintain ultimate responsibility for compliance with the ACO agreement.
 - All contracts or arrangements between or among the ACO and its participants must require compliance with the ACO's participation agreement as well as other laws.

6



ACO Program Integrity

- ACO governing body must adopt a conflicts of interest policy that applies to members of the governing body.
- ACOs must adopt screening procedures for participants (program integrity history, sanctions, affiliations with excluded individuals, etc.).
- This is consistent with current Medicare regulations prohibiting payment to individuals excluded from federal health programs.

7



Mandatory Compliance Plans

- Along with other program integrity requirements, CMS finalized regulations for Mandatory ACO Compliance Plans (42 C.F.R. § 425.300(a)).
- Generally, the elements required for ACO compliance plans are similar to the elements outlined by the OIG for other individual provider types (*i.e.*, hospitals, nursing facilities, small physician groups, home health and ambulance suppliers).

8

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The health law solution. 9

Mandatory Compliance Plans

- ACOs can use existing guidance to anticipate CMS's and the OIG's expectations.
- Compliance guidance documents are available on the OIG's Website:
<http://oig.hhs.gov/compliance/compliance-guidance/>
- ACOs can also refer to the Final Rule for CMS's comments on the elements of an effective ACO compliance plan.

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The health law solution. 10

Mandatory Compliance Plans

- Over the years, the government has used the terms "compliance plan" and "compliance program" interchangeably.
 - The term "compliance plan" seems to describe the document that sets forth the general framework of a compliance program; whereas, the compliance program is the operationalized compliance plan (*i.e.*, a living, breathing part of the organization).
 - CMS requires ACOs to have a "compliance plan," although more likely, the expectation is that the ACO have a fully implemented, operational, dynamic, and effective compliance program

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The health law solution. 11

ACO Compliance Plan

- Does your ACO Compliance Plan contain all of the elements?
- There is one question on the ACO Application about compliance plans.
 - When completing the ACO MSSP Application, an ACO must attest that it has a compliance plan in place that meets the minimum requirements.

See Attachment 2: Sample ACO Compliance Plan

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ACO Compliance Plan

- Here is what the attestation looks like on the ACO application.
 - NOTE that ACOs are not required to submit a copy of the compliance plan with the application, but must make it available to CMS upon request.

17. Does the ACO have a compliance plan that includes at least the following elements:

- A designee/compilation official or individual who is not legal counsel to the ACO and reports directly to the ACO's governing body
- Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance
- A method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, or for other entities performing functions or services related to ACO activities, to anonymously report suspected problems or violations of law to the ACO
- Compliance training for the ACO, ACO participants, and ACO providers/suppliers
- A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency

Yes No

Image captured from 2013 MSSP Application

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The Elements of an Effective ACO Compliance Plan (42 C.F.R. § 425.300(a))

1. Designated compliance official who is *not legal counsel* to the ACO and reports directly to the ACO's governing body
 - Legal counsel to the ACO and the compliance officer must be different individuals, in order to ensure independent and objective legal reviews of financial analyses of the organization's compliance efforts and activities by the compliance officer.
 - ACOs may use their current compliance officer provided that the compliance officer is not legal counsel to the existing organization.

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The Elements of an Effective ACO Compliance Plan (42 C.F.R. § 425.300(a))

2. Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance
 - ACO compliance officials must ensure that policies and procedures adequately define how ACO participants can report potential compliance and quality issues so that the compliance officer can take steps to investigate or audit ACO activities.
 - This also includes collecting and reporting on various quality measures.
 - There are currently 33 such measures.



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The Elements of an Effective ACO Compliance Plan (42 C.F.R. § 425.300(a))

3. A method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer
 - Compliance plans on their own do not stop fraud and abuse; however, compliance programs provide a resource for:
 - Increased likelihood of identifying and preventing unlawful and unethical conduct;
 - Providing a centralized source for distributing information on health care statutes, regulations, and other program directives related to fraud and abuse; and
 - Creating an environment that encourages employees and others to anonymously report potential problems.

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The Elements of an Effective ACO Compliance Plan (42 C.F.R. § 425.300(a))

4. Compliance training for ACO, ACO participants and the ACO providers/suppliers.
 - Requiring compliance training for the ACO and all of its ACO participants and ACO providers/suppliers helps to ensure that every ACO participant, ACO provider/supplier, and contractor understands their legal obligations with respect to the ACO's operations and performance, as well as the requirements of the compliance program and the manner in which their ACO is implementing such requirements.

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The Elements of an Effective ACO Compliance Plan (42 C.F.R. § 425.300(a))

5. A requirement for the ACO to report *probable violations of law* to an appropriate law enforcement agency.
 - The OIG has outlined industry best practices for compliance programs as well as a description of the risks of fraud and abuse that various providers may face.
 - CMS suggests that providers without experience developing compliance programs review the various resources that are available from the OIG's web site to help determine the risk of fraud and abuse in the ACO and when an activity may rise to the level of a violation that may need to be reported.
 - CMS encourages the use of the OIG Self-Disclosure Protocol to determine which activities amount to a "probable violation."

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ACO Fraud and Abuse Waivers

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- ACO Pre-Participation Waiver
 - Protections against the AKS, Stark and Gainsharing CMP.
- ACO Participation Waiver
 - Protections against the AKS, Stark and Gainsharing CMP.
- Shared Savings Distribution Waiver
 - Protections against the AKS, Stark and Gainsharing CMP.
- Compliance With Stark Exception Waiver
 - Protections against the AKS and Gainsharing CMP.
- Patient Incentives Waiver
 - Protections against the AKS and Beneficiary Inducement CMP.

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ACO Fraud and Abuse Waivers

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- Pre-Participation Waiver
 - Protections begin in the year preceding the ACO's target year of Participation.
 - Only one party to the financial arrangement must be an ACO or ACO participant.
 - However, the party cannot be a DME Drug/Device, or Home Health Supplier
 - The ACO Governing Body must make a *bona fide* determination that the financial arrangement is reasonably related to the MSSP's triple-aim.
 - Parties must maintain adequate documentation for the financial arrangement including the "diligent steps" toward becoming an ACO by the selected target year.

See Attachment 3A: Pre-Participation Flow Chart

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ACO Fraud and Abuse Waivers

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- Participation Waiver
 - Protections are available to ACOs that are in good standing under an ACO participation agreement.
 - Only one party to the financial arrangement must be an ACO or ACO participant.
 - The ACO Governing Body must make a *bona fide* determination that the financial arrangement is reasonably related to the MSSP's triple-aim.
 - Parties must maintain adequate documentation for the financial arrangement.

See Attachment 3B: Participation Waiver Flow Chart

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ACO Fraud and Abuse Waivers

- Shared Savings Distribution Waiver
 - Protections are available to ACOs that are in good standing under an ACO participation agreement.
 - Protects financial disbursements of earned shared savings.
 - Disbursements can be made at any time as long as the savings were earned during the term of the ACO's participation agreement
 - Disbursements can be made to:
 - Current ACO participants, providers and suppliers;
 - Individuals or entities that were ACO participants, providers or suppliers during the year that the shared savings were earned by the ACO; or
 - To other parties if their activities are reasonably related to the MSSPs triple-aim.
 - Disbursements from hospitals cannot be intended to prevent physicians from referring patients for medically necessary services.

See Attachment 3C: Shared Savings Distribution Waiver Flow Chart

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ACO Fraud and Abuse Waivers

- Compliance with Physician Self-Referral Waiver
 - Protections are available to ACOs that are in good standing under an ACO participation agreement.
 - The financial arrangement must be reasonably related to the MSSP's triple-aim.
 - The financial arrangement must fit into one of the Stark Law's current exceptions (42 C.F.R. § 411.355 through 411.357).

See Attachment 3D: Compliance With Physician Self-Referral Flow Chart

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The logo for HDJN (Health Law Solution) features the letters "HDJN" in a bold, black, sans-serif font. To the left of the letters is a small square icon containing a stylized letter "H". Below the main letters, the words "The health law solution." are written in a smaller, all-caps, sans-serif font.

ACO Fraud and Abuse Waivers

- Patient Incentives Waiver

- Protections are available to ACOs that are in good standing under an ACO participation agreement.
- ACOs and ACO participants, providers and suppliers may offer items or services for free or below market value to Medicare beneficiaries.
- Items and services must be “in-kind”.
 - NO CASH INCENTIVES
- Items and services must be meant to promote preventative care or the advancement of patient care goals.

See Attachment 3E: Patient Incentives Waiver Flow Chart

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ACO Fraud and Abuse Waivers

- ACOs can enjoy broad applicability of Waivers to financial arrangements with non-ACO participants.
 - Activities “Reasonably Related” to the MSSP’s “Triple-Aim” can qualify for Waiver protections.
 - Only one party to most agreements must be an ACO or ACO participant.
- In many cases, Waiver protections will not be triggered because the arrangement fits within an existing exception or safe harbor.

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ACO Fraud and Abuse Waivers

- CMS has indicated that it is willing to consider additional Waivers as ACOs begin to offer services to beneficiaries.
 - May include ability to offer cash incentives for beneficiary participating in preventative health screenings.
 - Waivers may need to be expanded to pre-empt applicable state fraud and abuse laws.
- However, there is no guarantee that the CMS or the OIG will not tighten the Waiver requirements as time goes on.

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Conflict of Interest for ACOs

- MSSP requires 75% of the ACO’s Board to be ACO Participants.
 - This means that board members will also have financial interests in the operation of the ACO.
- MSSP requires disclosure of Conflicts of Interest.
 - Conflict of interest policy must:
 - Provide for disclosure of financial interests;
 - Create procedure for identifying and addressing conflicts; and
 - Establish remedies for violation of policy.

See Attachment 4: Sample Conflict of Interest Policy

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Other ACO Compliance Functions

- Adhering to Marketing Limitations
 - 42 C.F.R. § 425.310
- Complying with Patient Engagement Requirements
 - 42 C.F.R. § 425.112
- Ensuring Freedom of Choice
 - 42 C.F.R. § 425.304(c)
- Proper Record Management and Retention
 - 42 C.F.R. § 425.314
- Protecting Privacy of Patient Data (HIPAA)
 - 42 C.F.R. § 425.700 *et seq.*
- Appropriate Billing and Coding
 - 42 C.F.R. § 425.208(b)
 - “The ACO must agree, and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO’s activities to agree, or to comply with all applicable laws.”

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CMS Monitoring of ACOs

- ACO compliance plans should include policies and procedures for proactive internal audits to ensure that all 5 elements of the compliance plan are effective.
 - This means that compliance officials should have access to all patient charts and medical records to confirm quality and utilization information.
 - Consider the use of integrated EHR and other centralized electronic communications systems for consistent data collection.
 - Compliance Officers must be able to identify and correct deficient practices before issues become sanctionable non-compliance.

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CMS Monitoring of ACOs

- “WHEN” not “IF”
 - CMS has indicated that ACOs **will** be audited through:
 - Analysis of financial and quality measurement data reported by ACO;
 - Site visits;
 - Beneficiary and provider complaints; and
 - Claims analysis, chart reviews, beneficiary surveys, and coding audits.
- Because CMS will be auditing ACO activity, it is important that ACOs implement their compliance plans early, self-audit often, and revise policies periodically.

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ACO Compliance First Steps

- If an ACO is comprised of participants that have never operated under a compliance plan, compliance program development should start with a **Readiness Assessment**.
- If an ACO is able to leverage an ACO participant's existing compliance program, compliance program development should start with a **Gap Analysis**.

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ACO Compliance First Steps

- Compliance Program Readiness Assessment
 - A Readiness Assessment should focus on the ACO's and ACO participants' infrastructure to ensure that all ACO participants start on equal footing in the compliance program.
 - Factors to consider:
 - Teamwork; participant buy-in; and current business cultures
 - Technologies; EHR compatibility; and communication systems
 - Costs and charges

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ACO Compliance First Steps

- Compliance Program Gap Analysis should focus on the ACOs current compliance needs and resources and how they compare to the best practice.
 - Best practice may be difficult to assess at this early stage but, some factors to consider include:
 - Quality Assurance Data Collection Practice
 - Billing and Coding Compliance
 - Clinical Integration
 - Patient Engagement Efforts
 - Reporting Obligations (public reporting and CMS reporting)

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ACO Compliance First Steps

- Create an Action Plan
 - For each item that is identified as a shortcoming during the **Readiness Assessment** or **Gap Analysis**, create an **Action Plan**.
 - Start with 5 to 10 shortcomings that need to be addressed.
 - Create step by step goals and dates to implement a procedure to correct each shortcoming.
 - Monitor and track the goals to ensure that the tasks are accomplished.
 - Share accomplishments or deficiencies during regular compliance meetings.
 - Once all goals on the Action Plan have been complete, replace the task with another shortcoming from the Readiness Assessment or Gap Analysis until all shortcomings have been addressed.

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ACO Compliance First Steps

- The Importance and Role of the Compliance Officer
 - **Create a Culture of Compliance**
 - Actively develop an organizational structure that supports compliance activities
 - Individuals should be comfortable participating with compliance activities, including reporting potentially non-compliant activities without fear of retaliation from the governing body

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ACO Compliance First Steps

- The Importance and Role of the Compliance Officer
 - **Integrate Care and Communication**
 - Open communication among all ACO participants, management and governing body allows the compliance officer to manage potential risks in real time, which is essential to preventing systemic compliance deficiencies.

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ACO Compliance First Steps

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- The Importance and Role of the Compliance Officer
 - **Develop Training and Education Programs**
 - The importance of training and education programs cannot be stressed enough.
 - Experience shows that ACO compliance officers can use training to gauge whether the ACO is accomplishing its compliance goals.
 - For MSSP ACOs, training and education programs are required as conditions of participating in the MSSP.
 - ACOs that fail to educate all levels of the ACO organization, including the governing body, will likely see the compliance program's efficacy diminish over time.

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ACO Compliance First Steps

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- Collaboration with Risk Managers and ACO Executives
 - In some organizations compliance officers are incorporated into the overall management hierarchy and are highly integrated with the governing body.
 - In other organizations the compliance officer is almost completely isolated from the governing body but more in touch with ACO staff and participants.
 - The goal is to strike the right balance.
 - Participants need to trust the compliance officer, but the compliance officer must also maintain support from the governing body.

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ACO Compliance First Steps

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- Participant Buy-In
 - When approaching an independent physician group, the group must understand what the benefits are of giving up their autonomy and buying in to ACO compliance oversight.
 - Those benefits are:
 - Assuring that care is medically necessary;
 - Removing obstacles/distractions to the provision of care; and
 - Assuring that coding is accurate for purposes of fully and accurately representing the care that was delivered.
 - Buying into the ACO compliance program must also make good *cents*.
 - The ACO must demonstrate to all participants, including clinicians, the benefits of being a participant in a larger organization compliance program.
 - Increased billing and coding efficiency;
 - Decreased claims denials;
 - Faster payments;
 - Reduced fraud and abuse liability exposure for improper billing; and
 - Increased trust and confidence in the patient community.

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Predictions for the Future of ACO Compliance Plans

- Litigation Issues
 - Because of the loose language used in many of the ACO regulations (*i.e.*, “reasonably related,” “bona fide determination,” etc.), there is ample opportunity for CMS and the OIG to interpret and reinterpret how ACO’s should operate.
 - Litigation may include:
 - Waiver applicability;
 - Participation Agreement obligations; and
 - Individual provider fraud and abuse liability.

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Predictions for the Future of ACO Compliance Plans

- Waiver Evolution
 - CMS will evaluate the need to reduce or expand Waiver protections as ACOs and the MSSP program evolves.
 - One definite hurdle for the near future is the fact that the Waivers do not operate to pre-empt applicable state fraud and abuse laws.
 - For example, compliance with the federal ACO Participation Waiver rules does not automatically assuage an ACO’s obligations to comply with state physician anti-kickback statutes (*i.e.*, Virginia False Claims Act (**Va. Code §§ 8.01-216 et. seq.**) and Anti-kickback Statute (**Va. Code § 54.1-2962.1**)).

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Predictions for the Future of ACO Compliance Plans

- How much will Compliance Cost?
 - It is likely that many providers entering into compliance plans for the first time will have to devote a great amount of resources to aligning themselves with partners that can provide compliance program training and tools.
 - Will shared savings be enough to make the expenses worth it?
 - Audits of the ACO will likely cause greater scrutiny on individual providers.
 - What will the cost be for those participants when audits reveal compliance deficiencies for time periods preceding the ACO participation agreement and compliance plan implementation?

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We are in this together.

- ACOs are all in the same boat trying to figure out how to operationalize an effective compliance program.
- This is also new territory for CMS.
- By using the existing guidance and CMS's comments in the final rules, ACOs can at least anticipate CMS's compliance expectation and begin to adopt policies and practices that minimize ACO compliance risks.

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Questions



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CMS Eligibility Requirements Checklist for MSSP ACO Participation

1. General Eligibility Requirements

- ACO participants work together to manage and coordinate care for Medicare fee-for-service beneficiaries. The ACO must become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.
- ACOs must meet or exceed a minimum savings rate established by CMS, meet minimum quality performance standards, and otherwise maintain their eligibility to participate in the MSSP in order to receive shared savings payments.
- ACOs operating under the two-sided model that meet or exceed a minimum loss rate must share losses with the Medicare program.

2. Eligible Providers and Suppliers

- ACO participants or combinations of ACO participants must qualify as one, or more, of the following providers or suppliers or participate through an ACO formed by one or more of the following:
 - Professionals in group practice arrangements.
 - Networks of individual professional practices.
 - Partnerships or joint venture arrangements between hospitals and ACO professionals.
 - Hospitals employing ACO professionals.
 - CAHs that bill under Method II.
 - RHCs.
 - FQHCs.

3. Organizational and Management Requirements

- An ACO must be a legal entity, formed under applicable State, Federal, or Tribal law, and authorized to conduct business in each State in which it operates for the following purposes :
 - Receiving and distributing shared savings.
 - Repaying shared losses or other monies determined to be owed to CMS.
 - Establishing, reporting, and ensuring provider compliance with health care quality criteria, including quality performance standards.
 - Fulfilling other ACO functions identified in this part.
- An ACO must maintain an identifiable governing body with authority to execute the functions of an ACO, including but not limited to, promoting evidence-based medicine and patient engagement, reporting on quality and cost measures, and coordination of care.

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- The governing body must have responsibility for the oversight and strategic direction of the ACO and holding ACO management accountable for the ACO's activities.
- The governing body must have a transparent governing process.
- The governing body members must have a fiduciary duty to the ACO and must act consistent with that fiduciary duty.
- The governing body of the ACO must be separate and unique to the ACO in cases where the ACO comprises multiple independent ACO participants.
- If the ACO is an existing entity, the ACO governing body may be the same as the governing body of that existing entity, provided it satisfies all other ACO governing body requirements.
- The ACO must provide for meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives.
 - The ACO governing body must include a Medicare beneficiary representative(s) served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with a conflict of interest with the ACO.
 - At least 75 percent control of the ACO's governing body must be held by ACO participants.
 - The governing body members may serve in a similar or complementary manner for an ACO participant.
 - In cases in which the composition of the ACO's governing body does not meet the requirements above, the ACO must describe why it seeks to differ from these requirements and how the ACO will involve ACO participants in innovative ways in ACO governance or provide meaningful representation in ACO governance by Medicare beneficiaries.
- The ACO governing body must have a conflict of interest policy that applies to members of the governing body. The conflict of interest policy must—
 - Require each member of the governing body to disclose relevant financial interests; and
 - Provide a procedure to determine whether a conflict of interest exists and set forth a process to address any conflicts that arise.
 - The conflict of interest policy must address remedial action for members of the governing body that fail to comply with the policy.
- An ACO must have a leadership and management structure that includes clinical and administrative systems that align with and support the goals of the Shared Savings Program and the three aims of **better care for individuals, better health for populations, and lower growth in expenditures**.
 - The ACO's operations must be managed by an executive, officer, manager, general partner, or similar party whose appointment and removal are under the control of the ACO's governing body and whose leadership team has demonstrated the ability to influence or direct clinical practice to improve efficiency processes and outcomes.

- Clinical management and oversight must be managed by a senior-level medical director who is a physician and one of its ACO providers/suppliers, who is **physically present on a regular basis at any clinic, office, or other location participating in the ACO**, and who is a board-certified physician and licensed in a State in which the ACO operates.
- Each ACO participant and each ACO provider/supplier must demonstrate a meaningful commitment to the mission of the ACO to ensure the ACO's likely success.
 - o Meaningful commitment may include, for example, a sufficient financial or human investment (for example, time and effort) in the ongoing operations of the ACO such that the potential loss or recoupment of the investment is likely to motivate the ACO participant and ACO provider/supplier to achieve the ACO's mission under the Shared Savings Program.
 - o A meaningful commitment can be shown when an ACO participant or ACO provider/supplier agrees to comply with and implement the ACO's processes and is held accountable for meeting the ACO's performance standards for each required process.
- The ACO must include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO.
 - The ACO must have at least 5,000 assigned beneficiaries.
 - o CMS deems an ACO to have initially satisfied the requirement to have at least 5,000 assigned beneficiaries if the number of beneficiaries historically assigned to the ACO participants in each of the three years before the start of the agreement period, is 5,000 or more.
 - o If at any time during the performance year, an ACO's assigned population falls below 5,000, the ACO will be issued a warning and placed on a Corrective Action Plan.

4. Required ACO Processes and Functions

- An ACO must—
 - Promote evidence-based medicine and beneficiary engagement, internally report on quality and cost metrics, and coordinate care;
 - Adopt a focus on patient centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams; and
 - Have defined processes to fulfill these requirements.
 - Have a qualified healthcare professional responsible for the ACO's quality assurance and improvement program, which must include the defined processes below.
- For each process below, the ACO must—
 - o Explain how it will require ACO participants and ACO providers/suppliers to comply with and implement each process, including the remedial processes and penalties (including the potential for expulsion) applicable to ACO participants and ACO providers/suppliers for failure to comply with and implement the required process; and
 - o Explain how it will employ its internal assessments of cost and quality of care to improve continuously the ACO's care practices.

- The ACO must define, establish, implement, evaluate, and periodically update processes to accomplish the following:
 - Promote evidence-based medicine.
 - o These processes must cover diagnoses with significant potential for the ACO to achieve quality improvements taking into account the circumstances of individual beneficiaries.
 - Promote patient engagement.
 - o These processes must address the following areas:
 - Compliance with patient experience of care survey requirements;
 - Compliance with beneficiary representative requirements; and
 - A process for evaluating the health needs of the ACO's population, including consideration of diversity in its patient populations, and a plan to address the needs of its population.
 - In its plan to address the needs of its population, the ACO must describe how it intends to partner with community stakeholders to improve the health of its population.
 - An ACO that has a stakeholder organization serving on its governing body will be deemed to have satisfied the requirement to partner with community stakeholders.
 - Communication of clinical knowledge/evidence-based medicine to beneficiaries in a way that is understandable to them.
 - Beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities;
 - Written standards in place for beneficiary access and communication, and a process in place for beneficiaries to access their medical record.
 - Develop an infrastructure for its ACO participants and ACO providers/suppliers to internally report on quality and cost metrics that enables the ACO to monitor, provide feedback, and evaluate its ACO participants and ACO provider(s)/supplier(s) performance and to use these results to improve care over time.
 - Coordinate care across and among primary care physicians, specialists, and acute and post-acute providers and suppliers. The ACO must
 - o Define its methods and processes established to coordinate care throughout an episode of care and during its transitions, such as discharge from a hospital or transfer of care from a primary care physician to a specialist (both inside and outside the ACO); and
 - o As part of its application, the ACO must:
 - Submit a description of its individualized care program, along with a sample individual care plan, and explain how this program is used to promote improved outcomes for, at a minimum, its high-risk and multiple chronic condition patients.
 - Describe additional target populations that would benefit from individualized care plans. Individual care plans must take into account the community resources available to the individual.

5. Prohibition from Participation in Other Shared Savings Initiatives

- ACOs may not participate in the Shared Savings Program if they include an ACO participant that participates in the independence at home medical practice pilot program, a model tested or expanded that involves shared savings, or any other Medicare initiative that involves shared savings.

6. Mandatory Compliance Plan

- The ACO must develop a Compliance Plan that contains at least the following elements
 - A designated compliance official or individual that is not legal counsel to the ACO and reports directly to the ACO's governing body.
 - Mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance.
 - A method for employees or contractors of the ACO, ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance officer.
 - Compliance training for ACO, ACO participants and the ACO providers/suppliers.
 - A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency.

SAMPLE
ACO COMPLIANCE PLAN

I. Introduction

[ACO NAME] (“ACO”) was formed as an accountable care organization to enter into a Medicare Shared Savings Program Agreement with the Centers for Medicare & Medicaid Services (“CMS”) to participate in the Medicare Shared Savings Program (“MSSP”) through which ACO provides services to Medicare fee-for-service beneficiaries assigned to ACO in order to facilitate coordination and cooperation among healthcare providers to improve the quality of care for Medicare fee-for-service beneficiaries.

To protect the integrity of the MSSP and the purpose and mission of ACO, ACO will establish and maintain an effective Compliance Program designed to detect, correct and prevent incidences of non-compliance with applicable state and federal statutes, regulations, rules and guidance including, but not limited to, incidences of fraud, waste and abuse relating to the MSSP and federal health care programs. ACO will contractually require its employees, participants, contractors and providers/suppliers to comply with all requirements of the ACO Compliance Program.

II. Compliance Program Elements

1. Designated Compliance Official

The Compliance Officer is responsible for oversight and operation of this Plan. He or she will report on the nature and status of material compliance issues or matters affecting the ACO to the Board of Managers quarterly, and when necessary and appropriate. He or she will not serve as legal counsel to the ACO.

2. Monitoring Compliance of Operations and Performance

The Compliance Officer will initiate reviews of regulatory issues in conjunction with or independent of the relevant participants. The purpose of these reviews is to identify and address any compliance issues with ACO's operations and performance. Results of these reviews will be reported to the affected participant and the ACO Board of Managers. The Compliance Officer also may request results of reviews or audits performed by ACO participants that relate to the operations of ACO.

3. Internal Reporting of Compliance Issues

ACO employees and participants have an affirmative duty to report in good faith any known or suspected violations of applicable law or policy. These reports may be made to management or directly to the Compliance Officer. The Compliance Officer will coordinate with the Compliance officials of participants to obtain reports of compliance issues related to ACO that may be raised at a participant. ACO shall establish a confidential disclosure mechanism through the Compliance Hotline, a toll-free telephone line, as a means to enable employees, contractors, ACO participants, ACO providers/suppliers, or for other entities performing functions or services related to ACO activities, to anonymously report suspected problems related to the ACO and/or make inquiries on compliance issues. All employees, participants, ACO providers/suppliers, and other entities performing functions or services related to ACO activities have the right to use the Compliance Hotline. Information concerning the Hotline is regularly publicized throughout the organization through posters, websites, and training materials. Reports made to the Compliance Officer will be treated confidentially. Reports may be made anonymously.

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ACO is committed to a policy of non-retaliation against employees and participants who report suspected violations in good faith. Any action taken by an ACO employee or participant to retaliate against anyone making a good faith report alleging suspected improper activities is strictly prohibited. Any employee or participant who commits or condones any form of retaliation will be subject to discipline up to, and including, termination of employment or exclusion from the ACO.

4. External Reporting of Compliance Issues

If ACO discovers from any source credible evidence of misconduct related to ACO's operations and performance and, after a reasonable inquiry, believes that the misconduct represents a probable violation of law, ACO will promptly report the probable violation to the appropriate law enforcement agency within the appropriate period.

5. Compliance Training and Education

ACO employees and participants will receive compliance training upon becoming employed or engaged by ACO or the respective participant and at least annually thereafter. Such training may be provided by ACO or by a participant and may be provided in-person or on-line. The training will include introduction to this Plan, ACO's commitment to responsible and compliant business practices, the mandatory reporting requirements, reporting options, including the Compliance Hotline, and the ability to report confidentially and be free from retaliation. Targeted and as-needed training on compliance issues specific to ACO and its participation in the MSSP will be provided periodically where needed and applicable. Personnel whose work is linked to recognized risk areas will receive specialized compliance education pertaining to their functions and responsibilities. Documentation of all ACO Compliance Program training and education will be maintained by the Compliance Officer.

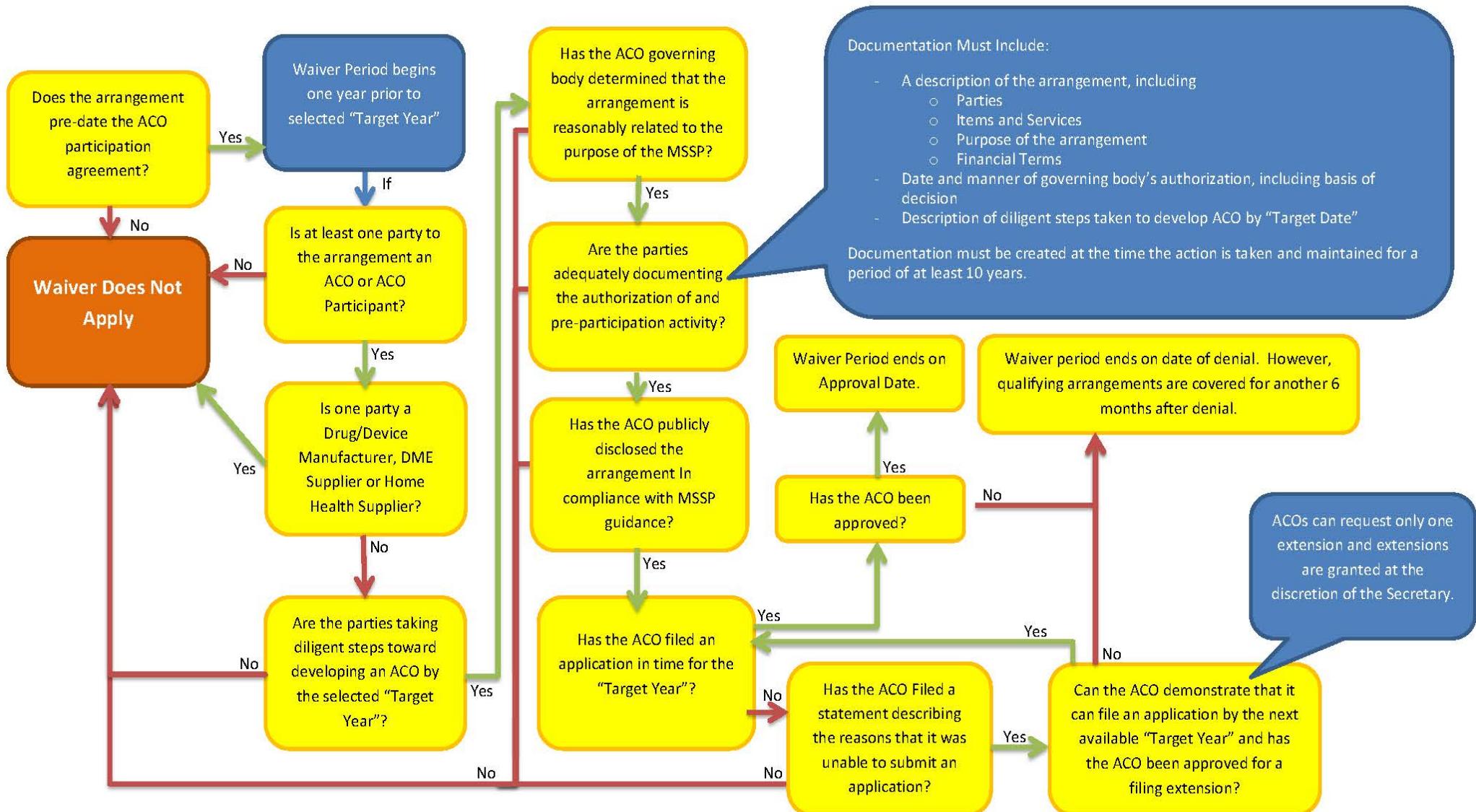
6. Exclusion Screening

Neither ACO nor its participants will knowingly hire, employ or contract with an individual or entity that has been excluded from participation in any federal health care program. All ACO employees and participants will be screened against the OIG List of Excluded Individuals and Entities ("OIG LEIE") and the U.S. General Services Administration's Excluded Parties List System ("GSA EPLS") prior to initial hire and monthly thereafter. Documentation of such screening will be maintained by the Compliance Officer. ACO employees and participants will immediately notify ACO of the identification of any person or entity who provides services to or on behalf of ACO or its participants that (a) has been excluded according to the OIG LEIE or GSA EPLS; (b) has been subject to any conviction or adverse action that subjects the individual to federal health care program exclusion under 42 U.S.C. 1320a-7; or (c) has a history of health care program integrity, including any history of Medicare program exclusion or other sanctions and affiliations with individuals or entities that have a history of program integrity issues. ACO will immediately remove any excluded individual from any work related directly or indirectly to services furnished by ACO.

III. Plan Amendments

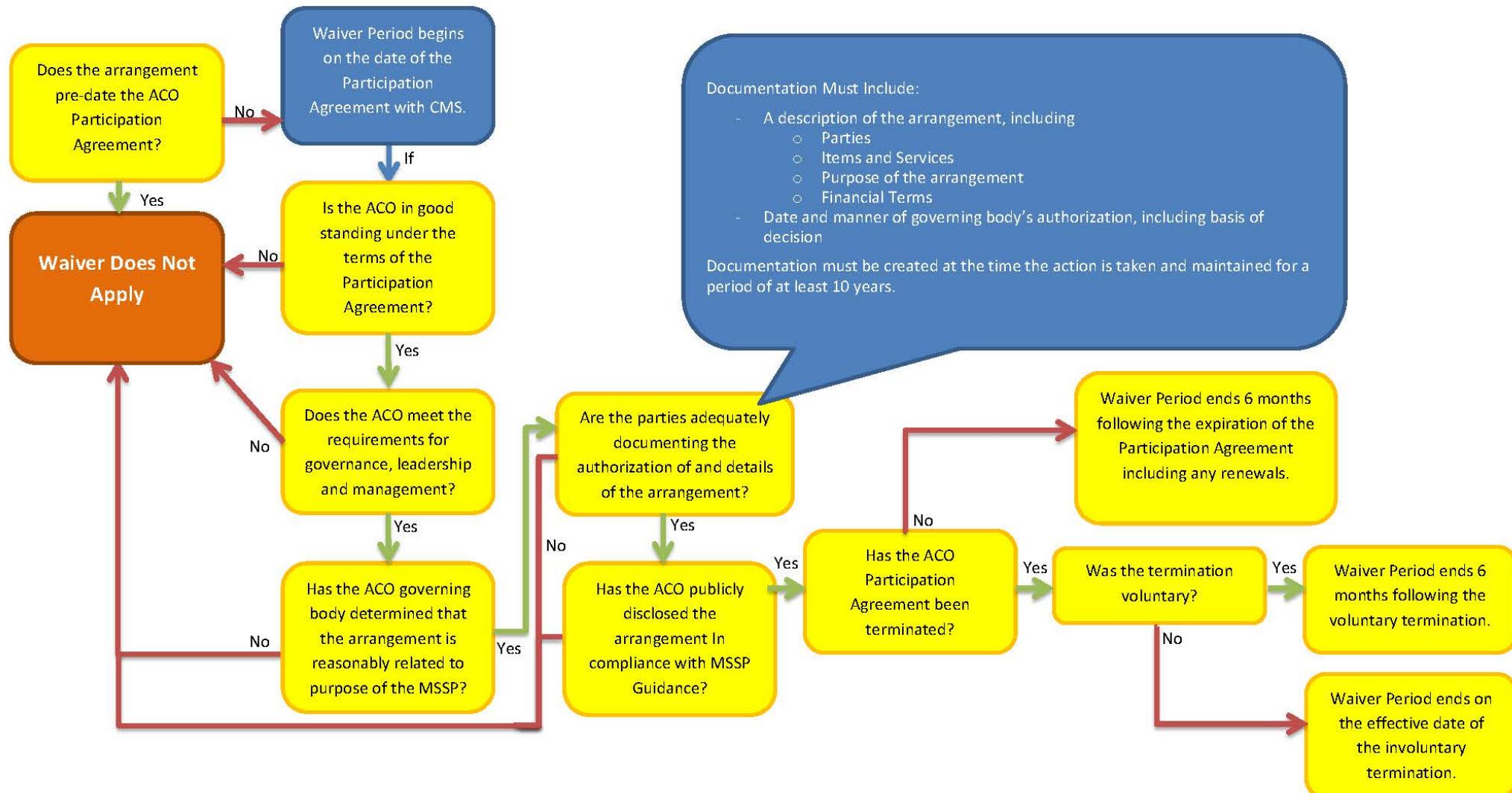
The Compliance Officer will review this Plan as necessary and at least annually, and update the Plan and any related policies to reflect changes in applicable law or regulations, ACO operations, and compliance improvement initiatives identified through the ACO Compliance Program.

ACO Pre-Participation Waiver



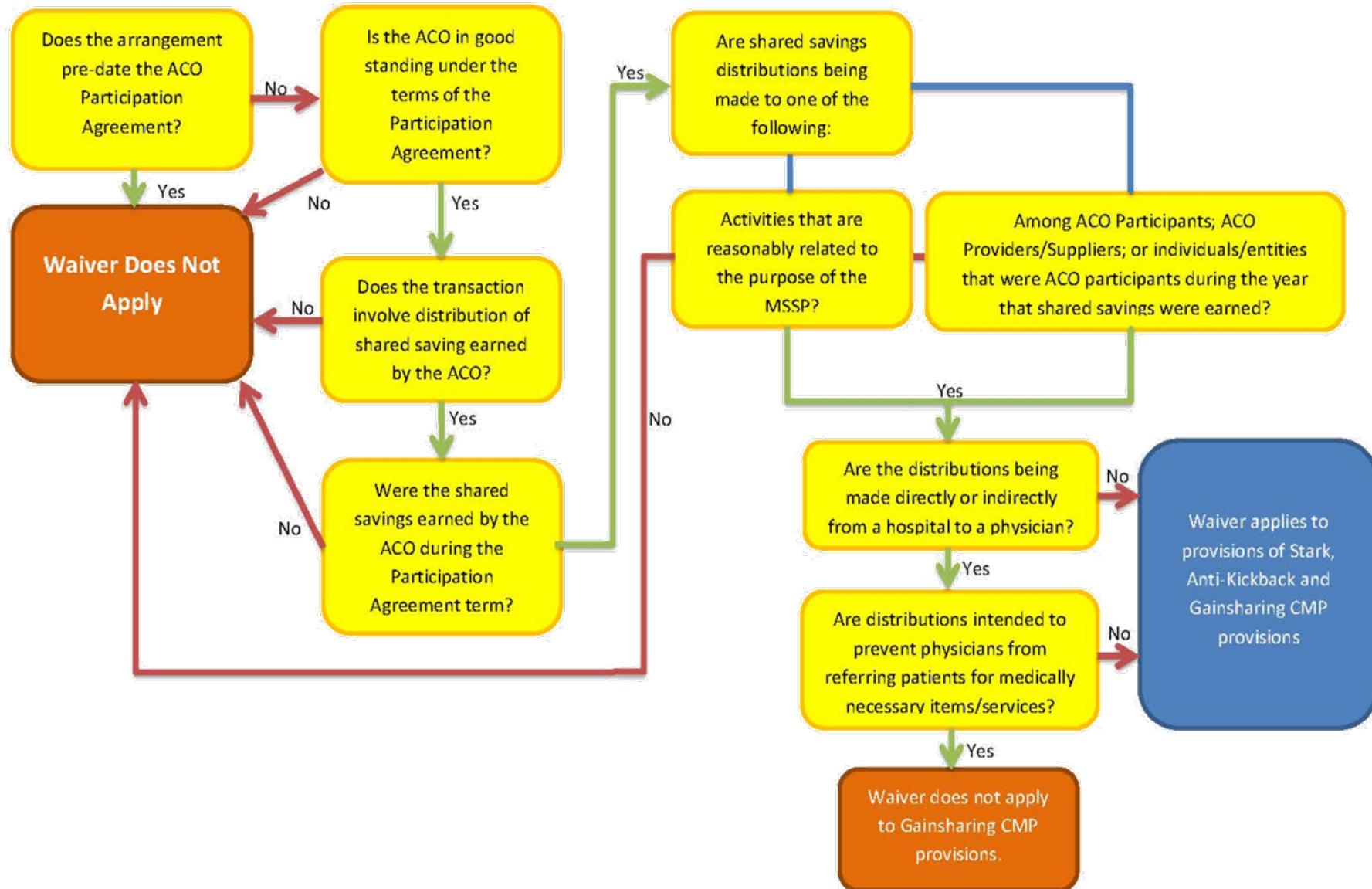
These materials are provided for informational purposes only and do not constitute legal advice. These materials are intended, but not promised or guaranteed to be current, complete, or up-to-date and should in no way be taken as an indication of future results. Transmission of the information is not intended to create, and the receipt does not constitute, an attorney-client relationship. These are not offered as and do not constitute legal advice or legal opinions. You should not act or rely on any information contained herein without first seeking the advice of an attorney.

ACO Participation Waiver



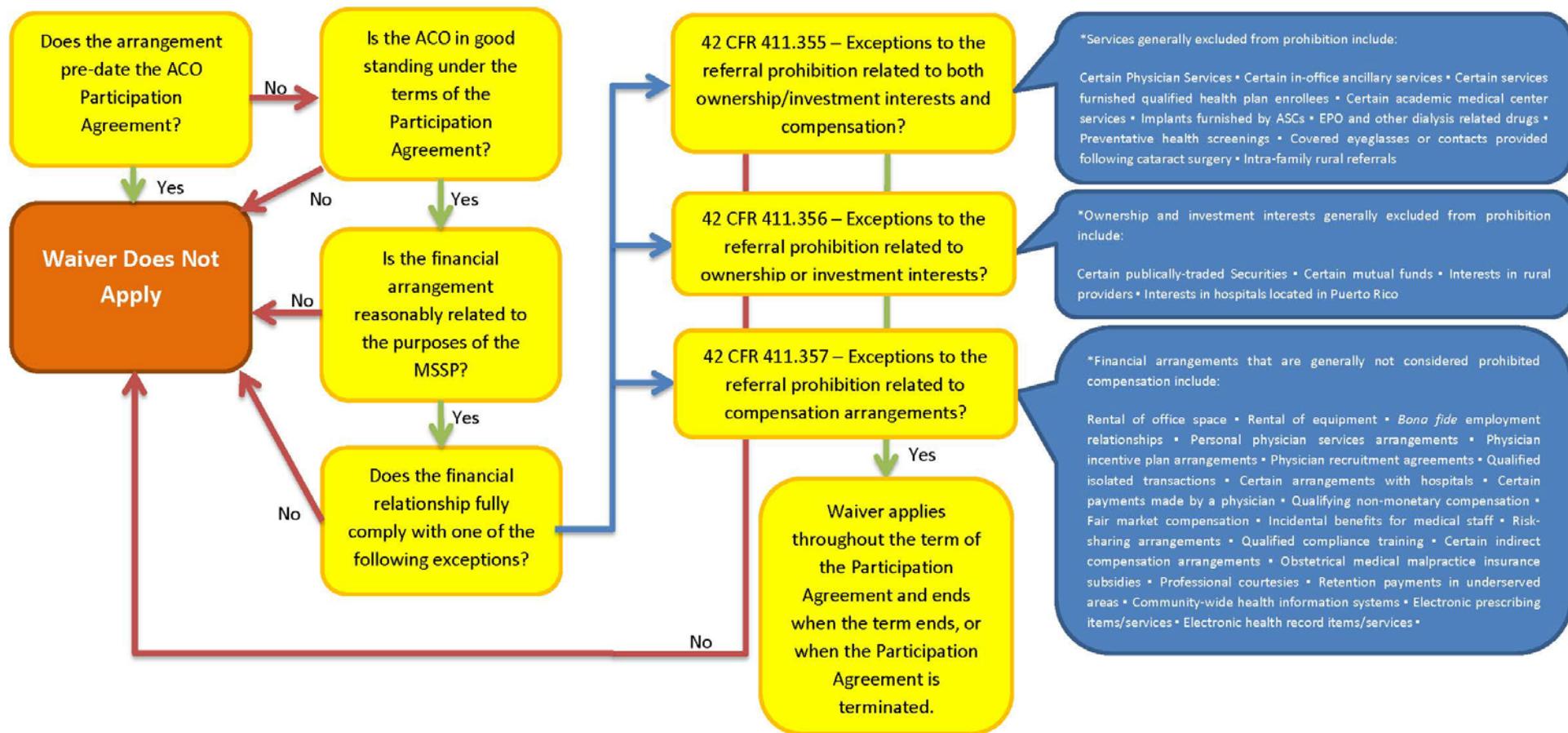
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ACO Shared Savings Distribution Waiver



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ACO Compliance with Physician Self-Referral Law Waiver



*The listings here are intended to provide a general reference for items and arrangements that are generally excluded from the physician self-referral prohibition. Each item, service or arrangement must meet the specific criteria set forth in the regulation in order for the waiver to apply in the specific circumstances.

ACO Patient Incentives Waiver



These materials are provided for informational purposes only and do not constitute legal advice. These materials are intended, but not promised or guaranteed to be current, complete, or up-to-date and should in no way be taken as an indication of future results. Transmission of the information is not intended to create, and the receipt does not constitute, an attorney-client relationship. These are not offered as and do not constitute legal advice or legal opinions. You should not act or rely on any information contained herein without first seeking the advice of an attorney.

TEMPLATE**CONFLICTS OF INTEREST POLICY****Article I
Purpose**

The purpose of this conflicts of interest policy is to protect [ACO PARTICIPANT]'s interest, when it is contemplating entering into a transaction or arrangement that might benefit the private interest of an officer or director of [ACO PARTICIPANT] or that might result in a possible excess benefit transaction. This policy is intended to supplement, but not replace, any applicable state and federal laws governing conflicts of interest applicable to nonprofit and charitable organizations.

**Article II
Definitions**

1. Interested Person shall mean any director, principal officer, or member of a committee with powers delegated to it by [ACO PARTICIPANT]'s governing board, who has a direct or indirect Financial Interest in a transaction or arrangement being considered by [ACO PARTICIPANT].

2. Financial Interest shall mean a situation where a person has, directly or indirectly, through a business, an investment, or family:

a. An ownership or investment interest in any entity with which [ACO PARTICIPANT] has a transaction or arrangement; or

b. A Compensation arrangement with [ACO PARTICIPANT] or with any entity or individual with which [ACO PARTICIPANT] has a transaction or arrangement (compensation includes direct and indirect remuneration and gifts or favors which are substantial in nature); or

c. A potential ownership or investment interest in, or Compensation arrangement with, any entity or individual with which [ACO PARTICIPANT] is negotiating a transaction or arrangement, or might reasonably in the future enter into a transaction or arrangement.

A Financial Interest is not necessarily a conflict of interest. Under Article III, Section 2 of this policy, a person who has a Financial Interest will have a conflict of interest only if the appropriate governing board or committee decides that a conflict of interest exists.

3. Compensation shall include direct and indirect remuneration as well as gifts or favors that are not insubstantial.

Article III Procedures

1. Duty to Disclose. In connection with any actual or possible conflict of interest, an Interested Person must disclose the existence of the Financial Interest and be given the opportunity to disclose all material facts to the directors and/or members of committees to which the board of directors has delegated powers concerning the proposed transaction or arrangement.

2. Determining Whether a Conflict of Interest Exists. After the disclosure of a Financial Interest and all material facts, and after any discussion with the Interested Person, the Interested Person shall leave the governing board or committee meeting while the determination of a conflict of interest is discussed and voted upon. The remaining board or committee members shall decide if a conflict of interest exists.

3. Procedures for Addressing the Conflict of Interest.

a. An Interested Person may make a presentation at the governing board or committee meeting. Following such presentation, the Interested Person shall leave the meeting to allow the remaining board or committee members to discuss and the vote on the transaction or arrangement involving the possible conflict of interest.

b. The chairperson of the governing board or committee shall, if appropriate, appoint a disinterested person or committee to investigate alternatives to the proposed transaction or arrangement.

c. After exercising due diligence, the governing board or committee shall determine whether [ACO PARTICIPANT] can obtain with reasonable efforts a more advantageous transaction or arrangement from a person or entity that would not give rise to a conflict of interest.

d. If a more advantageous transaction or arrangement is not reasonably possible under circumstances that would not result in a conflict of interest, the governing board or committee shall determine, by a majority vote of the disinterested directors, whether the transaction or arrangement is in [ACO PARTICIPANT]'s best interest, for [ACO PARTICIPANT]'s own benefit, and whether the transaction or arrangement is fair and reasonable. In conformity with the above determination, the governing board shall make its decision as to whether to enter into the transaction or arrangement.

4. Violations of the Conflicts of Interest Policy.

a. If the governing board or committee has reasonable cause to believe a member has failed to disclose an actual or possible conflict of interest, it shall inform that member of the basis for such belief and afford the member an opportunity to explain the alleged failure to disclose.

b. If, after hearing the member's response and after making further investigation as warranted by the circumstances, the governing board or committee

determines that the member has failed to disclose an actual or possible conflict of interest, it shall take the appropriate disciplinary and corrective actions.

Article IV **Records of Proceedings**

The minutes of the governing board and all committees to whom the board has delegated powers shall contain:

- a. The names of the persons who disclosed or otherwise were found to have a Financial Interest in connection with an actual or possible conflict of interest, the nature of that Financial Interest, any action taken to determine whether a conflict of interest was present, and the governing board's or committee's decision as to whether a conflict of interest existed.
- b. The names of the persons who were present for discussions and votes relating to the transaction or arrangement, the content of those discussions including any alternatives to the proposed transaction or arrangement, and a record of any votes taken in connection with the proceedings.

Article V **Annual Statements**

Each director, principal officer, and member of a committee with governing board delegated powers shall annually sign a statement which affirms such person:

- a. has received a copy of the conflicts of interest policy;
- b. has read and understands the policy;
- c. has agreed to comply with the policy; and
- d. [IF APPLICABLE – understands [ACO PARTICIPANT] is charitable and that in order to maintain its federal tax-exempt status it must engage primarily in activities which accomplish one or more of its tax-exempt purposes.]

Article VI **Periodic Reviews**

To ensure [ACO PARTICIPANT] operates in a manner consistent with its purposes and does not engage in inappropriate activities, periodic reviews shall be conducted. The periodic reviews shall, at a minimum, include the following subjects:

- a. Whether Compensation arrangements and benefits are reasonable, based on competent survey data, and are the result of arm's length bargaining; and
- b. Whether partnerships, joint ventures, and arrangements with management organizations conform to [ACO PARTICIPANT]'s written policies, are

properly recorded, reflect reasonable investment or payments for goods and services, applicable charitable purposes, and do not result in inurement, impermissible private benefit, or an excess benefit transaction.

Article VII **Use of Outside Experts**

When conducting the periodic reviews as provided for in Article VII, [ACO PARTICIPANT] may, but shall not be required to, use outside experts. If outside experts are used, their use shall not relieve the governing board of its responsibility for ensuring periodic reviews are conducted.

**CONFLICT OF INTERESTS AND STANDARDS OF CONDUCT
ACKNOWLEDGEMENT FORM**

I hereby acknowledge that I have received a copy of the Conflict of Interests and Standards of Conduct Policy Statement. I have read and understand each of these, including the fact that they apply to me.

Policy Statement

It is the policy of the Board of Directors of [ACO PARTICIPANT] (the “Board”) to assure that all of its directors, officers, managers, and members of committees with Board delegated powers (“Committee members”) act in accordance with the [ACO PARTICIPANT]Standards of Conduct and vote, conduct business and make decisions with the best interests of the community in mind and without the presence of a conflict of interest which may arise in part or wholly by a financial, personal or pecuniary interest. Accordingly, each director, officer, manager and Committee member of this Corporation and any of its affiliate/subsidiary corporations shall adhere to the following Conflict of Interests Policy. This policy is intended to supplement but not replace any applicable Federal or State laws governing conflicts of interest and fiduciary duties of directors of nonprofit and charitable organizations.

I hereby agree to be legally bound and comply with the Conflict of Interests and Standards of Conduct Policy as a condition of my continued association with the Corporation. Accordingly, I acknowledge that I have completed a Disclosure Statement and I understand that each written statement must be submitted annually, and that failure to comply may result in removal from my position.

Date

Signature

Printed or Typed Name

CONFLICT OF INTERESTS DISCLOSURE STATEMENT

I hereby certify that I have the following interests in the following organizations with which this Corporation has, or might reasonably in the future enter into, a relationship or a transaction or arrangement in which I may have a Financial or Conflicting Interest:

NAME OF ORGANIZATION	ADDRESS	DESCRIPTION

1. “Conflicting Interest” shall mean service as a member, shareholder, trustee, director, officer, or employee of any organization or governmental entity that either: competes with this Corporation or Affiliate/Subsidiary, or is involved or is likely to become involved in any litigation or adversarial proceeding with this Corporation or any Affiliate/Subsidiary.
2. “Financial Interest” shall occur if the Board member, officer or manager has, directly or indirectly, through business, investment or family:
 - a. An **ownership or investment interest** in any entity with which the Corporation has a transaction or arrangement; or
 - b. A **compensation arrangement** with the Corporation or with any entity or individual with which the Corporation has a transaction or arrangement (compensation includes direct and indirect remuneration and gifts or favors which are substantial in nature) or
 - c. A **present or potential ownership or investment interest in, or compensation arrangement** with, any entity or individual with which the Corporation is negotiating a transaction or arrangement, or might reasonably in the future enter into a transaction or arrangement.

I hereby certify that the above information is true, correct, and complete to the best of my knowledge, information and belief.

Please Note:

If there are no financial or conflict of interests to disclose, please check this box and complete the date, signature and printed name lines below.

Date

Signature

Printed or Typed Name

Please sign and return BOTH the Acknowledgement Form and Disclosure Statement to _____, _____, in the enclosed envelope. Initial and attach additional sheets if more space is necessary.



What Was, Is and Will Be

Brian Flood

April 2014

© Husch Blackwell LLP

Regulatory Risks to Providers-2005

Improper Payment Act of 2001 starts us rolling

Deficit Reduction Act of 2005 shifts us into gear

Tax Relief Act of 2007 adds fuel

Allison Engine slowed us a bit but...

Changes to False Claims Act under FERA in 2010 over rules Allison and lowers mental state

ACA 6401 adds more focus and fuel to stoke through 2018

18 USC 24(b) now covers everything

2

Congress Taking Notice ...

U.S. House members create health taskforce. Modern Healthcare (1/21/2008, Dobias) reported, "Three former healthcare professionals turned Democratic lawmakers are forming a congressional task force with the intent of pushing through previously stuck legislation." The House members, "Reps. Lois Capps (D-Calif.), a former nurse; Allyson Schwartz (D-Pa.), a former healthcare administrator; and Jason Altmire (D-Pa.), a one-time hospital executive, will lead a task force that's part of a broader voting bloc of Democrats whose aim is to advance long-discussed proposals that have become casualties of congressional wrangling." The team hopes "to tackle chronic-disease management, aid the adoption of electronic prescribing and develop comparative effectiveness and pay-for-performance programs."

3

Congress Taking Notice ... RACS

- February 28, 2008
- CMS PROGRAM IDENTIFIES \$371.5 MILLION IN IMPROPER MEDICARE PAYMENTS IN THREE STATES
The Centers for Medicare & Medicaid Services (CMS) today announced that \$371.5 million in improper Medicare payments has been collected from or repaid to health care providers and suppliers as part of a demonstration program using recovery audit contractors (RACs) in California, Florida and New York in 2007. Nearly \$440 million has been collected since the program began in 2005.
- Acting CMS Administrator Kerry Weems said, "The RAC demonstration program has proven to be successful in returning overpayments to the Trust Fund and identifying ways to prevent future improper payments. We will use the lessons we learned from the demonstration program to help us implement the national RAC program next year."

4

Congress Taking Notice...

- Congressional Quarterly (2/11/08, Richard) reports CMS "said this week it will have its 53 quality improvement organizations concentrate more of their efforts on nursing homes and hospitals that offer the best opportunity for quality improvement. The agency announced the sharpened focus as part of a new set of 'QIO' responsibilities that responds to criticism by the Institute of Medicine and the Senate Finance Committee that the organizations need tighter management and structural changes."

5

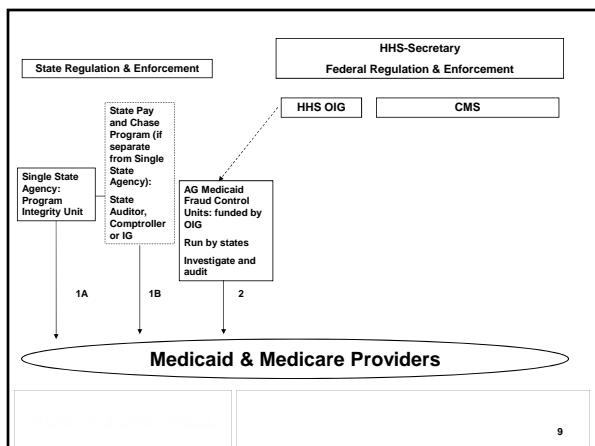
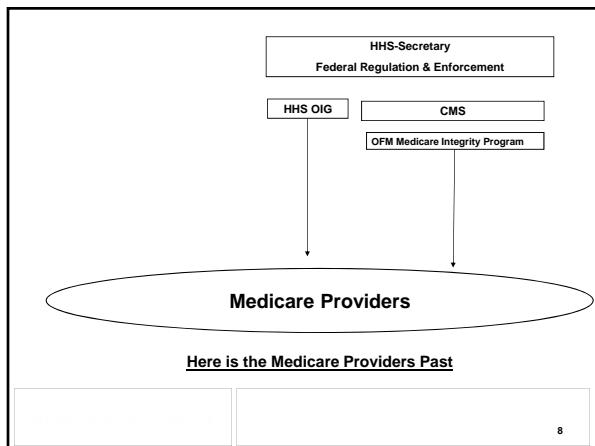
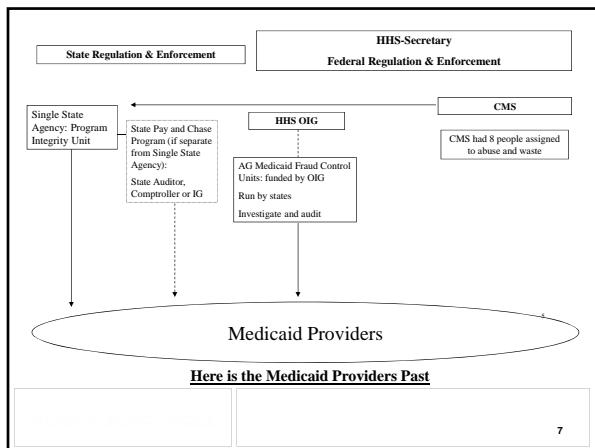
Wall Street Journal - Increased Managed Care Enforcement

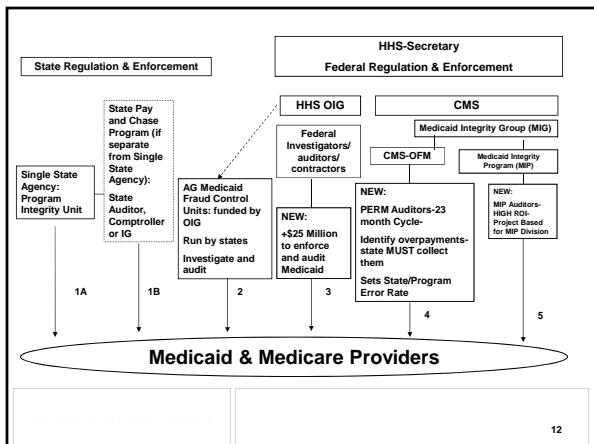
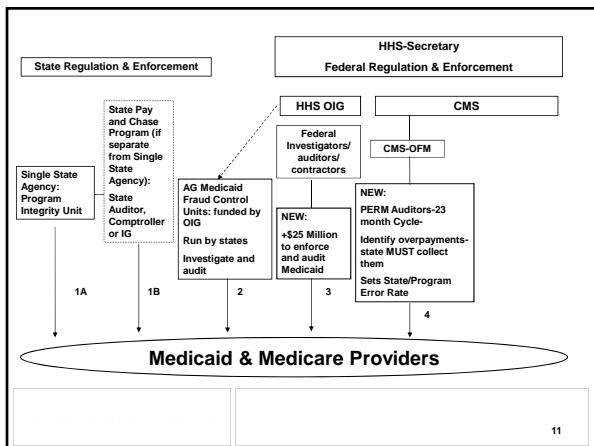
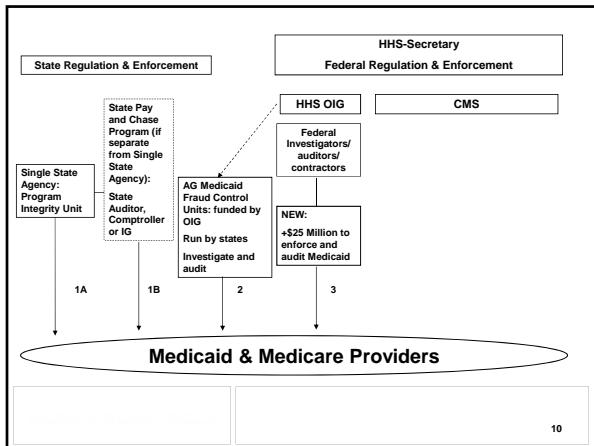
Medicare, Medicaid Managed Care Gets Scrutiny for Fraud

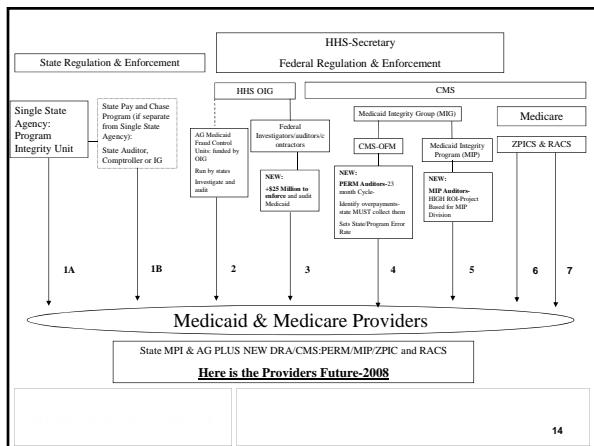
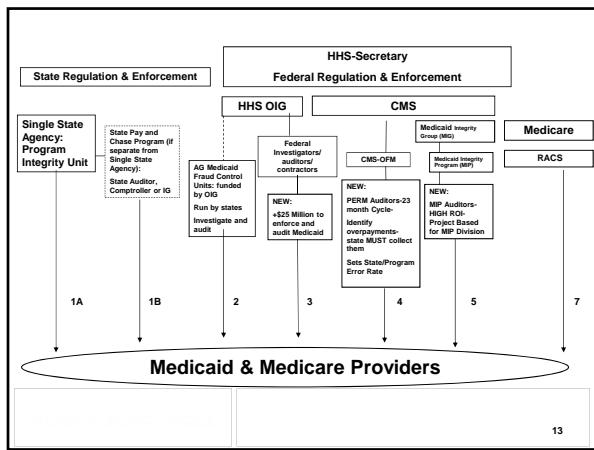
By THEO FRANCIS
March 10, 2008, Page B1

- As the government increases the private sector's role in delivering Medicare and Medicaid services, new kinds of fraud are cropping up that are harder to spot, more complicated to prosecute and potentially more harmful to patients. Now, regulators are belatedly ramping up scrutiny of the managed-care industry, which has grown to cover more than 37 million state and federal beneficiaries.

6







... Congress Taking Notice ...

“CMS’ first national strategy to combat fraud & abuse in the 41 year history of the Medicaid program ...”

Pg. 4 of the CMIP Plan – 2007.

CMS Medicaid Integrity Program Initiative -- September 2007

- ... David Frank, the Director of CMS's Medicaid Integrity Group (MIG) tells MCN ... that "the contractor hired ... will begin with audits of providers in Washington, Florida, Mississippi, and Texas. Frank, a former federal prosecutor tells MCN that "MIP audits will go full-steam ahead" nationally by Spring 2008."

HCCA-AIS Medicaid Compliance News (MCN), Volume 1, No. 1, September 1, 2007.

16

CMS Medicaid Reform Initiative -- October 2007

- "In a major shift in its war on fraud, CMS is replacing program safeguard contractors (PSCs) with seven "zone program integrity contractors" (ZPICS). They will tackle all benefit-integrity activities across the country and form "rapid response teams" with a more aggressive fraud fighting mandate, said Kim Brandt, director of the CMS Program Integrity Group ... Five of the seven ZPICS will be assigned to "hot spot" areas-California, Florida, New York, Illinois and Texas...CMS intends to resolve fraud-and-abuse and overpayment matters administratively more often, when possible ... including sanctions and education ..."

Report on Medicare Compliance, Volume 16, No. 35, October 1, 2007.

17

CMS Medicare and Medicaid Reform -- Initiative 2008

Director of Field Operations for the Center for Medicare and Medicaid Services Medicaid Integrity Group Robb Miller said September 25th that: "Congress clearly intended a positive return on investment and the Office of Management and Budget is tracking how CMS spends the [DRA] money."

Bureau of National Affairs, Inc. Vol. 11 No. 20, October 10, 2007.



18

CMS Medicare and Medicaid Reform -- Initiative 2008

- Director Robb Miller said the first step is a surveillance utilization review of providers, which Miller called "robust and dynamic," to determine whether fraud, waste, or abuse is involved or whether there is a potential overpayment resulting in expenditure of funds in Medicaid that was not intended.

Bureau of National Affairs, Inc. Vol. 11 No. 20, October 10, 2007.



19

CMS Medicare and Medicaid Reform -- Initiative 2008

- Medicaid Integrity Group Robb Miller said the second step is an audit of the providers claims or services, including cost reports, consulting contracts, and risk contracts.
- The third step "is identifying providers receiving federal funds."
- The fourth step is "educating providers on payment integrity and quality of care matters."
- As a note, he said there is no federal mechanism to adjudicate audit findings, so states will be responsible for adjudication.

Bureau of National Affairs, Inc. Vol. 11 No. 20, October 10, 2007.

20

Medicaid Integrity Group Medicaid Integrity Contractors

CMS--2007-DB01

Awarded December 17, 2007

Contract Awarded December 2007

21

Duties

Review of Providers

- The contractor shall use data-mining and analysis techniques to develop models that combines healthcare quality indicators, billing practices and Medicaid specific business rules to predict aberrant provider patterns to identify and rank by risk providers to be audited.
- The contractor will develop reporting tools that show ranked providers according to risk of fraud/overpayment problems with sufficient detail for auditors to begin their audits.

22

Duties

Review of Providers

- This risk assessment report that can be run upon demand for any provider group will provide a risk assessment of all providers, within their respective group within the Medicaid System. ... At a minimum, the risk assessment tool shall identify high risk/problem areas of providers and details of why they place the program at risk.
- The contractor shall conduct simulations using models, to include peer groupings, and the business rules in real world conditions and provide enhancements as new data and technology becomes available.

23

Duties

Near Term Approach

- The contractor shall work ... identify and apply appropriate data analysis techniques to the state's Medicaid data to identify payments and/or billing practices of Medicaid provider's and related entities at the greatest risk of being fraudulent or inappropriate.
- The contractor shall analyze data on a national level or multi-state to identify national and regional trends and patterns, which will assist the audit MICs and the State's in the identification of national issues beyond individual State's ability for identification.

24

Duties Near Term Approach

- The contractor shall work collaboratively with the MICs completing the audit function in addition to the States.
- ... Contractor shall produce reports containing suspect claims and/or relevant providers, with recommendations for recovery action or audit as they deem appropriate.
... [with] sufficient detail for follow-up by audit.

25

Audits: Audits of Providers, Fee for Service Providers, Managed Care Entities

- The Contractor shall plan individual audits of providers, including but not limited to:
 - fee for service providers,
 - managed care entities, and
 - individual providers and institutional providers of Medicaid services within the region.



26

Duties Cost Report Audits

- Some providers receiving payments under the Medicaid program are subject to cost report audits for all payments applicable to services rendered to Medicaid beneficiaries. Cost report audits of a selected provider's financial and statistical records are conducted in order to determine the propriety of the costs claimed on the Medicaid cost report. Cost report auditing ensures that program payments were made on the basis of allowable cost of covered services and ensures the reliability of information reported on the cost report.

27

Duties

Special Review Initiatives

- Special Review Initiatives (SRIs) are used to implement new legislation and policy and respond to issues raised by agencies such as the Government Accountability Office (GAS), the OIG, and CMS. The SRIs may include reviews of Managed Care Organizations (MCOs).



28

CMS Medicare Reform Initiative 2008

Medicare Reform

- RESHAPING THE MACS and PSCs
- THE BIG SHIFT—Starting May 2008!

29

RFI Statement of Work for CMS Medicare Reform Initiative October 2007

- As result of contracting reform, seven zones have been created based on the newly established Medicare Administrative Contractor (MAC) jurisdictions. Included in the seven zones are five high risk areas. As a result of the seven zones, new entities entitled Zone Program Integrity Contractors (ZPICs) have been created to perform program integrity for Medicare Parts A, B, C, D, Durable Medical Equipment (DME), Regional Home Health Intermediary (RHHI) and Medi-Medi ...

See previous slide 18.

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RFI #3:

General Information

The purpose of this RFI is to provide the anticipated RFP Cycle schedule for the future Zone Program Integrity Contract (ZPIC) and to provide information on a pre-solicitation conference call regarding Conflict of Interest (COI).

Cycle One

It is anticipated that this cycle will be awarded before May 31, 2008.

Zone 4: Texas, Oklahoma, Colorado, and New Mexico.

Zone 7: Florida, Puerto Rico, and the U.S. Virgin Islands.

Zone 5: West Virginia, Virginia, North Carolina, South Carolina, Georgia, Alabama, Mississippi, Tennessee, Arkansas, and Louisiana.

Cycle Two

It is anticipated that this cycle will be awarded before December 31, 2008.

Zone 2: Alaska, Washington, Oregon, Montana, Idaho, Wyoming, Utah, Arizona, North Dakota,

South Dakota, Nebraska, Kansas, Iowa and Missouri.

Zone 1: California, Nevada, Hawaii, American Samoa, Guam and the Mariana Islands.

Cycle Three

It is anticipated that this cycle will be awarded before June 30, 2009.

Zone 3: Minnesota, Wisconsin, Illinois, Indiana, Michigan, Ohio, and Kentucky.

Zone 6: Pennsylvania, New York, Maryland, Washington D.C., Delaware, Maine, Massachusetts, New Jersey, Connecticut, Rhode Island, New Hampshire, and Vermont.

31

The following language comes from the public CMS' Statement of Work, SOW:

1.1.4 - Fundamental Activities

- *Fundamental activities of the Zone Program Integrity Contractor (ZPIC) that will help ensure payments are appropriate and consistent with Medicare and Medicaid coverage, coding, and audit policy, and will also identify, prevent, or correct potential fraud, waste and/or abuse may include, but are not limited to, the following:*



32

The following language comes from the public CMS' Statement of Work, SOW:

- *performing BI investigations;*
- *referring cases to law enforcement;*
- *making coverage and coding determinations;*
- *review of audit, settlement, and reimbursement of cost reports;*
- *reviewing bids for participation in the prescription drug program;*
- *assisting CMS in developing a list of entities that may require future monitoring based upon past history;*
- *conducting specified audits;*



33

The following language comes from the public CMS' Statement of Work, SOW:

- conducting specified complaint investigations (Part C and Part D only);
- conducting preliminary investigations into entities conducting fraudulent enrollment, eligibility determination and benefit distribution;
- matching and analysis of Medicare and Medicaid data;
- coordinating potential fraud, waste and abuse activities with the appropriate MMEs; and
- complaint screening (Part C and Part D only).



34

CMS RFI Statement of Work

2.2 – General

The ZPIC shall review and analyze a variety of data in order to focus its program integrity efforts by identifying vulnerabilities and/or specific providers for review and investigation within its zone, referral of potential fraud and abuse cases to law enforcement, and pursuance of administrative actions, which include but are not limited to payment suspension, provider revocation and the implementation of claims processing edits that limit or stop payment to suspect providers. Further, the ZPIC shall be proactive and aggressive in pursuing many different sources and techniques for analyzing data in order to reduce any of its risks within this SOW.

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CMS RFI Statement of Work

October 2007

1.7 – Medical Review

ZPICs are authorized to conduct medical and utilization reviews (in accordance with 42 U.S.C. 1395ddd(b)(1)). These reviews, by necessity, have always included reopening the claim and obtaining and reviewing providers' medical records. (Comp. Gen. Dec. No. B-282777 at 2 (September 2, 1999)).

The ZPIC shall perform:

- A. Prepay medical review (MR)
- B. Postpay MR
- C. Medical review in support of Benefit Integrity
- D. Provider Notification and Feedback
- E. Coordination with POE staff at the AC or MAC on education referrals
- F. Program Integrity Management Reporting (PIMR)

36

The New Liabilities Focus on the Board:

- IRS Guidance's and Form 990
- The Disclosure of Financial Relationships Report (DFRR)-DRA Section 5006
- OIG/AHQA Resource Documents to Board and Senior Leaders (OIG.HHS.GOV)
 - Corporate Responsibility and Corporate Compliance (2003)
 - An Integrated Approach to Corporate Compliance (2004)
 - Corporate Responsibility and Health Care Quality (2007)

37

Targeting Programmatic Vulnerabilities:

CMSO has identified several specific issues that will be audited by CMS and measured by PERM - page 14, 2007.

Strategic Plan:

- Nursing and personal care facilities/agencies
- Prescription drugs
- Durable medical equipment
- Improper claims for payment

38

Regulatory Risks to Providers



39

The Law Now

40

Improper Payment Act

Improper Payment Definition:

- (e) DEFINITIONS.—Section 2 of the Improper Payments Information Act of 2002 (31 U.S.C. 3321 note) as amended:
- (2) IMPROPER PAYMENT. The term ‘improper payment’ —
(A) means any payment that should not have been made or that was made in an incorrect amount (including overpayments and underpayments) under statutory, contractual, administrative, or other legally applicable requirements; and
(B) includes any payment to an ineligible recipient, any payment for an ineligible good or service, any duplicate payment, any payment for a good or service not received (except for such payments where authorized by law), and any payment that does not account for credit for applicable discounts.

41

Improper Payment Act

(3) PAYMENT. The term ‘payment’ means any transfer or commitment for future transfer of Federal funds such as cash, securities, loans, loan guarantees, and insurance subsidies to any non-Federal person or entity, that is made by a Federal agency, a Federal contractor, a Federal grantee, or a governmental or other organization administering a Federal program or activity.



(4) PAYMENT FOR AN INELIGIBLE GOOD OR SERVICE. The term ‘payment for an ineligible good or service’ shall include a payment for any good or service that is rejected under any provision of any contract, grant, lease, cooperative agreement, or any other funding mechanism.”

42

FERA-31 U.S.C. § 3729

- The term "obligation" (to repay an overpayment) is defined as "an established duty, whether or not fixed ..." that arises from "a contractual, grantee, licensure or fee based relationship, from a statute or regulation, or from the retention of any overpayment."
- Under the FCA, "knowingly" is defined not only to comprise "actual knowledge" of a "falsity," but also includes "deliberate ignorance" or "reckless disregard" of the "truth or falsity" of a claim or statement. 31 U.S.C. § 3729(b).

43

FERA-31 U.S.C. § 3729

- FEPA amends the "reverse false claims" provisions of the FCA to expand liability to "knowingly and improperly avoid[ing] or decreasing[an] obligation to pay or transmit money or property to the government."
- In order to create a "reverse false claim" violation it is no longer required that the payor or provider be shown to have taken an "affirmative act": making a false statement or record. Instead, the mere ongoing possession of an overpayment, with an "obligation" to repay, can trigger an FCA violation and liability.



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Summary-PPACA

- Section 6402 of the Act requires providers to report and return overpayments and to report in writing the reason that the overpayment occurred. The new law creates an affirmative and express obligation.
- Report of an overpayment must be made within sixty (60) days after discovering the overpayment.
- The failure to report an overpayment could be deemed to be a false claim under the False Claims Act.
- Specific authorization to assess Civil Monetary Penalties is created for cases where a provider knows about an overpayment but does not report or return it.
- Section 6402 amends the Medicare Anti-kickback Statute to clarify that claims for services resulting from a kickback constitute a false claim under the Federal False Claims Act.
- The element of "intent" under the Anti-kickback Statute is also statutorily modified to clarify that a specific intent to violate the Anti-kickback Statute is not required for a violation.

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Compliance Implications Under PPACA

§6402 (d) REPORTING AND RETURNING OF OVERPAYMENTS. — the effective date of the statutory provision is March 23, 2010.

(d) REPORTING AND RETURNING OF OVERPAYMENTS.

(1) IN GENERAL. If a person has received an overpayment, the person shall:

(A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing and including the reason for the overpayment.

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PPACA 6402(d)(2)(3)

- (2) An overpayment must be reported and returned . . . by the later of –
- (A) the date which is sixty (60) days after the date on which the overpayment was identified;
 - (B) the date on which any corresponding cost report is due, if applicable.
- (3) ENFORCEMENT. Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title. (False Claims Act)

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Healthcare Reform Law Sets New 60-Day Deadline to Repay and Report Overpayments



As amended by the Fraud Enforcement Recovery Act of 2009 (FERA), liability under the False Claims Act (FCA) was expanded to specifically include improper retention of an overpayment of federal funds.

Improper retention of overpayments may now trigger treble damages and penalties of \$5,500 to \$11,000 per claim under the FCA.

However, the FERA amendments did not specify the exact point at which improper retention of an overpayment would trigger FCA liability. The 60-day deadline under the PPACA now becomes part of that question. But PPACA still leaves open the questions of what is meant by the "identified" date upon which an overpayment creates liability and creates the level of culpability under "improper" retention of an overpayment.

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Healthcare Reform Law Sets New 60-Day Deadline to Repay and Report Overpayments

CMS requires hospitals to report and return credit balances like improper Medicare payments every ninety (90) days on Form 838. Hospitals are bound either by health reform's 60-day requirement or the CMS 60-day quarterly credit-based requirement. Failure to return the payment could result in FERA liability.

Bottom line: failure to meet the PPACA 60-day deadline may trigger severe penalties including penalties under the FCA.

The deadline was March 23, 2010, for compliance and liability for improper payments began on May 22, 2010.

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State Activity Under 60-day Rule as Parallel

- "Criteria for Medicaid Provider Overpayments"
- CMS cites section 1903(d)(2) of the Act as the principal authority in disallowing the Federal share for provider overpayments. The Consolidated Omnibus Budget Reconciliation Act of 1985 amended this section and states that CMS will adjust reimbursement to a State for any overpayment. Furthermore, States are required to return the Federal share of overpayments within sixty (60) days of the date of discovery, whether or not the recovery was made. This legislation is codified in 42 CFR 433 subpart F, "Refunding of Federal Share of Medicaid Overpayments to Providers," which requires States to credit the Federal share of overpayments on the CMS 64 report for the quarter in which the 60-day period following discovery ends.

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State Activity Under 60-day Rule as Parallel

- According to 42 CFR 433.316, an overpayment resulting from a situation other than fraud or abuse is "discovered" on the earliest date that:
 - 1) any Medicaid agency official or other State official first notifies a provider in writing of an overpayment and specifies a dollar amount that is subject to recovery,
 - 2) a provider initially acknowledges a specific overpaid amount in writing to the Medicaid agency, or
 - 3) any State official or fiscal agent of the State initiates a formal action to recoup a specific overpaid amount from a provider without having first notified the provider in writing.

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State Activity Under 60-day Rule as Parallel

- Additionally, the regulation specifies that overpayments resulting from fraud or abuse be considered discovered on the date of the final written notice of the State's overpayment determination that a Medicaid agency official or other State official sends to the provider.
- Finally, Departmental Appeals Board decision 1391 addresses overpayment settlements between the State and a provider. States are not allowed to reduce the Federal share by settling overpayment receivables with a provider for less money than is supported by the provider's records.

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Effective October 14, 2012 - The New Texas Rules in Subchapter G:

- New Section 371.1655 that incorporates the new requirement that Medicaid, CHIP providers who fail to repay overpayments or who are affiliated with and who control a prohibited provider be terminated.(Health and Safety Code §62.1561 as amended by 1720).
 - that requires that all Medicaid program participants or providers establish an effective compliance program for detecting criminal, civil and administrative violations;
 - that promotes quality of care (PPACA §6401's amendment to 42 U.S.C. 1395cc(j));
 - contains the core elements identified in the federal sentencing guidelines for corporations; or
 - established by the United States Secretary of Health and Human Services.

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TAC Section 371.1655 Program Compliance

A person Commits a Program Violation if the person:

- (4) fails to repay overpayments within sixty (60) calendar days of self-identifying or discovering an overpayment that was made to the person by the Medicaid, CHIP or other HHS program.
- (7) fails to establish an effective compliance program for detecting criminal, civil, and administrative violations, that promotes quality of care and contains the core elements identified in the federal sentencing guidelines for corporations or established by the United States Secretary of Health and Human Services.

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Forecast - Cloudy

- For over 14 years, the Office of Inspector General (OIG) has been encouraging Medicare and Medicaid providers to adopt voluntary compliance programs. Since 1998, the OIG has issued compliance guidance to 11 healthcare sectors, including:
 - Nursing Facilities;
 - Hospitals;
 - Hospices;
 - Durable Medical Equipment, Prosthetics, Orthotics, and Supply (DMEPOS) businesses;
 - Third-Party Medical Billers; and
 - Home Healthcare.
- However, under the Patient Accountability and Affordable Care Act (PPACA), compliance programs will no longer be voluntary for Medicare and Medicaid providers. They will be mandatory for those providers who participate in any federal healthcare program.
- Section 6401 of PPACA requires that all healthcare providers establish compliance and ethics programs that contain required "core elements" as a condition of participation in the federal healthcare programs. Health and Human Services (HHS) has not yet defined the "core elements."

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The 7 Elements Plus

- Now nursing facilities are subject to Section 6102, which identifies eight elements for nursing facility compliance programs, including:
 - Establish compliance standards and procedures to be followed by employees and agents;
 - Designate "high-level personnel" to oversee compliance and give them sufficient resources and authority to assure compliance;
 - Avoid giving discretionary authority to individuals the organization knows or should know have a "propensity to engage in criminal, civil, and administrative violations";
 - Provide effective communication of the standards and procedures to all employees and agents;

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The 7 Elements Plus

- Establish monitoring and auditing systems as well as reporting systems that include anti-retaliation protections for employees who report suspected offenses;
 - Consistently enforce standards through disciplinary action;
 - Report the offense and take steps to prevent further similar offenses, if an offense is detected; and
 - Undertake periodic reviews of the compliance program to identify necessary changes.
- **Generally, the core and required elements follow the seven steps of the federal Sentencing Guidelines at §8B2.1.** However, if they have an associated PBM then the new CH 21 requirements apply. Also, the Federal Acquisition Rules were updated 12-12-2008 to require similar programs in all federal contracts over five million dollars.

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New Federal Requirements - Effective 07-27-12

Prescription Drug Benefit Manual Chapter 9 – Compliance Program Guidelines
and
Medicare Managed Care Manual Chapter 21 – Compliance Program Guidelines
(Chapter 9 - Rev. 15, 07-27-12)
(Chapter 21 - Rev. 109, 07-27-12)

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New Federal Requirements - Effective 07-27-12

The following definitions apply for purposes of these guidelines only:

- **Abuse:** includes actions that may, directly or indirectly, result in: unnecessary Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically. Abuse involves payment for items or services when there is no legal entitlement payment and the provider has not knowingly and/or intentionally misrepresented obtain payment. Abuse cannot be differentiated categorically from fraud, distinction between "fraud" and "abuse" depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.
- **Waste:** is the over utilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.

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30 – Overview of Mandatory Compliance Program

All sponsors are required to adopt and implement an effective compliance program, which must include measures to prevent, detect and correct Part C or D program noncompliance as well as FWA.

The compliance program must, at a minimum, include the following core requirements:

1. Written Policies, Procedures and Standards of Conduct;
2. Compliance Officer, Compliance Committee and High Level Oversight;
3. Effective Training and Education;
4. Effective Lines of Communication;
5. Well Publicized Disciplinary Standards;
6. Effective System for Routine Monitoring and Identification of Compliance; and
7. Procedures and System for Prompt Response to Compliance Issues.

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To Be Effective -



In order to be effective, a sponsor's compliance program must be fully implemented, and should be tailored to each sponsor's unique organization, operations and circumstances.

A compliance program will not be effective unless sponsors devote adequate resources to the program. Adequate resources include those that are sufficient to do the following:

1. Promote and enforce its Standards of Conduct;
2. Promote and enforce its compliance program;
3. Effectively train and educate its governing body members, employees and FDRs;
4. Effectively establish lines of communication within itself and between itself and its FDRs;
5. Oversee FDR compliance with Medicare Part C and D requirements;
6. Establish and implement an effective system for routine auditing and monitoring; and
7. Identify and promptly respond to risks and findings.

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50.6.1 – Routine Monitoring and Auditing

- Sponsors must undertake monitoring and auditing to test and confirm compliance with Medicare regulations, sub-regulatory guidance, contractual agreements, and all applicable Federal and State laws, as well as internal policies and procedures to protect against Medicare program noncompliance and potential FWA.
 - Monitoring activities are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.
 - An audit is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.

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50.6.3 – Development of the Monitoring and Auditing Work Plan

- Sponsors must have a system of ongoing monitoring and auditing that is reflective of its size, organization, risks and resources to assess performance in, at a minimum, areas identified as being at risk.
- The monitoring and auditing work plan must be coordinated, overseen and/or executed by the compliance officer, assisted if desired by the compliance department staff and/or the compliance committee.
- The compliance officer may coordinate with the audit department, if any, in connection with these activities.
- Sponsors must have a system of ongoing monitoring and auditing that is, the compliance officer must receive regular reports from the audit department or from those who are conducting the audits regarding the results of auditing and monitoring and the status and effectiveness of corrective actions taken.
- It is the responsibility of the compliance officer or his/her designee to provide updates on monitoring and auditing results to the compliance committee, the CEO, senior leadership and the sponsor's governing body.

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The Report - 50.6.4

Sponsors should prepare a standard audit report that includes items such as:

- Audit Objectives;
- Scope and Methodology;
- Findings;
- Condition;
- Criteria;
- Cause;
- Effect; and
- Recommendations.



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50.6.4 – Audit Schedule and Methodology

- In developing the types of audits to include in the work plan sponsors must:
 - Determine which risk areas will most likely affect the sponsor, and prioritize the monitoring and audit strategy accordingly.
- Utilize appropriate methods in:
 - Selecting sponsor facilities, pharmacies, providers, claims, and other areas for audit;
 - Determining appropriate sample size;
 - Extrapolating audit findings using statistically valid methods that comply with generally accepted auditing standards to the full universe; and
 - Applying targeted or stratified sampling methods driven by data mining and complaint monitoring.
- Use special targeted techniques based on aberrant behavior.
- Assess compliance with internal processes and procedures.

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50.6.7 – Tracking and Documenting Compliance and Compliance Program Effectiveness

- Sponsors should track and document compliance efforts. In addition to formal audits and monitoring, ... and other mechanisms that show the extent to which operational areas and FDRs are meeting compliance goals.
- Compliance of operational areas should be tracked by management and publicized to employees.
- Issues of noncompliance identified in dashboards, scorecards and self-assessment tools, etc., should be shared with senior management. Sponsors should consider including compliance performance as a measure for staff, management, and FDR evaluations.

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Take Away



- Integrated compliance, monitoring and auditing programs are now mandatory.
- Failing to have a program that is material and commensurate to the risk creates more problems for the organization.
- Having an integrated program with subject matter knowledge from coding, audit, legal and management is key to success.

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2014 and Forward



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UPIC-The New Model

- CPI must seek new and innovative approaches...to swiftly anticipate and adapt to ... those involved in health care fraud, waste, and abuse activities.
- CPI is developing a unified program integrity strategy
- The concept ... involves contractors performing work across the Medicare and Medicaid program integrity continuum. The program incorporates data matching, coordination, and information sharing to identify fraudulent or wasteful billing behavior that goes undetected when the programs are reviewed in isolation.
- This approach will result in a more seamless and rigorous program integrity strategy ... fostering further program integrity coordination with other private and governmental payers across the entire health care industry.

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Unified Program Integrity Contractor or UPIC

- Primary function will be to realize and execute the CPI's nationally-set priorities and goals.
- Expects the number of UPICs will fall between five and fifteen.
- Have expertise in and knowledge of auditing and health care data analysis and investigative methods, techniques, and processes used to prevent, detect, and combat fraud, waste, abuse, and overpayments in the Medicare and Medicaid programs.

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The Scope of the UPICs



They will encompass functions that are currently performed by several contractors, including; Zone Program Integrity Contractors (ZPICs, including their Medicare-Medicaid Data Match ("Medi-Medi") responsibilities), Program Safeguard Contractors (PSCs), and the Medicaid Integrity Contractors (MICs). [In a future stage ... incorporate the work performed by the Medicare Drug Integrity Contractors (MEDICs) as well as Medicare Part C program integrity tasks ...

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1. Identify and Prioritize Leads

- The most fundamental priority of protecting program dollars [is] by stopping future inappropriate payments by use of any appropriate administrative tool or remedy, or recovering past illegitimate payments ...
- The first workload category shall be leads prioritized ... on the results of sophisticated analytics ...
 - ii. The second workload category shall be leads identified and prioritized through collaboration between the Contractor and CMS.
- The third workload category shall be leads that are requested to be worked by law enforcement ...

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The Contractor shall consider the following overarching principles when recommending priority areas:

- i. Patient abuse or harm;
- ii. Ability to prevent future fraud, waste or abuse by taking administrative actions to remove providers or suppliers from the affected Program, or otherwise prevent inappropriate future payments;
- iii. Multi-State fraud;
- iv. High dollar amounts of potential overpayments;
- v. Likelihood for an increase in the amount of fraud or enlargement of a pattern, including the potential that findings can be used to refine CMS's anti-fraud prevention efforts and analytic models;
- vi. Fraud complaints made by Medicare supplemental insurers;
- vii. Law enforcement requests for assistance that involve court-imposed deadlines;
- viii. Law enforcement requests for assistance in ongoing investigations that involve interagency initiatives or projects;
- ix. Law enforcement requests for early administrative actions to prevent or mitigate losses to the affected Program(s); and
- x. Other new elements that may be identified by CMS through technical direction.

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2. Conduct Data Analysis and Manage Leads

- The Contractor shall analyze data to identify trends and patterns of potential fraud, waste, and abuse from three perspectives: the Medicare-only perspective, the Medicaid-only perspective, and the joint/composite Medicare and Medicaid perspective. The Contractor shall develop annual data analysis plans that address methodologies and findings within and across both programs.



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HFPP-Public Private Partners in UPIC

- The Contractor shall support CMS in the evaluation of information and data from the HFPP. The HFPP is an opportunity for public and private sectors to exchange facts and information in order to reduce the prevalence of fraud in the healthcare industry ... As requested by CMS, the Contractor shall analyze and research data developed by a Trusted Third Party (TTP) (on behalf of the HFPP) and furnished to CMS. The Contractor shall develop leads referred to it by CMS identified through the HFPP.

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3. Conduct Investigations

- The Contractor shall conduct a variety of reviews to determine the appropriateness of Medicare Part A and Part B payments, even when there is no evidence of fraud. All Medicare Part A and Part B claims types may be reviewed, including claims submitted by individual practitioners, institutional providers such as hospitals, and other fee for service (FFS) providers. As specified in the Medicare Program Integrity Manual ... the Contractor may request and review additional Medicare FFS data (including Medicare cost report data) from the MAC as part of the investigative process.

2013 MEDICARE PART A		ARE PART B	
Part A & B Hospital Payment System Hospital Care and Skilled Nursing Facility	Part B Physician Services and Other Professional Services	Part B Hospital Care and Skilled Nursing Facility	Part B Physician Services and Other Professional Services
How long are the services provided?	How much are the payments?	How long are the services provided?	How much are the payments?
1 - 49 days	\$1184 \$1184	1 - 49 days	\$0 \$0
50 - 90 days	\$296 \$296	50 - 90 days	\$0 \$0
91 - 120 days	\$592 \$592	91 - 120 days	\$0 \$0
121 days or more	NOTHING 100% \$148	121 days or more	20% \$0 \$0

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Medicaid too



- The Contractor shall work with each State within their region to develop processes for investigating issues involving Medicaid. This includes Medicaid only investigations and investigations involving both Medicare and Medicaid (relating to providers and beneficiaries that participate in both programs).
- The Contractor shall determine the appropriate State agencies (including other entities contracted by a State to perform audits or PI activities, e.g. Recovery Auditors) to include in investigations and document a protocol for working those issues with the stakeholders. The Contractor shall be prepared to serve as the lead for Medicaid investigations or provide subject matter expertise based on the needs of the State.

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4. Protect Program Dollars

- The Contractor shall assess the results of its data analysis or investigative work and recommend the appropriate administrative action to CMS (or directly work with the MAC in keeping with CMS instructions), law enforcement (if applicable), and the State Medicaid agency.
- Administrative actions are the first step to stopping inappropriate payments to providers or removing abusive or fraudulent providers from the Medicare and Medicaid programs.
- Administrative actions that protect program dollars either by stopping future payment or recovering monies are the highest priority for CMS and its Contractors.

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Administrative Actions - Tell All

When the Contractor recommends an administrative action to CMS (or the MAC) for a provider that is also enrolled in Medicaid, the Contractor shall notify the State Medicaid agency.

When the Contractor recommends an administrative action to the State Medicaid agency for a provider that is also enrolled in Medicare, the Contractor shall notify CMS CPI (and/or the MAC in keeping with CMS instructions).

The Contractor shall coordinate with the State Medicaid agency to identify the appropriate administrative actions available and determine how to apply the rules so the actions are applied effectively as a result of data analysis or investigative work.

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Medicare and Medicaid Payment Suspensions:

- i. The Contractor shall request Medicare payment suspensions in accordance with 42 CFR §§405.370-372. Medicare payments due a provider may be suspended in whole or in part when:
 - CMS or a Medicare contractor (inclusive of the Contractor) has consulted with the HHS OIG (and DOJ as needed) and determined that a credible allegation of fraud exists;
 - CMS or a Medicare contractor (inclusive of the Contractor) possesses reliable information from any source that an overpayment exists or that the payments to be made may not be correct (though additional information may be needed for a final determination of the payment or overpayment amount); or
 - The provider fails to file a timely cost report.

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5. Identify Medicare and Medicaid Overpayments

- During the course of its analysis of Medicare and Medicaid payments, resulting from an internal investigation of leads (including medical review) or structured audits of paid claims, the Contractor will identify improper payments that do not involve fraudulent intent. In such cases, the Contractor shall identify, determine, and refer the overpayments made to providers (individuals or entities) receiving Federal funds under Medicare and Medicaid.
- The Contractor shall refer Medicare overpayments to the MAC that made the initial claims payment for collection ... The Contractor shall supply the required documentation supporting each overpayment to the MAC.

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Medicaid too

With respect to Medicaid overpayments, the Contractor shall prepare an Audit Report in a format agreed to by the State Medicaid agency and CMS that includes a section regarding opportunities to minimize future inappropriate Program expenditures. The Contractor shall document the audit protocol applicable to the State and shall submit audit findings and potential overpayments to the State Medicaid Agency and CMS.

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Accountability for Collection

- The Contractor shall coordinate with the MAC (in the case of Medicare overpayments) and the State Medicaid agency (in the case of Medicaid overpayments) to track the collection progress of all potential overpayments referred by the Contractor, in a format prescribed by CMS.



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6. Support to the Administrative Claims Appeals Process

The Contractor shall provide support throughout the Medicare and Medicaid claims administrative appeals process, with respect to any claims adjustments that were referred by the Contractor to the MAC (in the case of Medicare payments) or to the State Medicaid agency (in the case of Medicaid payments) that are subsequently appealed by the provider.

This includes providing supporting documentation (including the medical record) with appropriate reference to statutes, regulations, manuals and instructions.

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Medicare Appeals

- The Contractor shall provide support throughout the Medicare and Medicaid claims administrative appeals processes, with respect to any claims adjustments that were referred by the Contractor to the MAC (in the case of Medicare payments) or to the State Medicaid agency (in the case of Medicaid payments) that are subsequently appealed by the provider.
- This includes providing supporting documentation (including the medical record) with appropriate reference to statutes, regulations, manuals and instructions.

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Medicaid Appeals

- For Medicaid provider appeals, the Contractor shall adhere to State laws governing appeals and provide support to the State Medicaid agency, including attending appeals administrative hearings in-person (if this option is available) as needed.



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7. Provide Support to CMS

- The Contractor shall develop and investigate Medicare and/or Medicaid "problem providers" ...
- The Contractor shall work with CMS to ensure that all Federal, State and local health care partners within the respective geographic areas are sharing fraud information and trends so that all partners have a common understanding of the fraud concerns of the respective zones.
- The Contractor will also actively share and provide such data. The Contractor shall participate in and support regional "Fraud Coordination Committees" (FCCs) involving CMS Medicare or Medicaid Field Offices and the applicable State Medicaid staff, as FCCs are established.



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8. Provide Support for Law Enforcement Inquiries (Requests for Assistance)



- Consistent with the scope and breadth of its policy, clinical, and investigative expertise ... the Contractor shall be prepared to testify, when required, in Federal and state court. The Contractor shall have capability to testify (1) its own investigative work and administrative actions, as well as (2) function as experts at trial when required by law enforcement (e.g., HEAT Strike Force, MFCU, DOJ, etc. cases).

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Expected Outcomes

CMS expects the UPIC initiative to generate an increased number of proactive, high-quality, appropriate and timely administrative PI actions that are able to be sustained through any applicable administrative or legal review processes. CMS views such administrative actions, which stop inappropriate payments to providers and remove abusive or fraudulent providers from CMS programs, as a cornerstone of the agency's new PI strategy.

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More Administrative Actions and Referrals

- The range of administrative actions to be supported, developed and recommended by the Contractor to the appropriate Federal or State authority include but are not limited:
 - Medicare payment suspensions (42 CFR §§405.370-372)
 - Medicaid payment suspensions (42 CFR §§455.2 and 455.23)
 - Medicare enrollment revocations
 - Medicaid enrollment revocations
 - Medicare and Medicaid program exclusions
 - Civil Monetary Penalties
- The Contractor shall be prepared to support additional administrative actions as the Congress provides increased PI legal authorities to CMS in the coming years.
- The Contractor shall refer potential fraud cases to law enforcement and provide support, as required ...

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Questions?





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Thank You

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Analytics to Answers
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Season Your Compliance Program with PEPPER

March 31, 2014

Kim Hrehor
Cheryl Field

TMF
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Objectives

- PEPPER is a free data report for areas at risk for improper Medicare payments
- Learn how the data are compiled and what they mean to you
- Consider suggestions to integrate PEPPER into your compliance program

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What is PEPPER?

- Program for Evaluating Payment Patterns Electronic Report
- A comparative report that summarizes a provider's Medicare claims data statistics in areas identified as at risk for improper Medicare payments.
- Available for short-term and long-term acute care hospitals, critical access hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, partial hospitalization programs, hospices and skilled nursing facilities.

Compare Payment Patterns Electronic Report
Compare Targets Report, Four Quarters Ending Q4 FY 2012
00071 Hospital C2071

The Compare Report displays statistics for target areas that have reportable data (1+ target discharges) in the most recent quarter. The report compares the provider's payment percentiles to the national average and to other providers in the respective comparison group. For example, if a provider's payment percentile (one below) is 0.0 - 80% of the national average, it means the provider's payment is lower than the national average and higher than 80% of the providers in that provider's state percentile (displayed) and the provider related percentile values should be interpreted as being lower than the national average. The provider's state percentile is displayed. The provider related percentile values should be interpreted as being higher than the national average. The greater the difference between the provider's state percentile value and the national average value, or between the national state percentile values, the greater consideration should be given to that target area.

Target	Description	Number of Discharges	Hospital Days	Hospital Nuts	Hospital Tubs	Sum of Payments
1 to 5-Day Readmission	Definition: Provider of one or more admissions for hospital days in the same calendar year as the previous admission to the same or to another medical facility for the same or similar condition. Discharge date of the first admission must be earlier than the discharge date of the second admission. Discharge date of the second admission must be later than the discharge date of the first admission. Discharge date of the second admission must be on or after the 6th day of the month following the discharge date of the first admission. Discharge date of the second admission must be on or before the 15th day of the month following the discharge date of the first admission.	29	3.5%	43.3	42.9	\$195,164
30-Day Readmission	Definition: Provider of one or more admissions for hospital days in the same calendar year as the previous admission to the same or to another medical facility for the same or similar condition. Discharge date of the first admission must be earlier than the discharge date of the second admission. Discharge date of the second admission must be later than the discharge date of the first admission. Discharge date of the second admission must be on or after the 6th day of the month following the discharge date of the first admission. Discharge date of the second admission must be on or before the 15th day of the month following the discharge date of the first admission.	112	19.3%	75.9	74.1	\$1,100,062

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Why are SNFs Receiving PEPPER?

- CMS is tasked with protecting the Medicare Trust Fund from fraud, waste and abuse.
- The provision of PEPPER supports CMS' program integrity activities.
- PEPPER is an educational tool that is intended to help providers assess their risk for improper Medicare payments.

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PEPPER Statistics

- Medicare fee-for-service claims data (see p. 5 of SNF PEPPER user's guide)
- Organized in three 12-month time periods based on fiscal year (FY).
- 3 different comparison groups

FY 2010	FY 2011	FY 2012
---------	---------	---------

National Comparison MAC/Jurisdiction Comparison State Comparison

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Add some flavor to your Compliance Program...

1. Compliance policies & procedures, standards of conduct
2. Compliance office & compliance committee
3. Open lines of communication
4. Training & teaching
6. Response to detected deficiencies
7. Enforcement of disciplinary standards

5. Monitoring & auditing

Use a little
PEPPER
here!

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SNF Improper Payment Risks

- PEPPER does not identify improper payments.
- SNFs are reimbursed through the SNF prospective payment system (PPS).
 - Minimum Data Set (MDS)
 - Resource Utilization Group (RUG)
- Target areas were identified based on a review of literature regarding SNF payment vulnerabilities, review of the SNF PPS, analysis of claims data and coordination with CMS subject matter experts.

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What are the Risks?

- Office of Inspector General (OIG) FY 2013 work plan, OIG compliance program guidance (2000 and 2008)
 - Quality of care
- **Billing integrity**
 - Cost reporting
 - Anti-kickback
 - HIPAA
 - Etc.

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Office of Inspector General Report

- “Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More than a Billion Dollars in 2009”, November 2012, OEI-02-09-00200
- Identified 25% of SNF claims billed in error
- Available at <http://oig.hhs.gov/oei/reports/oei-02-09-00200.pdf>

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Target Area

- Area identified as potentially at risk for improper Medicare payments.
- Constructed as a ratio:
 - Numerator = RUG days/episodes of care identified as potentially problematic
 - Denominator = larger reference group that contains the numerator
- Target area percents are calculated for each target area and each time period.

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What is an “Episode of Care” (EOC)?

- To create an EOC: All claims submitted by a SNF for a beneficiary are collected and sorted from the earliest “Claim From” date to the latest.
- If the patient discharge status code on the latest claim in a series indicates that the beneficiary was discharged or did not return for continued care, that beneficiary’s EOC is included in the time period in which the latest “Through Date” falls.
- If there is a gap between one claim’s “Through Date” to the next claim’s “From Date” of more than 30 days, then that is considered the ending of one EOC and the beginning of a new EOC.
- If the latest claim in the series ends in the last month of the latest time period (Sept. 1-30, 2012 for the Q4FY12 release) and indicates that the beneficiary was still a patient (patient discharge status code ‘30’), then that beneficiary’s EOC is not included.
- Each EOC is included in the time period in which the latest “Through Date” falls.
- Claims are collected for four months prior to each time period so that the longer lengths of stay may be evaluated.

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EOC Examples for a SNF

Bene	Claim Number	From Date	Through Date	Day Count per claim	Gap Days Between Claims	SNF EOC
Bene A	1	10/19/09	10/31/09	13	n/a	1
Bene A	2	11/1/09	11/26/09	25	1	1
Bene A	3	11/30/09	11/30/09	1	4	1
Bene A	4	12/1/09	12/18/09	16	1	1
Bene A	5	12/24/09	12/31/09	8	6	1
Bene A	6	1/1/10	1/6/10	5	1	1
Bene A	7	1/8/10	1/31/10	24	2	1
Bene A	8	2/1/10	2/3/10	3	1	1
Bene A	9	4/21/10	4/30/10	10	77	2
Bene A	10	5/1/10	5/2/10	2	1	2

SNF PEPPER Target Areas	
	Target Area Definition
Coding of ADL	Target Area RUGs with High ADL N: count of days billed with RUG equal to RUX, RVX, RHX, RMX, RUC, RVC, RHC, RMC, RLB D: count of days billed for all therapy RUGs
	Nontherapy RUGs with High ADL N: count of days billed with RUG equal to SSC, CC2, CC1, BB2, BB1, PE2, PE1, IR2, IB1 in RUG III; HE2, HE1, LE2, LE1, CE2, CE1, BB2, BB1, PE2, PE1 in RUG IV D: count of days billed for all nontherapy RUGs
	Change of Therapy Assessment N: count of assessments with AI second digit "D" D: count of all assessments

SNF PEPPER Target Areas, cont.	
	Target Area Definition
Therapy	<p>Ultrahigh Therapy RUGs</p> <p><i>N:</i> count of days billed with RUG equal to RUX, RUL, RUC, RUB, RUA</p> <p><i>D:</i> count of days billed for all therapy RUGs</p>
	<p>Therapy RUGs</p> <p><i>N:</i> count of days billed for all therapy RUGs</p> <p><i>D:</i> count of days billed for all therapy and nontherapy RUGs</p>
	<p>90+ Day Episodes of Care</p> <p><i>N:</i> count of episodes of care at the SNF with LOS 90+ days</p> <p><i>D:</i> count of all episodes of care at the SNF</p>

- The target area percent measures billing patterns for each target area over time.
- More useful information comes from knowing how the SNF compares to other SNFs in the nation and jurisdiction, which is why we calculate percentiles.
- Definition of a percentile:
 - The percentage of SNFs with a lower target area percent

Percentile Calculation Example

Percentile Range	Percentages
80 th Percentile	63%, 52%, 49%, 44%, 43%, 40%, 33%, 29%
20 th Percentile	24%, 11%

- The top two SNFs' percents are at or above the 80th percentile.
- The bottom two SNFs' percents are at or below the 20th percentile (for areas at risk for undercoding only).



- Two sets (one for the SNF, one for the MAC jurisdiction), two reports:
 - Top RUGs for all EOC
 - Top RUGs for EOC with 90+ days
- List the top RUGs by number of days billed for EOC that end in FY 2012.
- Include number of RUG days billed, percent of RUG days to total days, percent of EOC with the RUG billed to total EOC, ALOS for RUG.
- Supplemental; have no impact on outlier status or risk for improper payments.

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Review: How does PEPPER identify SNFs at Risk?

- A SNF's target area percent is compared to other SNFs' percents in the state, MAC/FI jurisdiction and nation.
- If the SNF's target area percent is at/above the national 80th percentile or at/below the national 20th percentile, the SNF is identified as at risk for improper Medicare payments.
- Compare and Target Area reports:
 - Red bold print** – at or above the national 80th percentile for the target area.
 - Green italic print** – at or below the national 20th percentile for the target area (areas at risk for undercoding only)

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Compliance Program Timeline

- In 2000, Federal Register / Vol. 65, No. 52 / Thursday, March 16, 2000 / Notices 'MAY' develop programs – voluntary
 - OIG/DHHS issues the first Compliance Program Guidance (CPG) for Nursing Facilities
- In 2008, compliance programs, 'SHOULD' develop programs
 - OIG/DHHS issued a supplemental CPG
- In 2013, 'MUST' develop programs
 - PPACA of 2010 sets a deadline of 3/23/2013 for nursing facilities to have an active compliance program

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Mandatory Compliance Programs – For Nursing Homes

- Mandatory compliance program that is reasonably designed, implemented, and enforced so that it generally will be effective in preventing, detecting and mitigating criminal, civil, and administrative violations – and in promoting quality of care

"Promoting Quality of Care"

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ACA Compliance Program Requirements

- The facility must establish compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing compliance violations.
- The assignment of overall compliance program oversight to “high-level personnel” with “sufficient resources” and authority” to assure such compliance.
- The exercise of “due care” not to delegate “substantial discretionary authority” to individuals whom the nursing facility knew or should have known had a “propensity to engage in criminal, civil, or administrative violations.”

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ACA Compliance Program Requirements

- The effective communication of compliance standards and procedures to all employees and agents, including training programs or published materials.
- The adoption of reasonable monitoring and auditing systems reasonably designed to detect compliance violations by employees and other agents and a mechanism for employees and agents to report violations without fear of retribution.
- The consistent enforcement of appropriate disciplinary mechanisms, including for failure to detect an offense.

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ACA Compliance Program Requirements

- Following detection of an offense, reasonable responses to include steps to prevent further similar offenses, including any modifications to the compliance program.
- The periodic reassessment of its compliance program to identify modifications necessary to reflect changes within the nursing facility organization and its facilities

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Compliance requirement	What does this mean?	What internal systems do I review?
<p>1. The facility must establish compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing compliance violations.</p>	<ul style="list-style-type: none"> • Develop or review the facility's code of conduct • Review policies and procedures related to regulatory, civil, criminal financial and quality issues 	<ul style="list-style-type: none"> • Mission statements that reinforce the expectations for all individuals within the facility • Admission policies and procedures • Abuse identification, investigation and reporting according to Federal and State guidelines • Criminal background checks • State licensure and nurse aide registry checks • Drug and alcohol testing • Systems that audit and monitor hiring practices, resident rights, and employee practices • Percent of licensed staff with current licensure • Notifications to state agencies

		Analytics to Answers		
		PointRight		
		DETECT	PREVENT	MITIGATE
Practice	How do you detect potential issues in your practices?	How do you prevent potential issues in your practices?	How do you mitigate potential issues in your practices?	
	Measure outcomes	Monitor high risk areas	Conduct root cause analysis and change practice as needed	
	Example: OnPoint 30 adjusted rehospitalization rate	Review High Risk residents in PointRight's RADAR report	Use Rehospitalization Insights determine which diagnostic group is most likely to bounce back to the hospital and why	

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Great, But What's The MDS Tie In?



The illustration shows a simple black and white cartoon character with a large, bulbous head. Two large question marks are floating above the character's head, one on each side, suggesting confusion or a lack of understanding.

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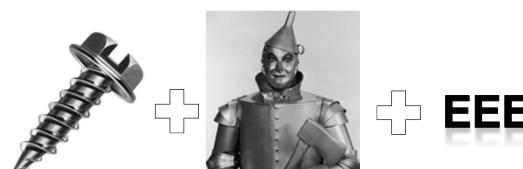
MDS Has Many External Stakeholders

- External entities who are directly or indirectly concerned about MDS
- Office of Inspector General (OIG)
- General Accounting Office (GAO)
- Center for Medicare and Medicaid Services (CMS)
- Medicare Administrative Contractors (MACs)
- State Agencies (SA)
- Others

And with many stakeholders comes much... 28

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As the Principle Driver, It's Also Essential in Compliance

- As a compliance tool, the MDS
 - Audits quality
 - Audits billing practices
 - Monitor access to care
 - Appropriate utilization of resources
 - Reinforces that industry standard practices are in place
 - Is a documented map to success...or failure 30

SNF upcoding rampant: OIG

Nursing homes are overcharging Medicare around \$1.5 billion annually, a federal report released in mid-November asserts.

The Office of Inspector General report says SNFs are upcoding claims for Medicare, either by listing more services than were done or by giving incorrect treatment. Under particular scrutiny are physical, occupational and speech therapy, and ADLs.

The OIG made the following recommendations, which were accepted by federal regulators: expand reviews of SNF claims; identify SNFs billing for higher paying RUGs; monitor new therapy assessment compliance; change the method for determining how much therapy is needed; improve MDS accuracy; and follow up on SNFs that billed in error.

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HHS Inspector General
Daniel Levinson

OIG Potential Compliance Risk Areas: MDS Related

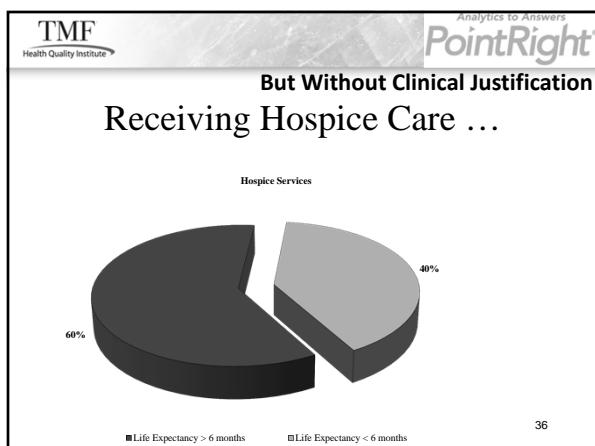
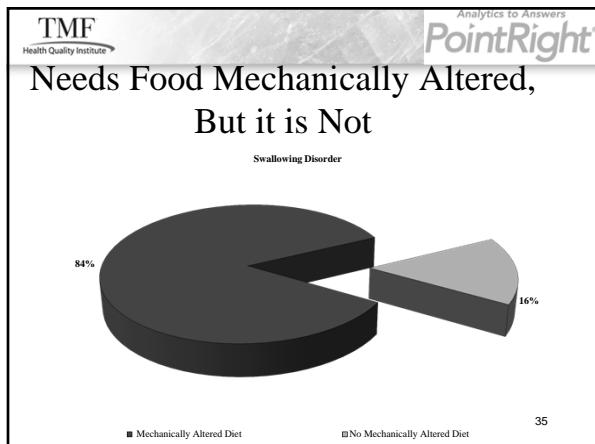
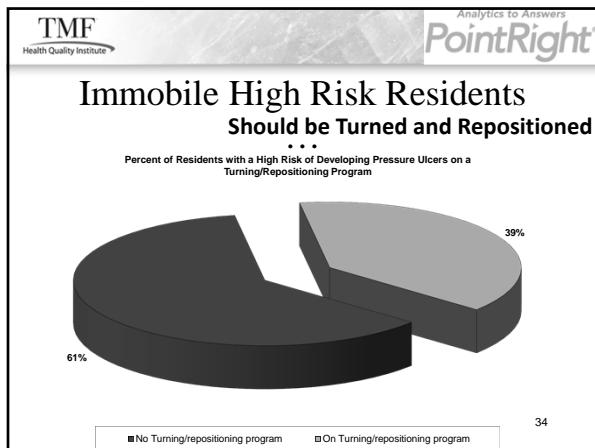
- Quality of Care
 - The entire MDS process, physician services, inappropriate Restraints, inadequate staffing, etc.
- Resident Rights
 - Access to care, abuse, restraints, HIPAA privacy rules, financial affairs
- Billing
 - Claims management, medical necessity rules, staff training r/t case-mix data, sufficient documentation, overutilization of Part A and Part B, false or fraudulent cost reports

The figure consists of a pie chart with two segments. The larger segment is dark gray and labeled "96%". The smaller segment is light gray and labeled "4%".

Intervention Status	Percentage
Preventative Interventions in Place	96%
Preventative Interventions Not in Place	4%

Percent of Residents with a High Risk of Developing Pressure Ulcers who have Preventative Interventions in Place

High Risk Residents Should Have Prevention



Speech Therapy but No Clinical Justification

Speech Therapy

Impairment Status	Percentage
No Impairment	57%
With Impairments	43%

Impairments Include: Cognitive Impairment, Swallowing Problem, Parkinson's Disease, Aphasia, Symbolic Dysfunction or Dysphagia

■ No Impairment □ With Impairments

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Are you an Outlier?

Ultrahigh Therapy RUGs

Period	SNF (Target Percent)	Natl: 80th %ile	Jurs: 80th %ile	State: 80th %ile
10/1/09 - 9:30/10	~55%	50%	50%	50%
10/1/10 - 9:30/11	~52%	50%	50%	50%
10/1/11 - 9:30/12	~55%	50%	50%	50%

Need to audit? When reviewing this information, you may want to consider auditing a sample of records if you identify:

- Increasing Target Percents over time resulting in outlier status
- Your Target Percent (first row in the table below) is above the national 80th percentile

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Considering Both High and Low Outliers

Nontherapy RUGs With High ADLs

The graph displays the Target Percent (Y-axis, 0% to 60%) against time periods (X-axis: 10/1/09 - 9/30/10, 10/1/10 - 9/30/11, 10/1/11 - 9/30/12). The legend indicates four series: SNF (solid line with square markers), Jurs 80th percentile (dashed line with diamond markers), Jurs 20th percentile (dash-dot line with circle markers), and State 80th percentile (dotted line with triangle markers). The SNF series shows a steady increase from approximately 18% in 2009 to 22% in 2011. The Jurs 80th percentile series starts at about 35% in 2009, dips slightly, and then rises to about 48% in 2012. The Jurs 20th percentile series starts at about 10% in 2009, remains flat until 2010, and then rises to about 15% in 2012. The State 80th percentile series starts at about 35% in 2009, rises to about 45% in 2010, and then rises again to about 52% in 2012.

Time Period	SNF	Jurs 80th percentile	Jurs 20th percentile	State 80th percentile
10/1/09 - 9/30/10	18%	35%	10%	35%
10/1/10 - 9/30/11	20%	35%	10%	45%
10/1/11 - 9/30/12	22%	48%	15%	52%

Need to audit? When reviewing this information, you may want to consider auditing a sample of records if you identify:

- Increasing or decreasing Target Percents over time resulting in outlier status
- Your Target Percent (first row in the table below) is above the national 80th percentile
- Your Target Percent is below the national 20th percentile

Non-therapy RUGs with HIGH ADL, cont.		Analytics to Answers		
YOUR SNF		10/1/09 - 9/30/10	10/1/10 - 9/30/11	10/1/11 - 9/30/12
Target Area Percent	19.1%	41.0%	26.7%	
Target Count (Numerator works here)	689	1,301	528	
Denominator Count (see Definitions works here)	3,606	3,175	1,976	
Target (Numerator) Average Length of Stay	36.3	27.7	18.2	
Denominator Average Length of Stay	26.9	22.2	21.2	

*Data not available when target count less than 11.

COMPARATIVE DATA				
National 80th Percentile	36.2%	36.3%	40.7%	
Jurisdiction 80th Percentile	34.0%	40.9%	46.5%	
State 80th Percentile	36.7%	46.0%	50.8%	
National 20th Percentile	10.2%	9.9%	11.2%	
Jurisdiction 20th Percentile	9.6%	11.7%	14.8%	
State 20th Percentile	10.5%	13.3%	16.5%	

Note: State Percentiles are zero when there are fewer than 11 SNFs in state. Jurisdiction's state or when there are no SNFs with at least 11 target discharges.

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COT Assessments

Need to audit? When reviewing this information, you may want to consider auditing a sample of records if you identify:

- Increasing Target Percents over time resulting in outlier status
- Your Target Percent (first row in the table below) is above the national 80th percentile

Change of Therapy Assessment

Period	SNF	Natl 80th %ile	Jurs 80th %ile	State 80th %ile
10/1/09 - 9/30/10	~2%	-	-	-
10/1/10 - 9/30/11	~2%	~10%	~10%	~10%
10/1/11 - 9/30/12	~15%	~12%	~12%	~12%

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COT Assessments, cont.

YOUR SNF	Target Area Percent	10/1/09 - 9/30/10	10/1/10 - 9/30/11	10/1/11 - 9/30/12
Target Count (Numerator: count of assessments with AI second digit equal to 'D' within episode of care ending in the report period)	Note: the COT Assessment became effective Oct. 1, 2011; statistics are not available for FYs 2010 and 2011	-	-	6.9%
Denominator Count (count of all assessments with episode of care ending in the report period)	-	-	60	871

COMPARATIVE DATA

	National 80th Percentile	Jurisdiction 80th Percentile	State 80th Percentile
Note: State Percentiles are zero when there are fewer than 11 SNFs in the jurisdiction's state or when there are no SNFs with at least 11 target discharges.	17.0%	14.3%	13.4%

SUGGESTED INTERVENTIONS FOR HIGH OUTLIERS:

This could indicate that the SNF is experiencing challenges with delivering services to the beneficiary as anticipated. The SNF may look into factors that lead to the need for the COT assessment (e.g., can care planning be improved? Are there issues with completing therapy as scheduled?) Note: SNFs that are using the COT assessment infrequently or not at all may be targeted by MACs or RACs for review to establish whether therapy assessments are being completed as required (see <https://oig.hhs.gov/oia/reports/cel-02-09-00200.asp>, page 15).

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Longer LOS?

Need to audit? When reviewing this information, you may want to consider auditing a sample of records if you identify:

- Increasing Target Percents over time resulting in outlier status
- Your Target Percent (first row in the table below) is above the national 80th percentile

90+ Day Episodes of Care

Period	SNF	Natl 80th %ile	Jurs 80th %ile	State 80th %ile
10/1/09 - 9/30/10	~15%	~27%	~27%	~22%
10/1/10 - 9/30/11	~15%	~27%	~27%	~22%
10/1/11 - 9/30/12	~10%	~25%	~25%	~22%

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90+ Day Episodes of Care, cont.

YOUR SNF	10/1/09 - 9/30/10	10/1/10 - 9/30/11	10/1/11 - 9/30/12
Target Area Percent	15.1%	15.8%	9.0%
Target Count (Numerator: count of episodes of care ending in the report period with a length of stay of 90+ days)	45	43	19
Denominator Count (count of all episodes of care ending in the report period)	299	273	212
Target (Numerator) Average Length of Stay	88.6	98.7	97.8
Denominator Average Length of Stay	42.4	41.2	34.3
Target (Numerator) Average Payment	\$35,652	\$45,331	\$46,066
Target (Numerator) Sum of Payments	\$1,684,363	\$1,992,247	\$875,262

COMPARATIVE DATA

	National 80th Percentile	Jurisdiction 80th Percentile	State 80th Percentile
Note: State Percentile are zero when there are fewer than 11 SNFs in the jurisdiction's state or when there are no SNFs with at least 11 target length stays.	26.8%	25.9%	25.4%
	20.7%	19.6%	21.3%
	22.5%	21.4%	21.9%

*Data not available when target count less than 11.

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Compliance: Systems and Internal Controls

- MDS accuracy
 - Internal/External auditing of MDS records
 - Manual review has merits but limited only to selected sample
 - Automated auditing of all assessments prior to state submission has proven most efficient
 - Assure balanced approach by third party auditor
 - Most major MDS software providers have interface with several auditing providers
- Some examples provided, and should be expanded upon by your Compliance Officer
 - Quality of Care
 - Resident's Rights
 - Billing
- High or Low outliers from PEPPER

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Strategies to Consider....

- Do Not Panic!
 - Indication of high outlier does not necessarily mean that compliance issues exist.
- But: Determine Why You are an "Outlier"
 - Sample claims using same inclusion criteria.
 - Review documentation in medical record.
 - Review claim; was it coded and billed appropriately based upon documentation in medical record?
- Ensure following best practices, even if not an outlier

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Conclusion

- Data Driven Solutions to Today's Qualitative Challenges requires you to "authentically address" the most prominent ACA requirements
 - Compliance
- If you integrate a handful of metrics into to your compliance program you will set yourself up for success
 - MDS accuracy
 - PEPPER Target areas
 - Especially any high outliers
- Be Measurable Successful!

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SNF PEPPER Training & Resources

- PEPPERresources.org
 - SNF PEPPER User's Guide
 - Training and Resources
 - Comparative data
 - Sample PEPPERS
 - Help/Contact Us

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How to obtain your SNF PEPPER

- First reports were mailed Aug. 30, 2013
- Next release to be completed electronically in May 2014 via secure portal on PEPPERresources.org.
 - See Secure PEPPER Access page for specifics
- Join the listserv to receive notification when the next PEPPER is available.

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Cheryl.Field@Pointright.com', and '• Help>Contact Us at PEPPERresources.org'. The page number '53' is located at the bottom center."/>

U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

**OFFICE FOR
CIVIL RIGHTS**

Stepping Up Compliance in 2014

Linda Sanches
Senior Advisor, Health Information Privacy Division

Yun-kyung Lee
Supervisory Investigator, Region IX

HCCA Compliance Institute
April 1, 2014

DHS/OCR April 2014
[1]

What's Done, What's to Come

HIPAA Privacy, Security & Breach Notification

- Policy/Rulemaking
- Guidance
- Compliance and Enforcement
- Outreach and Training

DHS/OCR April 2014
[2]

Rulemaking

- What's Done:
 - Omnibus Final Rule
 - HITECH provisions, including final rulemaking on IFR enforcement penalties & breach notification
 - GINA provisions
 - Other rule changes
 - NICS NPRM
 - CLIA Final Rules on access rights to test results direct from labs
- What's to Come:
 - From HITECH
 - Accounting of Disclosures
 - Methods for sharing penalty amounts with harmed individuals
 - NICS Final Rule

DHS/OCR April 2014
[3]

HIPAA/NICS NPRM

- January 2013 – one of 23 executive actions to reduce gun violence
- April 2013 – ANPRM on need for HIPAA rule change for NICS reporting – over 2000 comments
- January 2014 – NPRM
 - Express permission for designated NICS reporters or entities making commitment or adjudication decisions
 - Limited to identity, demographics; not clinical data or medical records
- Comment period closed March 10, 2014

DHHS, OCR

[4]

CLIA Final Rule

- Final Rule on display at FR – February 3
- CMS – Amends CLIA regulations to allow labs to give patient access to completed test results
- OCR – Amends HIPAA right to access to remove exemption for CLIA labs
 - Individual has right to access and get copy of PHI in DRS of labs, including right to electronic copy
 - Access obligations on labs same as for other covered entities
 - Individual can still go through physician to obtain test results
- Dates
 - Publish in FR -- February 6
 - Effective Date -- April 7
 - HIPAA Compliance Date -- October 8

DHHS, OCR

[5]

Guidance

What's Done:

- Omnibus Final Rule**
 - De-identification
 - Combined Regulation Text
 - Sample BA provisions
 - Refill Reminder
 - Factsheets on Student immunizations and Decedents
- Model Notices of Privacy Practices**
- Guide to Law Enforcement***
- Letters from Leon**
 - Dear Provider – duty to warn, serious and imminent threats
 - Right to access – updated for e-access requirements

Other Guidance

- Permitted mental health disclosures
- What's to Come:**
 - Omnibus Final Rule**
 - Breach Safe Harbor Update
 - Breach Risk Assessment Tool
 - Minimum Necessary
 - More on Marketing
 - More Factsheets on other provisions
 - Model Notice**
 - Web based version
 - Other Guidance**
 - Security Rule guidance updates

DHHS, OCR

[6]

WHAT'S TO COME

More Guidance:

- Business Associates
 - Breach Notification Rule
 - Security Rule
 - Individual Rights
 - Other Privacy Rule Topics

More Training:

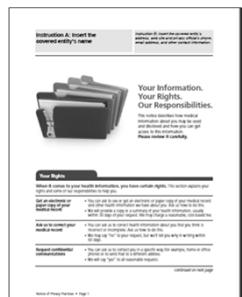
- Online Training Modules

Audit Program

DHS

-

Model Notices of Privacy Practices



- Notice as booklet;
 - Layered notice presenting summary on first page, the full content on the following pages;
 - Notice with booklet design elements, formatted for full page presentation;
 - Text only
 - Different versions for health plans and health care providers.
 - Customizable

DHHS, OCR April 2014

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<http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html>

New HIPAA Privacy Rule Blue Card for Law Enforcement

- Developed with the HHS Office of Assistant Secretary for Preparedness and Response & the Federal Bureau of Investigation
 - Provides basics of HIPAA Privacy Rule; identifies entities that are and are not required to comply.
 - Outlines the permissions to disclose health information to law enforcement in common law enforcement situations
http://www.hhs.gov/ocr/privacy/hipaa/understanding/special/emergency/final_hipaa_guide_law_enforcement.pdf

HHS, OCB April 2014

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<p>What's Done</p> <ul style="list-style-type: none"> Enforcement Highlights Web Updates Lessons Learned Breach Data Audits <p>What's to Come</p> <ul style="list-style-type: none"> Investigations <p>Audits—What's Done, What's in place for 2014-2015</p> <h2 style="text-align: center;">COMPLIANCE AND ENFORCEMENT</h2>		DHHS, OCR April 2014 [10]
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<h2>Compliance and Enforcement</h2> <ul style="list-style-type: none"> • What's Done <ul style="list-style-type: none"> • Resolution Agreements/Corrective Action Plans <ul style="list-style-type: none"> • 5 RA/CAPs in CY13 • Total Resolution Amounts of \$3,740,780 • Investigated Complaints/Compliance Reviews <ul style="list-style-type: none"> • 4,459 investigative closures in CY13 • 3,467 closed with corrective action • Breach Reports <ul style="list-style-type: none"> • 800 Breaches involving 500 or more individuals • 92,000 Breaches involving fewer than 500 individuals 		DHHS, OCR April 2014 [11]
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<h2>Compliance: What's Done</h2> <ul style="list-style-type: none"> • Web site improvements <ul style="list-style-type: none"> • New web portal for complaints/centralized intake <ul style="list-style-type: none"> • https://ocrportal.hhs.gov/ocr/cp/complaint_front_page_ifs • Redesigned web portal for reporting 500+ Breaches <ul style="list-style-type: none"> • http://www.hhs.gov/ocr/privacy/hipaa/administrative/breachnotificationrule/breatchtool.html 		DHHS, OCR April 2014 [12]
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What's Done: 2013 Highlights

- Continued focus on Security Rule compliance
 - Affinity Health Plan -- over \$1.2 million
 - ePHI left on photocopier drives
 - Wellpoint - \$1.7 million
 - Faulty testing of programming updates left information accessible on web portal
 - Idaho State University -- \$400,000
 - Disabled firewall exposed EPHI to breach
 - Adult & Pediatric Dermatology -- \$150,000
 - Stolen unencrypted thumb drive; lacked risk analysis, and policies/procedures for breach notification
 - Privacy
 - Shasta Regional Medical Center -- \$275,000
 - Patient medical records shared with media

• 2000 • 2001

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RECENT ENFORCEMENT ACTIONS

Lessons Learned:

- Covered entities and their business associates must undertake a careful risk analysis to understand the threats and vulnerabilities to individuals' data, and have appropriate safeguards in place to protect this information.
 - Take caution when implementing changes to information systems, especially when those changes involve updates to Web-based applications or portals that are used to provide access to consumers' health data using the Internet.
 - Senior leadership helps define the culture of an organization and is responsible for knowing and complying with the HIPAA privacy, security and breach notification requirements to ensure patients' rights, a well as the confidentiality of their health data, are fully protected.

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14

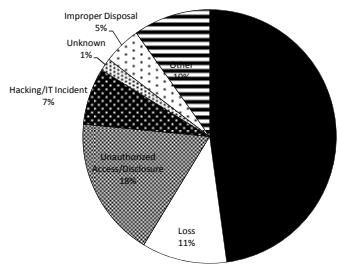
What's Done: Casework (As of December 31, 2013)

	TOTAL (since 2003)
Complaints Filed	90,000
Cases Investigated	31,925
Cases with Corrective Action	22,026
Civil Monetary Penalties & Resolution Agreements (since 2008)	\$18.6 million

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15

Breach Notification: 500+ Breaches by Type of Breach



Data as of February 2014.

DHHS, OCR April 2014

(16)



Data as of February 2014.

DHHS, OCR April 2014

(17)

Lessons Learned: Appropriate Safeguards Prevent Breaches of e-PHI

- Evaluate the risk to e-PHI when at rest on removable media, mobile devices and computer hard drives
 - Take reasonable & appropriate measures to safeguard
 - Store all e-PHI to a network
 - Encrypt data on portable/movable devices & media
 - Employ a remote device wipe to remove data when device is lost or stolen
 - Train workforce members on how to effectively safeguard data and timely report security incidents

HHS, OCB April 2014

{ 18 }

OCR Breach Investigations

- OCR opens a review of all breach reports involving > 500 individuals
- CE should be prepared to respond with:
 - Determination of the root cause of disclosure
 - Identification of gaps in compliance that resulted in breach
 - Evidence that the root cause has been addressed to insure that further breaches do not occur

DHHS, OCR

April 2014

19

What evidence is OCR looking for in an investigation?

Documentation of:

- Policies & procedures
- Implementation of policies & procedures
- Internal investigation reports, interview statements
- Appropriate sanctions applied
- Training
- Business Associate Agreements

DHHS, OCR

April 2014

20

What evidence is OCR looking for in an investigation? (Continued)

- Risk Analysis documentation
- Risk Management policies, procedures and implementation
- Encryption/Decryption evidence
- Mobile Device Policies and Implementation

DHHS, OCR

April 2014

21

Compliance and Enforcement

- What's to Come
 - Resolution Agreements/Corrective Action Plans
 - Continue to increase activity and resources
 - Maintain focus on fundamentals of compliance programs
 - Investigated Complaints/Compliance Reviews
 - Address emerging issues
 - Strategic approach to increase efficiencies, identify cases for investigation

OCB since 2001

(22)

Compliance and Enforcement Audit – What's Done

Description	Vendor	Status/Timeframe
Audit program development study	Booz Allen Hamilton	Closed 2010
Covered entity identification and cataloguing	Booz Allen Hamilton	Closed 2011
Develop audit protocol and conduct audits	KPMG, Inc.	Closed 2011-2012
Evaluation of audit program	PWC, LLP	Closed 2013

APRIL 2014

23

Compliance and Enforcement Audit – What's Done Identified Challenges

Privacy

- Notice of Privacy Practices;
 - Access of Individuals;
 - Minimum Necessary; and,
 - Authorizations.

Security

- Risk Analysis;
 - Media Movement and Disposal; and,
 - Audit Controls and Monitoring.

WINE OCT 2014

24

What's to Come: Audit 2014-2015

- Creation of pool of covered entities eligible for audit complete
 - Screening “pre-survey” to be sent to entities summer 2014—to confirm size, type, contacts
 - Selected entities will receive notification and data requests in fall 2014—to include identification of business associates
 - Business associates in second wave
 - Both desk and on-site audits
 - Updated protocol will available on web site

April 2014

25

OUTREACH AND TRAINING

- AIDS.gov Information is Powerful Medicine
- OCR YouTube Videos
- Medscape Resources/Trainings
- Mobile Devices—Training & Downloadable Materials
- Security video game

Volume 30 Number 4 December 2011

26

Public Awareness/Compliance Tools

What's Done

- Emphasis on Access
 - Information Is Powerful Medicine Campaign
 - Privacy and Security on YouTube
 - <http://www.youtube.com/user/USGovHHSOCR>
 - Medscape: free CME and CE Training
 - Resource Center
 - 5 Training Modules
 - ONC collaborations on Security
 - Mobile Devices
 - Security Rule Games
 - Fact Sheets/Translations into 7 languages

What's to Come

- Find new partners to extend IIPM campaign
 - Find new YouTube content and more translations
 - 6th Medscape Module coming soon
 - Risk analysis tool for small providers
 - New consumer content and always improving “usability” of website

Dunes OCB April 2014

27

AIDS.gov/privacy Highlights

- 27,435 unique visitors to AIDS.gov/privacy
 - May 20 – Sept 30
- Total Impressions/Views:
 - Outdoor impressions of 3,532,622
 - Online impressions of 19,362,659
 - Transit impressions 8,514,168
 - Print impressions 4,345,800 (readers)

DHHS_OCR April 2014

(28)

Information Is Powerful Medicine

AIDS.gov/privacy

Clear and concise

- Fact Sheets
- Posters
- Brochure
- FAQs
- Video
- Mobile Platform

DHHS OCR April 2014

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OCR's YouTube Videos

	Your New Rights Under HIPAA 264,781 Views		The HIPAA Omnibus Rule 273,927 Views
	Your Health Information, Your Rights 116,291 Views		Su Informacion de Salud, Sus Derechos 503,898 Views
	The Right to Access Your Health Information 84,909 Views		Treatment, Payment and Health Care Operations 77,967 Views
	EHRs: Privacy and Security 5,645 Views		Communicating with Friends And Family 97,428 Views
	Explaining the Notice of Privacy Practices 124,888 Views		HIPAA Security Rule 291,263 Views

DHHS OCR April 2014

TOTAL VIEWS FROM FEBRUARY 16 2012 - JANUARY 30, 2013: 1,840,997 [31]

Visit us at <http://www.youtube.com/USGovHHSOCR>

OCR's YouTube Videos

	Your New Rights Under HIPAA 624 Views		The HIPAA Omnibus Rule 3,938 Views
	Your Health Information, Your Rights 2,984 Views		Su Informacion de Salud, Sus Derechos 67 Views
	The Right to Access Your Health Information 488 Views		Treatment, Payment and Health Care Operations 156 Views
	EHRs: Privacy and Security 345 Views		Communicating with Friends And Family 181 Views
	Explaining the Notice of Privacy Practices 183 Views		HIPAA Security Rule 648 Views

DHHS OCR April 2014

DECEMBER - JANUARY INCREASE: 9,614 [32]

Protecting Patients Rights: New OCR Resource Center at Medscape.org

Video Programs module imbedded into page for dynamic interest

OCR Educational Links, Including Mobile Device Content

HIPAA/OCR Poll Question Updated Quarterly

<http://www.medscape.org/sites/advances/patients-rights>

U.S. Department of Health and Human Services, Office for Civil Rights

[33]

Understanding the Basics of Risk Analysis and Risk Management

Posting Date: 9/13/13

- 11,964 Total Learners
- 26,974 Total Page views
- 6,640 MD Learners
- 2,599 Nurse Learners
- 2,000 Physician Learners
- 231 Physician Assistants
- 2,110 (Other HCPS)
- 3,168 MD Test Takers
- 1574.75 Credits



Supported by the U.S. Department of Health and Human Services, Office for Civil Rights

Credits Available
Physicians - maximum of 0.50 AMA PRA Category 1 Credit(s)™
You Are Eligible For
■ AMA PRA Category 1 Credit(s)™
Accreditation Statements
For Physicians
Medscape

Medscape, LLC is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

<http://www.medscape.org/viewarticle/810563>

[34]

Your Mobile Device and Health Information Privacy and Security

Posting Date: 9/13/13

- 13,969 Total Learners
- 28,518 Total Page Views
- 7,657 MD Learners
- 3,627 Nurse Learners
- 252 Pharmacist Learners
- 586 Physician Assistants
- 1,847 (Other HCPS)
- 3,378 MD Test Takers
- 836.50 Credits



Supported by the U.S. Department of Health and Human Services, Office for Civil Rights

Credits Available
Physicians - maximum of 0.50 AMA PRA Category 1 Credit(s)™
You Are Eligible For
■ AMA PRA Category 1 Credit(s)™
Accreditation Statements
For Physicians
Medscape

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<http://www.medscape.org/viewarticle/810568>

[35]

Patient Privacy: A Guide for Providers

Posting Date: 4/26/13

- 23,484 Total Learners
- 55,935 Total Page Views
- 7,831 MD Learners
- 6,355 Nurse Learners
- 534 Pharmacist Learners
- 772 Physician Assistants
- 9,691 (Other HCPS)
- 4,497 MD Test Takers
- 2225.25 Credits



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Credits Available
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You Are Eligible For
■ AMA PRA Category 1 Credit(s)™
Accreditation Statements
For Physicians
Medscape

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<http://www.medscape.org/viewarticle/781892?src=ocr>

[36]

HIPAA and You: Building a Culture of Compliance

CME Released: 06/29/2012; Reviewed and Renewed: 06/28/2013; Valid for credit through 06/28/2014

- 10,199 Total Learners
- 26,222 Total Page Views
- 1,832 MD Learners
- 2,651 Nurse Learners
- 223 Pharmacist Learners
- 174 Physician Assistants
- 5,319 (Other HCPS)
- 1,165 MD Test Takers
- 577 Credits

* Report reflects 6/28/13 to 10/20/13



<http://www.medscape.org/viewarticle/762170?src=cmsocr>

Supported by the U.S. Department of Health and Human Services, Office for Civil Rights

Credits Available
Physicians - maximum of 0.50 AMA PRA Category 1 Credit(s)™
You Are Eligible For
■ AMA PRA Category 1 Credit(s)™
Accreditation Statements
For Physicians
Medscape
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DHHS, OCR April 2014

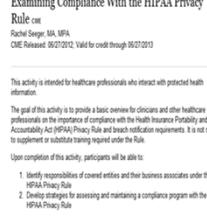
[37]

Examining Compliance with the HIPAA Privacy Rule

CME Released: 06/27/2012; Reviewed and Renewed: 06/27/2013; Valid for credit through 06/27/2014

- 10,199 Total Learners
- 26,222 Total Page Views
- 1,832 MD Learners
- 2,651 Nurse Learners
- 223 Pharmacist Learners
- 174 Physician Assistants
- 5,319 (Other HCPS)
- 1,165 MD Test Takers
- 577 Credits

* Report reflects 6/27/13 to 10/20/13



<http://www.medscape.org/viewarticle/763251?src=cmsocr>

Supported by the U.S. Department of Health and Human Services, Office for Civil Rights

Credits Available
Physicians - maximum of 0.50 AMA PRA Category 1 Credit(s)™
You Are Eligible For
■ AMA PRA Category 1 Credit(s)™
Accreditation Statements
For Physicians
Medscape
Medscape, LLC is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

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[38]

ONC/OCR Mobile Device Program Instructional Video Series

The videos explore mobile device risks and discuss privacy and security safeguards providers and professionals can put into place to mitigate risks.



Securing Your Mobile Device is Important!



Dr. Anderson's Office Identifies a Risk



A Mobile Device is Stolen



Can You Protect Patients' Health Information When Using a Public Wi-Fi Network?



Worried About Using a Mobile Device for Work? Here's What To Do!

DHHS, OCR April 2014

[39]

Downloadable Materials

www.healthit.gov/mobiledevices

- Fact sheets
- Posters
- Brochures

Mobile Devices: Know the RISKS. Take the STEPS. Protect & SECURE Health Information

10 tips to protect and secure health information when using mobile devices

1 Use a password or other user authentication.

2 Authenticate.

3 Encrypt or activate remote wiping.

4 Do not install or use file sharing applications.

5 Install and enable a firewall.

6 Install security software and keep it up-to-date.

7 Research mobile applications before downloading.

8 Assign specific mobile devices to your personal use.

9 Assign specific mobile devices to your professional use.

10 Delete all stored health information before discarding or reusing the mobile device.

Mobile Devices: Know the RISKS. Take the STEPS. Protect & SECURE Health Information

Be a team player: Understand and follow your organization's mobile device privacy policies. It's your responsibility, and your organization's.

Mobile Devices: Know the RISKS. Take the STEPS. Protect & SECURE Health Information

Managing Mobile Devices in Your Health Care Organization

DHHS, OCR April 2014

(40)

Mobile Device Program: Tips to Protect and Secure Health Information

<p>Use a password or other user authentication.</p>	<p>Keep security software up to date.</p>
<p>Install and enable encryption.</p>	<p>Research mobile apps before downloading.</p>
<p>Install and activate wiping and/or remote disabling.</p>	<p>Maintain physical control of your mobile device.</p>
<p>Disable and do not install file-sharing applications.</p>	<p>Use adequate security to send or receive PHI over public Wi-Fi networks.</p>
<p>Install and enable a firewall.</p>	<p>Delete all stored health information before discarding or reusing the mobile device.</p>

DHHS, OCR April 2014

(41)

Training Materials:

Security Video Game Released September 2012

Privacy & Security Training Games

Integrating Privacy & Security into Clinical Practice

Health Information Privacy and Security Act of 1996

Health IT Privacy and Security Resources

Cybersecurity

Mobile Device Privacy and Security

Model Policies of Privacy Practices

Patient Consent for PHI

Privacy & Security Training Games

Take the Contingency Planning Challenge

Cybersecure: Contingency Planning

Take the Privacy & Security Challenge

Cybersecure: Privacy & Security

DHHS, OCR April 2014

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New Tools for Consumers

The screenshot shows the HHS.gov Health Information Privacy website. The main navigation bar includes links for "Office for Civil Rights", "Civil Rights", and "Health Information Privacy". The left sidebar has sections for "HIPAA", "PIQIA", and "How to File a Complaint". The right sidebar features a video titled "Basic HIPAA: Your Health Information, Your Rights" and links to "Consumer Brochures in More Languages". A vertical sidebar on the right indicates the page is from "DHS, OCR" and dated "April 2014".

Questions?

OCR website www.HHS.gov/OCR

DHS, OCR April 2014

[44]

Educate the Medical School to Educate the Physician

Health Care Compliance Association National Meeting
San Diego, California
March 2014

Presented by:

James S. Dunnick, MD, FACC, CHCQM, CPC
SESEDN, LLC

Contact Information:

SESEDN@gmail.com

SESEDN LLC

Disclaimer:

1. Do NOT assume I am correct, I make mistakes.
2. Read and self educate.
3. CPT books, government manuals, online resources.
4. Obtain professional teaching, from more than one source.
5. Auditors opinions will vary.
6. States will vary.
7. Rules change.
8. This is meant as general and initial information only.

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2

Medicare/Medicaid

"Medicare trust fund will be exhaust of reserves
by 2022"

(Congressional Budget Office 2/9/2012)

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Medicare/Medicaid

Social Security Disability Funds

"Money will be gone in 2016"

(Public Trustees, Charles Blahous III and Robert Reischauer)

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Medicare/Medicaid

"Medicare Hospital Insurance Fund (Part A)
will exhaust in 2019"

(Medicare Trustee Report)

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Medicare/Medicaid

- Medicare is in Trouble
- The Government is not kidding about cost containment
- Medicare feels it is being treated unfairly

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6

Medicare/Medicaid

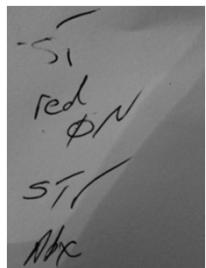
Question: What percent of charges submitted to Medicare are fraudulent?

- A. 5%
- B. 10%
- C. 30%
- D. 50%

Answer: C. Medicare believes that 30% of submitted claims are fraudulent.

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Cost

- Highest cost to Medicare – E/M
- Highest focus of upcoming audits
- Third party payers are also motivated to recoup dollars

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Cost

What is E/M?

- Evaluation and management
- Turns cognitive labor into economic reimbursement

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USA Health Expenditure GDP

2009 2010 2011
17.7 17.6 17.9

(worldbank.org/indicator/SH.XPD.TOTL.ZS)

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USA Spending Estimate for 2014

Health Care	20%
Pensions	18%
Education	15%
Defense	13%

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USA Spending Estimate

“Healthcare spending in the US... the sector continues to grow 1.2 percent above real GDP growth... for the coming decades”

(Brookings. A Fall 2013 BPEA paper by Amitabh Chandra, Jonathan Holmes and Jonathan Skinner)

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Individual Cost to Educate

Median tuition	2012	2013
Resident public	\$28,719	\$32,197
Non resident public	\$49,000	\$54,625
Private	\$47,673	\$50,078

(Tara Kuther, Ph.D.
<http://gradschool.about.com/od/medicalschool/f/MedSchoolCost.htm>)

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Individual Cost to Educate

2013 Medical Student Education Graduates Debt

Public	Mean \$162,736 (up 4%)
	Median \$168,000 (up 5%)
Private	Mean \$181,058 (down 1%)
	Median \$190,000 (no change)
All	Mean \$169,901 (up 2%)
	Median \$175,000 (up 3%)

(Debt, Costs, and Loan Repayment Fact Card, October 2013)

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Individual Cost to Educate

\$1 Million Mistake: Becoming a doctor

(Kathy Krist, MONEYWATCH. September 10, 2013)

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Government Cost for Education

- HHS through CMS is the single largest funder of graduate medical education
 - Over 1,000 teaching hospitals
 - Provide a key labor percentage for these hospitals

(HEALTH POLICY BRIEFS
http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=73)

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Government Cost for Education

- Each year the federal government contributes about \$9.5 billion in Medicare funds, and approximately \$2 billion in Medicaid dollars, to help pay for GME
 - The federal government also funds (through HHS/CMS/DOD/DVA/HRSA/NIH) a newer program called Teaching Health Centers GME

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Government Cost for Education

Average Cost Per Physician

- 115,000 residents
- \$100,000 per resident per year
- \$500,000 for complete training per physician

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Availability of physicians

- Access to care is limited
- Women can do what men can do
- Women are a far greater percent of the physician work force than ever before
- They balance family and career differently than their male counterparts

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Availability of physicians

- Stress
- Medical crisis
- Legal
- Government regulations
- Time restraints with patients
- Job satisfaction and happiness continue to fall

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Availability of physicians

Less satisfaction leads to fewer years in practice

- Change careers
- Earlier retirement

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Availability of physicians

Return on investment (ROI) of medical education

Individual Contributed
Dollars + Government
Contributed Dollars



Number of Years a Physician
Provides Care



Society's Cost per Physician
per Year in Practice

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Availability of physicians

- Tort Reform
- Control Work Hours
- Medical Crisis
- Economics
- Government Regulations

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24

What Should Our Education Entail?

- Medical crisis
- Economics
Office
Hospital
- Government regulations
E/M
ICD 9
ICD 10

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What Should our Education Entail?

- E/M
- ICD 10
- Ethics

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What Should our Education Entail?

- E/M – This is the complete basis of all provider notes

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What is E/M?

- E/M has parts
- Each part has parts
- The second part has components
- Each component has elements
- The elements leads to levels
- Each level has requirements
- All are needed and in the correct combination

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What is E/M?

Key Components of E/M

HISTORY

- History present illness
- Past medical family social history
- Review of systems

PHYSICAL EXAM (1995 or 1997)

- Body Parts
- Organ systems

MEDICAL DECISION MAKING

- Problem points
- Data points
- Risk tables

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What is E/M?

History of Present Illness (HPI)

8 elements:

- | | |
|------------|-----------------------------|
| • location | • timing |
| • severity | • duration |
| • quality | • modifying factors |
| • context | • associated symptoms/signs |

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30

What is E/M?

Levels of HPI

Problem Focused	Brief (1-3)
Expanded PF	Brief (1-3)
Detailed	Extended (4-8)
Comprehensive	Extended (4-8)

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Magic Words

John is a 55 year old Hispanic male who has noticed chest pain. His wife saw him grimacing and rubbing his chest and wanted him seen. Her brother died of a heart attack last summer. John does not seem to know his family well but his father may have had some cardiac problems. I don't have the feeling we have reliable details with this.

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HPI Elements

- Severity - no
- Quality - no
- Location - chest
- Duration - no
- Associated Signs and Symptoms - no
- Modifying Factors - no
- Timing - no
- Context - no

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Magic Words

- John is a 55 year old Hispanic male who has noticed chest pain. His wife saw him grimacing and rubbing his chest and wanted him seen. Her brother died of a heart attack last summer. John does not seem to know his family well but his father may have had some cardiac problems. I don't have the feeling we have reliable details with this.
- He felt the discomfort was quite severe and this further caused alarm. He has been putting off being seen due to a new job and not wanting to miss days of work.

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HPI Elements

- Severity - severe
- Quality - no
- Location - chest
- Duration - no
- Associated Signs and Symptoms - no
- Modifying Factors - no
- Timing - no
- Context - no

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35

Magic Words

- John is a 55 year old Hispanic male who has noticed chest pain. His wife saw him grimacing and rubbing his chest and wanted him seen. Her brother died of a heart attack last summer. John does not seem to know his family well but his father may have had some cardiac problems. I don't have the feeling we have reliable details with this.
- He felt the discomfort was quite severe and this further caused alarm. He has been putting off being seen due to a new job and not wanting to miss days of work.
- At work the company nurse gave him tums and told him he may have an ulcer. She sent him home and told him to obtain medical clearance prior to returning to work.

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HPI Elements

- Severity - severe
- Quality - no
- Location - chest
- Duration - no
- Associated Signs and Symptoms - no
- Modifying Factors - still no
- Timing - no
- Context - no

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37

Magic Words

- John is a 55 year old Hispanic male who has noticed chest pain. His wife saw him grimacing and rubbing his chest and wanted him seen. Her brother died of a heart attack last summer. John does not seem to know his family well but his father may have had some cardiac problems. I don't have the feeling we have reliable details with this.
- He felt the discomfort was quite severe and this further caused alarm. He has been putting off being seen due to a new job and not wanting to miss days of work.
- At work the company nurse gave him Tums and told him he may have an ulcer. She sent him home and told him to obtain medical clearance prior to returning to work.
- He felt the Tums may have helped and is hoping this means his heart is all right.

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HPI Elements

- Severity - severe
- Quality - no
- Location - chest
- Duration - no
- Associated Signs and Symptoms - no
- Modifying Factors - Tums helped
- Timing - no
- Context - no

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What is E/M?

Levels of HPI

Problem Focused	Brief (1-3)
Expanded PF	Brief (1-3)
Detailed	Extended (4-8)
Comprehensive	Extended (4-8)

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New Patient Physician Charges

Level	HX	PE	MDM	Time	\$
99201	PF	PF	SF	10	\$41.11
99202	EPF	EPF	SF	20	\$71.01
99203	Det	Det	Low	30	\$102.95
99204	Comp	Comp	Mod	45	\$158.33
99205	Comp	Comp	High	60	\$197.06

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Magic Words

John presents with 3 weeks of severe dull chest pain

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HPI Elements

- Severity - severe
- Quality - dull
- Location - chest
- Duration - 3 weeks
- Associated Signs and Symptoms - no
- Modifying Factors - no
- Timing - no
- Context - no

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What is E/M?

Levels of HPI

Problem Focused	Brief (1-3)
Expanded PF	Brief (1-3)
Detailed	Extended (4-8)
Comprehensive	Extended (4-8)

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What is E/M?

- John presents with 3 weeks of severe dull chest pain

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What is E/M?

Past Family Social History (PFSH)

- **Past Medical History**
Surgeries, Illnesses, Allergies, Medicines
- **Family History**
Hereditary Disease in First Degree Relatives
- **Social History**
Married, Occupation, Tobacco, Alcohol

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What is E/M ROS?

Body Systems – 14 total

- | | |
|----------------|--------------|
| • constitution | • ms |
| • eyes | • skin |
| • enmt | • neuro |
| • card | • psych |
| • resp | • endo |
| • GI | • hem/lymph |
| • GU | • all/immuno |

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What is E/M?

HISTORY

Level	HPI	PFSH	ROS
PF	brief	none	none
EPF	brief	none	1
Detailed	ext	1 of 3	2 of 9
Comprehensive	ext	2* of 3	10

Need 3 of 3

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What is E/M?

Key Components of E/M

HISTORY

- History present illness
- Past medical family social history
- Review of systems

PHYSICAL EXAM (1995 or 1997)

- Body Parts
- Organ systems

MEDICAL DECISION MAKING

- Problem points
- Data points
- Risk tables

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What Should Our Education Entail?

Coding

- ICD-9
- ICD-10

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What Should Our Education Entail?

Ethics

- medical necessity

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When Should Our Education Start?

- **Medical school**

Early years – Basic Science

Later years – Clinical

- **Residency**

Clinical and Specialty

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How Should Education be Presented?

Physician to physician for credibility

- Four one hour presentations
 - One hour overview
 - Three separate one hour presentations
 - History
 - Physical Exam
 - Medical Decision Making

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When Should Education Start?

- Start the first month of the first year of residency with E/M.
- Revisit E/M in months 2 and 3. Add ICD-10 introduction with frequently used codes.
- Review E/M and advanced ICD-10 training in months 9 thru 11 of the first year.

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When Should Education Start?

- First month of the second year, revisit an overview of E/M. Start electronic health records education with meaningful use, templates, cloning, and caution with automatic EHR coding.
- Advance EHR use and revisit first year ICD-10 education in months 2 and 3.
- Detailed ICD-10 education in months 9 thru 11 of second year.

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When Should Education Start?

- Senior residents – 3rd year and beyond – repeat the earlier year presentations as needed and to obtain annual coding updates
- Individual private sessions available upon request

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Fellowship Training Schedule

- First month of the first year, overview E/M and offer repeat presentations as necessary. Start specialty specific coding with frequent illnesses by specialty.
- Months 2 thru 5 have advanced ICD-10 training by specialty.

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Medical School Education

Problems in summary

- Cost to educate
- Return on investments
- What needs to be covered
- Who? When? How?

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Thank you for attending!

Presented by:

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DME Compliance and Regulatory Issues

HCCA 18th Annual Compliance Institute

Nathaniel Lackman
Foley & Lardner, LLP

Denise Fletcher-Lerd
Brown & Fortunato, P.C.

80 83

March 31, 2014

BREAKING NEWS

CMS JUST ANNOUNCED THE DME COMPETITIVE BID
PROGRAM WILL BE TERMINATED

CMS WILL PAY SUPPLIERS UNDER A FFS SCHEDULE EQUAL TO
200% OF 2013 REIMBURSEMENT RATES

OMHA WILL IMPLEMENT STREAMLINED APPEAL PROCESS,
GUARANTEEING ALL APPEALS WILL BE HEARD WITHIN THE
STATUTORY DEADLINES

DME MACS WILL BE KINDER, GENTLER

2



3

Overview

2014 DME Documentation & Reimbursement Issues

- o F2F
- o PECOS
- o WOPD
- o ICD-10
- o New CMS Form 1500
- o OMHA Appeal Problems
- o Competitive Bid Program Status



4

Overview (cont'd)

DME Issues in OIG 2014 Work Plan

- o Overview
- o New DME Projects

2014 DME Business Arrangements

- o Lead Generation vs. Referrals
- o Telemarketing
- o Closets

Case Studies

Q&A

Resources/Handouts



5

2014 DME Documentation & Reimbursement Issues:

Face to Face Requirement

- so Enacted as part of Affordable Care Act (Section 6407).
- so Under the face to face requirement, a physician must document that a physician, Nurse Practitioner, Physician Assistant, or Clinical Nurse Specialist has had a face to face encounter with the patient.
- so The face to face encounter must document that the beneficiary was evaluated and/or treated for a condition that supports the DME ordered.
- so For list of covered items, see MM8304 (face to face rule does not apply to power mobility devices as the Local Coverage Determination already requires a face to face)
- so The encounter must occur within the 6 months before the order is written for the DME.

6

**2014 DME Documentation & Reimbursement Issues:
Face to Face Requirement (cont'd)**

- » Physicians can obtain extra payment using HCPCS G0454 for signing/co-signing the face to face encounter of the Nurse Practitioner/Physician Assistant/Clinical Nurse Specialist.
- » CMS will start actively enforcing and will expect full compliance with the face to face rule beginning on a date that will be announced in CY 2014. (per CMS 9/9/13 announcement)
- » Question remains on when enforcement begins if it will be enforced effective July 1, 2013 or some later date.

7

**2014 DME Documentation & Reimbursement Issues:
Written Orders Prior to Delivery ("WOPD") Requirement**

- » Per CMS, effective July 1, 2013, DME items on the "Specified Covered Items" list require the supplier obtain a WOPD the order must be a detailed written order ("DWO").
- » Confusion with face to face rule led the DME MACs to commence compliance enforcement effective Jan 1, 2014. (see various DME MAC announcements in late Dec 2013)
- » DWO must follow the guidance in the PIM Ch. 5 Section 5.2.3:
 - o The beneficiary's name;
 - o The DME item ordered;
 - o The prescribing practitioner's National Provider Identification (NPI);
 - o The signature of the prescribing practitioner; and,
 - o The date of the order.

8

**2014 DME Documentation & Reimbursement Issues:
Written Orders Prior to Delivery ("WOPD") Requirement (cont'd)**

- » Generally, DWOs must also include the following (per DME MAC and LCD requirements):
 - o Physician's Name;
 - o Start date of the order (if different from the date of the order);
 - o Signature date personally entered by the ordering practitioner;
 - o Dosage or concentration, if applicable;
 - o Route of administration, if applicable;
 - o Frequency of use;
 - o Duration of infusion, if applicable;
 - o Quantity to be dispensed; and
 - o Number of refills, if applicable.
- » Failure to obtain a WOPD may result in the item being denied as excluded by statute.

9

**2014 DME Documentation & Reimbursement Issues:
PECOS Requirement**

- » Enacted as part of Affordable Care Act (Section 6405).
- » PECOS denial edits (Phase 2) effective Jan 6, 2014 - DME items now included.
- » Under the PECOS rule, a physician must be enrolled in Medicare to order or refer items or services for beneficiaries.
- » But many docs, not enrolled in Medicare, order DME items for beneficiaries. Now, the supplier won't get paid for those items, even if med necessary and properly documented.

10

**2014 DME Documentation & Reimbursement Issues:
PECOS Requirement (cont'd)**

- » For DOS on/after Jan 6, 2014, if the ordering/referring provider:
 - o Is on the claim, Medicare will verify that the ordering/referring provider is in PECOS and eligible to order and refer.
 - o Is not in PECOS (or is in PECOS but is not of the specialty to order or refer), the claim will not be paid. It will be denied.
 - o If the name submitted on the claim does not match the provider's name in PECOS, the claim will be denied.
- » Consider a "dear patient" letter when provider is not enrolled in PECOS
- » CMS guidance states that an ABN is not appropriate for use with claims where the provider is not enrolled in PECOS. See MLN SE1305.

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**2014 DME Documentation & Reimbursement Issues:
ICD-10 and new CMS Form 1500**

ICD-10

Will be required beginning on October 1, 2014

- » What's the big deal?
 - o ICD-9 is 30 years old which means has outdated and obsolete terms. Its codes are mostly numeric and have 3 to 5 digits.
 - o ICD-10 will accommodate new diagnoses, procedures and technological innovations. Its codes are alphanumeric and contains 3 to 7 characters. It will be more descriptive and result in more streamlined and efficient billing process.
- » Will not affect CPT coding for outpatient procedures and physician services

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**2014 DME Documentation & Reimbursement Issues:
ICD-10 and new CMS Form 1500 (cont'd)**

CMS HCFA 1500

- » CMS 1500 Claim Form has been Revised for Effective Date of Use on January 6, 2014. The form will say 02/12 in the lower right, replacing the current 08/05 version.
- » January 6, 2014: Payers begin receiving and processing paper claims submitted on the revised 1500 Claim Form (version 02/12). January 6 through March 31, 2014: Dual use period during which payers continue to receive and process paper claims submitted on the old 1500 Claim Form (version 08/05).
- » April 1, 2014: Payers receive and process paper claims submitted only on the revised 1500 Claim Form (version 02/12).

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**2014 DME Documentation & Reimbursement Issues:
Office of Medicare Hearing and Appeals ("OHMA")**

- » From 2010 to 2013 OHMA claims and entitlement workload grew by 184% with no new resources.
 - January of 2012 the number of weekly receipts in Central Operations Division averaged 1250
 - December of 2013 the number of weekly receipts in Central Operations Division averaged 15,000 per week
- » July 15, 2013 approximately 357,000 claims assigned to the 65 Administrative Law Judges with OHMA.
- » Appeals received after July 15, 2013 will be entered into the OHMA case processing system and then held until it can be accommodated by an Administrative Law Judges docket.

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**2014 DME Documentation & Reimbursement Issues:
Office of Medicare Hearing and Appeals ("OHMA") (cont'd)**

- » Based on current workload and volume of new requests, it is anticipated that assignment of a request for hearing to an Administrative Law Judge may be delayed for up to 28 months.
- » The average processing time for appeals decided in fiscal year 2014 is 321.6 days.

15

**2014 DME Documentation & Reimbursement Issues:
DME Competitive Bid Program Update**

- » Competitive bidding remains a topic for discussion and debate.
- » It is here to stay and is not going away any time soon.
 - It is anti-competitive.
 - It reduces access to patient care, patient choice and quality of care.
 - It has forced HME companies to lay off employees or worse close their doors.
- » Medicare DMEPOS Market Pricing Program Act of 2013 (H.R. 1717)
 - Introduced by Rep Tom Price, M.D. (R-GA) and Rep. John Larson (D-Conn)
 - 169 Co-sponsors

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**2014 DME Documentation & Reimbursement Issues:
DME Competitive Bid Program Update (cont'd)**

- » Change of Ownership/Novation Agreements
 - Must have Competitive Bidding Implementation Contractor ("CBIC") approval to assume a Competitive Bid Contract
 - Contract cannot be subdivided
 - 60 days advance Notice
- » Commonly Owned Suppliers Ownership
 - Suppliers with 5% or more common ownership can be added to each other's competitive bid contract;
 - Accomplished by completing the Contract Supplier Location Update form with the CBIC

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**DME Issues in OIG 2014 Work Plan:
Overview**

- » Issued Jan 31, 2014
- » 12 DME Medicare projects (down from 16 in 2013) and 1 DME Medicaid project
- » 5 new projects; 7 continuing projects
- » Work Plan available at oig.hhs.gov/reports-and-publications/archives/workplan/2014/Work-Plan-2014.pdf.

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**DME Issues in OIG 2014 Work Plan:
New Projects**

- » **Reasonableness of Medicare's Fee Schedule for DME Compared to Amounts Paid by Other Payors.** Prior OIG studies contended that Medicare overpays for various types of DME. If CMS determines that the fee schedule methodologies result in fees that are "grossly deficient or excess[ive]," CMS can replace the current fee schedule amounts with special payment limits. This OIG review will compare the Medicare fee schedule amount for various DME (including commode chairs, folding walkers, and transcutaneous electrical nerve stimulators) with payments made for various DME by non-Medicare payers, such as private insurance companies and the Department of Veterans Affairs.

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**DME Issues in OIG 2014 Work Plan:
New Projects (cont'd)**

- » **Nebulizer Machines and Related Drugs – Supplier Compliance with Payment Requirements.** Prior OIG work contended DME suppliers were overpaid \$6 million for nebulizer inhalation drugs on the grounds the drugs were not medically necessary. Under this project, OIG will review Part B payments for nebulizer machines and drugs to assess medical necessity.
- » **Power Mobility Devices – Lump-Sum Purchase Versus Rental.** OIG will determine whether cost savings can be realized by Medicare if certain power mobility devices are rented over a 13-month period rather than acquired through a lump-sum purchase.

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**DME Issues in OIG 2014 Work Plan:
New Projects (cont'd)**

- » **Power Mobility Devices – Add-On Payment for Face-to-Face Exam**
 - . Medicare requires the treating physician to conduct a face-to-face exam of the beneficiary to determine medical necessity for power mobility devices, and the physician may bill Medicare for an E/M service, receiving an add-on payment for this work. OIG will review Part B payments for power mobility devices to determine if the face-to-face exam requirements were met.
- » **Competitive Bidding for Diabetes Testing Supplies – Mandatory Market Share Review.** OIG will determine the market share of different types of diabetic test strips following Round 2 of the DME Competitive Bidding Program. The Program statutes require that contracts for mail order test strips be awarded to suppliers that provide at least 50%, by volume, of all types of diabetic test strips.

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2014 DME Business Arrangements: Lead Generation vs Referrals

- ↳ Lead generation companies have been around for years in the non-health care space where there is little regulation and as a result are not often familiar with the multiple federal anti-fraud laws in the health care market, such as the Medicare anti-kickback statute and the telephone solicitation statute.
- ↳ It is acceptable to purchase a lead; however, it is a violation of the anti-kickback statute to pay for referral. The line between the two can be blurry. In the eyes of the OIG, there is a distinction between
 - o (i) a "raw" or "unqualified" lead and
 - o (ii) a "qualified" lead or a referral.
- ↳ Most Common way to Pay for Leads
 - o Per Lead
 - o Flat Fee

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2014 DME Business Arrangements: Telemarketing

- ↳ The telephone solicitation statute prohibits suppliers from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of a covered item, except in three specific situations:
 - o (i) the beneficiary has given written permission to the supplier to make contact by telephone;
 - o (ii) the contact is regarding a covered item the supplier has already furnished the beneficiary; or
 - o (iii) the supplier has furnished at least one covered item to the beneficiary during the preceding fifteen months.
- ↳ It is also a violation of Supplier Standard Number 11

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2014 DME Business Arrangements: Telemarketing (cont'd)

- ↳ Suppliers cannot do indirectly that which they are prohibited from doing directly which means a supplier is responsible for verifying that marketing activities performed by third parties do not involve prohibited activity and that information purchased from such third parties was neither obtained, nor derived, from prohibited activity.
- ↳ The telephone solicitation statute also specifically prohibits payment to a supplier that knowingly submits a claim generated pursuant to a prohibited telephone solicitation. Accordingly, such claims for payment are false and violators are potentially subject to criminal, civil, and administrative penalties, including exclusion from federal health care programs.

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2014 DME Business Arrangements: DME Closets

- » Not per se illegal but the government does not like loan closet arrangements.
- » An HME company may place inventory in an office or facility that is not owned by a physician or non-physician practitioner.
- » The inventory must be for the convenience only of the office's/facility's patients and the office/facility cannot financially benefit, directly or indirectly, from the inventory.
- » It is important that the office/facility ensure patient choice.
- » Technically, the HME company can pay rent to the office/facility so long as the rental agreement complies with the Space Rental safe harbor and takes into consideration the February 2000 Special Fraud Alert on Rental of Space In Physician Offices by Persons or Entities to Which Physicians Refer.

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2014 DME Business Arrangements: Case Studies

CASE STUDIES

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Questions?

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DME Compliance and Regulatory Issues

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Face-to-Face Encounter Requirement for Certain Durable Medical Equipment

Additional Time to Establish Protocols for Newly Required Face-to-Face Encounters for Durable Medical Equipment (DME) – December 3, 2013

On September 9, 2013, the Centers for Medicare & Medicaid Services (CMS) announced that it would begin actively enforcing and would expect full compliance with new DME face-to-face requirements on a date to be announced in Calendar Year 2014. We are publishing this announcement to make clear that the delay of enforcement only applies to the face-to-face encounter requirements and does not impact provisions related to written orders prior to delivery.

Due to continued concerns that some providers and suppliers may need additional time to establish operational protocols necessary to comply with face-to-face encounter requirements mandated by the Affordable Care Act (ACA) for certain items of DME, CMS will start actively enforcing and will expect full compliance with the DME face-to-face requirements beginning on a date that will be announced in Calendar Year 2014.

In a November 16, 2012 final rule titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013" we established a face-to-face encounter requirement and new requirements for written orders prior to delivery for certain items of DME (77 Federal Register 68892). These requirements may be found in the Code of Federal Regulations at 42 CFR § 410.38(g).

The law requires that a physician must document that a physician, nurse practitioner, physician assistant or clinical nurse specialist has had a face-to-face encounter with the patient. The encounter must occur within the 6 months before the order is written for the DME.

Although many durable medical equipment suppliers and physicians are aware of and are currently complying with this policy, CMS is concerned that some may need additional time to establish operational protocols necessary to comply with this new law. As such, CMS expects that during the next several months, suppliers and physicians who order certain DME items will continue to collaborate and establish internal processes to ensure compliance with the face-to-face requirement. CMS expects all durable medical equipment suppliers to have fully established such internal processes and have appropriate documentation of required encounters by a date that will be announced in Calendar Year 2014. Those suppliers and physicians who are currently implementing the face-to-face requirement should continue to do so.

The delay of enforcement only applies to the face-to-face requirements in CFR §410.38(g)(3). CMS expects full compliance with the remaining portions of the regulation.

CMS will continue to address industry questions concerning the new requirements and will update information on our web site at www.cms.gov/medical-review. CMS and its contractors will also use other communication channels to ensure that the provider and supplier community is properly informed of this announcement.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services



REVISED products from the Medicare Learning Network® (MLN)

- [The Durable Medical Equipment, Prosthetics, Orthotics, and Supplies \(DMEPOS\) Competitive Bidding Program: Traveling Beneficiary](#), Fact Sheet, ICN 904484, Downloadable only.

MLN Matters® Number: MM8304 Revised

Related Change Request (CR) #: CR 8304

Related CR Release Date: May 31, 2013

Effective Date: July 1, 2013

Related CR Transmittal #: R468PI

Implementation Date: July 1, 2013

Detailed Written Orders and Face-to-Face Encounters

Note: This article was revised on June 28, 2013, to provide clarifying language on page 2 and to provide a Web address for a relevant portion of the "Program Integrity Manual" on page 2. All other information remains the same.

Provider Types Affected

This MLN Matters® Article is intended for physicians, Physician Assistants (PAs), Nurse Practitioners (NPs), Clinical Nurse Specialists (CNSs) and suppliers submitting claims to Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for certain Durable Medical Equipment (DME) items and services provided to Medicare beneficiaries.

What You Need to Know

This article is based on Change Request (CR) 8304, which instructs DME MACs to implement requirements, which are effective July 1, 2013, for detailed written orders for face-to-face encounters

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conducted by the physician, PA, NP or CNS for certain DME items as defined in 42 CFR 410.38(g). (That section is available at <http://www.gpo.gov/fdsys/pkg/CFR-2011-title42-vol2/pdf/CFR-2011-title42-vol2-sec410-38.pdf> on the Internet.)

Due to concerns that some providers and suppliers may need additional time to establish operational protocols necessary to comply with face-to-face encounter requirements mandated by the Affordable Care Act for certain items of DME, the Centers for Medicare & Medicaid Services (CMS) will start actively enforcing and will expect full compliance with the DME face-to-face requirements beginning on October 1, 2013.

Section 6407 of the Affordable Care Act established a face-to-face encounter requirement for certain items of DME. The law requires that a physician must document that a physician, nurse practitioner, physician assistant or clinical nurse specialist has had a face-to-face encounter with the patient. The encounter must occur within the 6 months before the order is written for the DME.

Although many durable medical equipment suppliers and physicians are aware of and are able to comply with this policy, CMS is concerned that some may need additional time to establish operational protocols necessary to comply with this new law. As such, CMS expects that during the next several months, suppliers and physicians who order certain DME items will continue to collaborate and establish internal processes to ensure compliance with the face-to-face requirement. CMS expects durable medical equipment suppliers to have fully established such internal processes and have appropriate documentation of required encounters by October 1, 2013.

CMS will continue to address industry questions concerning the new requirements and will update information on at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/index.html> on the CMS website. CMS and its contractors will also use other communication channels to ensure that the provider community is properly informed of this announcement.

Background

As a condition for payment, Section 6407 of the Affordable Care Act requires a physician to document that the physician, PA, NP or CNS has had a face-to-face encounter examination with a beneficiary in the six (6) months prior to the written order for certain items of DME (the complete list of items is found in Appendix A at the end of this article). This section does not apply to Power Mobility Devices (PMDs) as these items are covered under a separate requirement.

This includes encounters conducted via the Centers for Medicare & Medicaid Services (CMS)-approved use of telehealth (as described in Chapter 15 of the "Medicare Benefit Policy Manual" and Chapter 12 of the "Medicare Claims Processing Manual"). Those manuals are available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html> on the CMS website.

Note that the date of the written order must not be prior to the date of the face-to-face encounter.

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The face-to-face encounter conducted by the physician, PA, NP, or CNS must document that the beneficiary was evaluated and/or treated for a condition that supports the item(s) of DME ordered.

In the case of a DME ordered by a PA, NP, or CNS, a physician (MD or DO) must document the occurrence of a face-to-face encounter by signing/co-signing and dating the pertinent portion of the medical record. CMS will accept a single confirming signature, including the date, as sufficient if there are several pertinent portions of the medical record.

The written order for the DME must follow the guidance in the CMS "Program Integrity Manual," Chapter 5, Section 5.2.3 (available at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.html>) and include, at a minimum:

1. the beneficiary's name,
2. the item of DME ordered,
3. the prescribing practitioner's National Provider Identifier (NPI),
4. the signature of the ordering practitioner and
5. the date of the order.

Failure to meet any of the above requirements will result in denial of the claim.

Physicians will be provided an additional payment, using code G0454, for signing/co-signing the face-to-face encounter of the PA/NP/CNS. The physician should not bill the G code when he/she conducts the face-to-face encounter. Note that the G code may only be paid to the physician one time per beneficiary per encounter, regardless of the number of covered items documented in the face-to-face encounter.

CR8304 implements these changes in Chapter 5 of the "Program Integrity Manual" to support 42 Code of Federal Regulations (CFR) 410.38(g) and the revised portion of that manual is attached to CR8304.

Additional Information

The official instruction, CR8304, issued to your DME MAC regarding this change, may be viewed at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R468PI.pdf> on the CMS website.

If you have any questions, please contact your DME MAC at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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Appendix A

The DME list of Specified Covered Items are as follows, the original list was at 77 FR 44798:

HCPSCS Code	Description
E0185	Gel or gel-like pressure mattress pad
E0188	Synthetic sheepskin pad
E0189	Lamb's wool sheepskin pad
E0194	Air fluidized bed
E0197	Air pressure pad for mattress standard length and width
E0198	Water pressure pad for mattress standard length and width
E0199	Dry pressure pad for mattress standard length and width
E0250	Hospital bed fixed height with any type of side rails, mattress
E0251	Hospital bed fixed height with any type side rails without mattress
E0255	Hospital bed variable height with any type side rails with mattress
E0256	Hospital bed variable height with any type side rails without mattress
E0260	Hospital bed semi-electric (Head and foot adjustment) with any type side rails with mattress
E0261	Hospital bed semi-electric (head and foot adjustment) with any type side rails without mattress
E0265	Hospital bed total electric (head, foot and height adjustments) with any type side rails with mattress
E0266	Hospital bed total electric (head, foot and height adjustments) with any type side rails without mattress
E0290	Hospital bed fixed height without rails with mattress
E0291	Hospital bed fixed height without rail without mattress
E0292	Hospital bed variable height without rail without mattress
E0293	Hospital bed variable height without rail with mattress
E0294	Hospital bed semi-electric (head and foot adjustment) without rail with mattress
E0295	Hospital bed semi-electric (head and foot adjustment) without rail without

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HCPCS Code	Description
	mattress
E0296	Hospital bed total electric (head, foot and height adjustments) without rail with mattress
E0297	Hospital bed total electric (head, foot and height adjustments) without rail without mattress
E0300	Pediatric crib, hospital grade, fully enclosed
E0301	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, without mattress
E0302	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, without mattress
E0303	Hospital bed Heavy Duty extra wide, with weight capacity 350-600 lbs with any type of rail, with mattress
E0304	Hospital bed Heavy Duty extra wide, with weight capacity greater than 600 lbs with any type of rail, with mattress
E0424	Stationary compressed gas Oxygen System rental; includes contents, regulator, nebulizer, cannula or mask and tubing
E0431	Portable gaseous oxygen system rental includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0433	Portable liquid oxygen system
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, content gauge, cannula or mask, and tubing
E0439	Stationary liquid oxygen system rental, includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Oxygen contents, gaseous (1 months supply)
E0442	Oxygen contents, liquid (1 months supply)
E0443	Portable Oxygen contents, gas (1 months supply)
E0444	Portable oxygen contents, liquid (1 months supply)
E0450	Volume control ventilator without pressure support used with invasive interface
E0457	Chest shell

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HCPCS Code	Description
E0459	Chest wrap
E0460	Negative pressure ventilator portable or stationary
E0461	Volume control ventilator without pressure support node for a noninvasive interface
E0462	Rocking bed with or without side rail
E0463	Pressure support ventilator with volume control mode used for invasive surfaces
E0464	Pressure support vent with volume control mode used for noninvasive surfaces
E0470	Respiratory Assist Device, bi-level pressure capability, without backup rate used non-invasive interface
E0471	Respiratory Assist Device, bi-level pressure capability, with backup rate for a non-invasive interface
E0472	Respiratory Assist Device, bi-level pressure capability, with backup rate for invasive interface
E0480	Percussor electric/pneumatic home model
E0482	Cough stimulating device, alternating positive and negative airway pressure
E0483	High Frequency chest wall oscillation air pulse generator system
E0484	Oscillatory positive expiratory device, non-electric
E0570	Nebulizer with compressor
E0575	Nebulizer, ultrasonic, large volume
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type for use with regulator or flowmeter
E0585	Nebulizer with compressor & heater
E0601	Continuous airway pressure device
E0607	Home blood glucose monitor
E0627	Seat lift mechanism incorporated lift-chair
E0628	Separate Seat lift mechanism for patient owned furniture electric
E0629	Separate seat lift mechanism for patient owned furniture non-electric

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HCPCS Code	Description
E0636	Multi positional patient support system, with integrated lift, patient accessible controls
E0650	Pneumatic compressor non-segmental home model
E0651	Pneumatic compressor segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor segmental home model with calibrated gradient pressure
E0655	Non- segmental pneumatic appliance for use with pneumatic compressor on half arm
E0656	Non- segmental pneumatic appliance for use with pneumatic compressor on trunk
E0657	Non- segmental pneumatic appliance for use with pneumatic compressor chest
E0660	Non- segmental pneumatic appliance for use with pneumatic compressor on full leg
E0665	Non- segmental pneumatic appliance for use with pneumatic compressor on full arm
E0666	Non- segmental pneumatic appliance for use with pneumatic compressor on half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor on full-leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor on full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor on half leg
E0671	Segmental gradient pressure pneumatic appliance full leg
E0672	Segmental gradient pressure pneumatic appliance full arm
E0673	Segmental gradient pressure pneumatic appliance half leg
E0675	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency
E0692	Ultraviolet light therapy system panel treatment 4 foot panel

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HCPSCS Code	Description
E0693	Ultraviolet light therapy system panel treatment 6 foot panel
E0694	Ultraviolet multidirectional light therapy system in 6 foot cabinet
E0720	Transcutaneous electrical nerve stimulation, two lead, local stimulation
E0730	Transcutaneous electrical nerve stimulation, four or more leads, for multiple nerve stimulation
E0731	Form fitting conductive garment for delivery of TENS or NMES
E0740	Incontinence treatment system, Pelvic floor stimulator, monitor, sensor, and/or trainer
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator electric shock unit
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spine application.
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal application
E0749	Osteogenesis stimulator, electrical, surgically implanted
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive
E0762	Transcutaneous electrical joint stimulation system including all accessories
E0764	Functional neuromuscular stimulator, transcutaneous stimulations of muscles of ambulation with computer controls
E0765	FDA approved nerve stimulator for treatment of nausea & vomiting
E0782	Infusion pumps, implantable, Non-programmable
E0783	Infusion pump, implantable, Programmable
E0784	External ambulatory infusion pump
E0786	Implantable programmable infusion pump, replacement
E0840	Tract frame attach to headboard, cervical traction
E0849	Traction equipment cervical, free-standing stand/frame, pneumatic, applying traction force to other than mandible
E0850	Traction stand, free standing, cervical traction
E0855	Cervical traction equipment not requiring additional stand or frame
E0856	Cervical traction device, cervical collar with inflatable air bladder

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HCPCS Code	Description
E0958	Manual wheelchair accessory, one-arm drive attachment
E0959	Manual wheelchair accessory-adapter for Amputee
E0960	Manual wheelchair accessory, shoulder harness/strap
E0961	Manual wheelchair accessory wheel lock brake extension handle
E0966	Manual wheelchair accessory, headrest extension
E0967	Manual wheelchair accessory, hand rim with projections
E0968	Commode seat, wheelchair
E0969	Narrowing device wheelchair
E0971	Manual wheelchair accessory anti-tipping device
E0973	Manual wheelchair accessory, adjustable height, detachable armrest
E0974	Manual wheelchair accessory anti-rollback device
E0978	Manual wheelchair accessory positioning belt/safety belt/ pelvic strap
E0980	Manual wheelchair accessory safety vest
E0981	Manual wheelchair accessory Seat upholstery, replacement only
E0982	Manual wheelchair accessory, back upholstery, replacement only
E0983	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, joystick control
E0984	Manual wheelchair accessory power add on to convert manual wheelchair to motorized wheelchair, Tiller control
E0985	Wheelchair accessory, seat lift mechanism
E0986	Manual wheelchair accessory, push activated power assist
E0990	Manual wheelchair accessory, elevating leg rest
E0992	Manual wheelchair accessory, elevating leg rest solid seat insert
E0994	Arm rest
E1014	Reclining back, addition to pediatric size wheelchair
E1015	Shock absorber for manual wheelchair
E1020	Residual limb support system for wheelchair
E1028	Wheelchair accessory, manual swing away, retractable or removable

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HCPCS Code	Description
	mounting hardware for joystick, other control interface or positioning accessory
E1029	Wheelchair accessory, ventilator tray
E1030	Wheelchair accessory, ventilator tray, gimbaled
E1031	Rollabout chair, any and all types with castors 5" or greater
E1035	Multi-positional patient transfer system with integrated seat operated by care giver
E1036	Patient transfer system
E1037	Transport chair, pediatric size
E1038	Transport chair, adult size up to 300lb
E1039	Transport chair, adult size heavy duty >300lb
E1161	Manual Adult size wheelchair includes tilt in space
E1227	Special height arm for wheelchair
E1228	Special back height for wheelchair
E1232	Wheelchair, pediatric size, tilt-in-space, folding, adjustable with seating system
E1233	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system
E1234	Wheelchair, pediatric size, tilt-in-space, folding, adjustable without seating system
E1235	Wheelchair, pediatric size, rigid, adjustable, with seating system
E1236	Wheelchair, pediatric size, folding, adjustable, with seating system
E1237	Wheelchair, pediatric size, rigid, adjustable, without seating system
E1238	Wheelchair, pediatric size, folding, adjustable, without seating system
E1296	Special sized wheelchair seat height
E1297	Special sized wheelchair seat depth by upholstery
E1298	Special sized wheelchair seat depth and/or width by construction
E1310	Whirlpool non-portable
E2502	Speech Generating Devices prerecord messages between 8 and 20 Minutes

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HCPCS Code	Description
E2506	Speech Generating Devices prerecord messages over 40 minutes
E2508	Speech Generating Devices message through spelling, manual type
E2510	Speech Generating Devices synthesized with multiple message methods
E2227	Rigid pediatric wheelchair adjustable
K0001	Standard wheelchair
K0002	Standard hemi (low seat) wheelchair
K0003	Lightweight wheelchair
K0004	High strength ltwt wheelchair
K0005	Ultra Lightweight wheelchair
K0006	Heavy duty wheelchair
K0007	Extra heavy duty wheelchair
K0009	Other manual wheelchair/base
K0606	AED garment with electronic analysis
K0730	Controlled dose inhalation drug delivery system

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5.1 – Home Use of DME

(Rev. 242: Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)

See Pub. 100-04, chapter 20, section 10.2, A2.a-e.

5.2 – Rules Concerning Orders

(Rev. 242: Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)

5.2.1 - Physician Orders

(Rev. 242: Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)

The supplier for all Durable Medical Equipment, Prosthetic, and Orthotic Supplies (DMEPOS) is required to keep on file a physician prescription (order). A supplier must have an order from the treating physician before dispensing any DMEPOS item to a beneficiary.

5.2.2 - Verbal and Preliminary Written Orders

(Rev. 242: Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)

Except as noted in chapter 5 section 5.2.3.1 suppliers may dispense most items of DMEPOS based on a verbal order or preliminary written order from the treating physician. This dispensing order must include: a description of the item, the beneficiary's name, the physician's name and the start date of the order. Suppliers must maintain the preliminary written order or written documentation of the verbal order and this documentation must be available to the DME MACs, DME PSCs, or Zoned Program Integrity Contractors (ZPICs) upon request. If the supplier does not have an order from the treating physician before dispensing an item, the item is noncovered.

For items that are dispensed based on a verbal order or preliminary written order, the supplier must obtain a detailed written order that meets the requirements of section 5.2.3 before submitting the claim.

5.2.3 – Detailed Written Orders

(Rev. 242: Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)

Detailed written orders are required for all transactions involving DMEPOS. Detailed written orders may take the form of a photocopy, facsimile image, electronically maintained, or original "pen-and-ink" document. (See chapter 3, section 3.4.1.1.B.)

All orders must clearly specify the start date of the order.

If the written order is for supplies that will be provided on a periodic basis, the written order should include appropriate information on the quantity used, frequency of change, and duration of need. (For example, an order for surgical dressings might specify one 4 x 4 hydrocolloid dressing that is changed 1-2 times per week for 1 month or until the ulcer heals.)

The written order must be sufficiently detailed, including all options or additional features that will be separately billed or that will require an upgraded code. The description can be either a narrative description (e.g., lightweight wheelchair base) or a brand name/model number.

If the supply is a drug, the order must specify the name of the drug, concentration (if applicable), dosage, frequency of administration, and duration of infusion (if applicable).

Someone other than the physician may complete the detailed description of the item. However, the treating physician must review the detailed description and personally sign and date the order to indicate agreement.

The supplier must have a detailed written order prior to submitting a claim. For items listed in chapter 5 section 5.2.3.1, the detailed written order must be obtained prior to delivery. If a supplier does not have a faxed, photocopied, electronic or pen and ink signed detailed written order in their records before they submit a claim to Medicare (i.e., if there is no order or only a verbal order), the claim will be denied. If the claim is for an item for which an order is required by statute (e.g., therapeutic shoes for diabetics, oral anticancer drugs, oral antiemetic drugs which are a replacement for intravenous antiemetic drugs), the claim will be denied as not meeting the benefit category and is therefore not appealable by the supplier (see Pub. 100-04, chapter 29, §10, 30.3, 60 for more information on appeals). For all other items (except those listed in section 5.2.3.1), if the supplier does not have an order that has been both signed and dated by the treating physician before billing the Medicare program, the item will be denied as not reasonable and necessary.

Medical necessity information (e.g., an ICD-9-CM diagnosis code, narrative description of the patient's condition, abilities, limitations) is NOT in itself considered to be part of the order although it may be put on the same document as the order.

In other sections of this chapter, the term "order" or "written order" means "detailed written order" unless otherwise specified.

5.2.3.1 - Written Orders Prior to Delivery **(Rev. 242: Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)**

A detailed written order prior to delivery is required for: pressure reducing pads, mattress overlays, mattresses, and beds; seat lift mechanisms; TENS units; power operated vehicles and power wheelchairs. DME MACs, DME PSCs, and ZPICs may identify other items for which they will require a written order prior to delivery.

For these items, the supplier must have received a written order that has been both signed and dated by the treating physician and meets the requirements of section 5.2.3 before dispensing the item.

If a supplier bills for an item without a detailed written order, when the supplier is required to have a written order prior to delivery, the item will be denied as excluded by statute (see Pub. 100-04, chapter 29, §10, 30.3, 60 for more information on appeals).

5.2.3.2 – Detailed Written Orders for Face-to-Face Encounter
(Rev. 468; Issued: 05-31-13; Effective: 07-01-13; Implementation: 07-01-13)

This section only applies to covered items as defined in 42 CFR 410.38(g). CMS will notify contractors of any annual updates to the list of covered items. CMS will notify the public of any updates in the list of covered items via the Federal Register. Contractors shall not apply this section to PMDs.

For covered items as defined in 42 CFR 410.38(g) a physician must document that the physician, a physician assistant (PA), a nurse practitioner (NP) or a clinical nurse specialist (CNS) has had a face-to-face encounter with the beneficiary within six (6) months prior to completing the detailed written order. On claims selected for review if there is no face-to-face encounter, contractors shall deny the claim.

5.2.3.2.1 – Face-to-Face Encounter Conducted by the Physician
(Rev. 468; Issued: 05-31-13; Effective: 07-01-13; Implementation: 07-01-13)

When conducting a review of a covered DME item, outlined in 42 CFR 410.38(g) ordered by a physician (MD or DO), the contractor shall ensure that the physician saw the beneficiary (including through the appropriate use of telehealth (see Pub 100-02, the Medicare Benefit Policy Manual, Chapter 15 and Pub 100-04, the Medicare Claims Processing Manual, Chapter 12) and conducted a face-to-face assessment. The contractor shall verify that the face-to-face documentation includes information supporting that the beneficiary was evaluated or treated for a condition that supports the item(s) of DME ordered. If this information is not included, the contractor shall deny the claim. If the physician completed the detailed written order before the face-to-face encounter, the contractor shall deny the claim.

5.2.3.2.2 – Face-to-Face Encounter Conducted by a Nurse Practitioner, Physician Assistant or Clinical Nurse Specialist
(Rev. 468; Issued: 05-31-13; Effective: 07-01-13; Implementation: 07-01-13)

When conducting a review of a covered DME item, outlined in 42 CFR 410.38(g) ordered by a PA, NP, or CNS, the contractor must ensure that the practitioner who conducted the face-to-face assessment saw the beneficiary (including through the appropriate use of telehealth (see Pub 100-02, the Medicare Benefit Policy Manual, Chapter 15 and Pub 100-04, the Medicare Claims Processing Manual, Chapter 12). If the face-to-face encounter documentation does not include information supporting that the beneficiary was evaluated or treated for a condition that supports the item(s) of DME ordered the contractor shall deny the claim.

When conducting a review of a covered DME item, outlined in 42 CFR 410.38(g) ordered by a PA, NP, or CNS, the contractor shall verify that a physician (MD or DO) documented the occurrence of a face-to-face encounter by signing/co-signing and dating (consistent with the signature requirement in PIM Chapter 3, Section 3.3.2.4) the pertinent portion of the medical record indicating the occurrence of a face-to-face. If this information is not included, the contractor shall deny the claim.

***NOTE:** A single confirming signature and date is sufficient in a situation where there are several pertinent portions of the medical record.*

5.2.3.2.3 – Detailed Written Order for Covered Items

(Rev. 468; Issued: 05-31-13; Effective: 07-01-13; Implementation: 07-01-13)

For a covered DME item, outlined in 42 CFR 410.38(g), the contractor shall ensure that the detailed written order is consistent with PIM Chapter 5 § 5.2.3. Consistent with 42 CFR 410.38(g) the order must include, at a minimum; the beneficiary's name, the item of DME ordered, the prescribing practitioner's NPI, the signature of the ordering practitioner (physician, PA, NP, or CNS) and the date of the order. If this information is not included on the detailed written order, the claim will be denied. Medicare requires that the detailed written order is completed after the face-to-face encounter. If the date of the detailed written order is prior to the date of the face-to-face encounter, the contractor shall deny the claim.

5.2.4 – Requirement of New Orders

(Rev. 242: Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)

A new order is required in the following situations:

- There is a change in the order for the accessory, supply, drug, etc.;
- On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy;
- When an item is replaced; and
- When there is a change in the supplier.

5.2.5 - Billing for Refills of DMEPOS Items Provided on a Recurring Basis

(Rev. 378, Issued: 07-01-11, Effective: 08-02-11, Implementation: 08-02-11)

This section applies to DME MACs, DME PSCs, and ZPICs.

For DMEPOS items and supplies that are provided on a recurring basis, billing must be based on prospective, not retrospective use. The following scenarios are illustrative of this concept:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services



In September 2012, the Centers for Medicare & Medicaid Services (CMS) announced the availability of a new electronic mailing list for those who refer Medicare beneficiaries for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). Referral agents play a critical role in providing information and services to Medicare beneficiaries. To ensure you give Medicare patients the most current DMEPOS Competitive Bidding Program information, CMS strongly encourages you to review the information sent from this new electronic mailing list. In addition, please share the information you receive from the mailing list and the link to the "[mailing list for referral agents](#)" subscriber webpage with others who refer Medicare beneficiaries for DMEPOS. Thank you for signing up!

MLN Matters® Number: SE1305 **Revised**

Related Change Request (CR) #: 6421, 6417, 6696, 6856

Related CR Release Date: N/A

Effective Date: N/A

Related CR Transmittal #: R6420TN, R6430TN,
R328PI, and R7810TN

Implementation Date: N/A

Note: This article was revised on February 6, 2014, to modify the answer to question J on page 10 (underlined). The article was previously changed on November 6, 2013, to provide updated information regarding the effective date of the edits (January 6, 2014). Additional clarifying information regarding the Advance Beneficiary Notice, CARC codes and DME rental equipment has also been updated. Please review the article carefully for these changes. All other information remains the same.

Full Implementation of Edits on the Ordering/Referring Providers in Medicare Part B, DME, and Part A Home Health Agency (HHA) Claims (Change Requests 6417, 6421, 6696, and 6856)

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Note: This article was previously revised on April 19, 2013, to add references to the CMS-1450 form and to add question H. on page 9. Previously, it was revised on April 3, 2013, to advise providers to **not include middle names and suffixes of ordering/referring providers on paper claims**. Physicians and others who are eligible to order and refer items or services need to establish their Medicare enrollment record with a valid National Provider Identifier (NPI) and must be of a specialty that is eligible to order and refer. If the ordering/referring provider is listed on the claim, the edits will verify that the provider is enrolled in Medicare. The edits will compare the first four letters of the last name. When submitting the CMS-1500 or the CMS-1450, **please only include the first and last name as it appears on the ordering and referring file found at <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/MedicareOrderingandReferring.html>** on the CMS website.

Provider Types Affected

This MLN Matters® Special Edition Article is intended for:

- Physicians and non-physician practitioners (including interns, residents, fellows, and those who are employed by the Department of Veterans Affairs (DVA), the Department of Defense (DoD), or the Public Health Service (PHS)) who order or refer items or services for Medicare beneficiaries,
- Part B providers and suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) who submit claims to carriers, Part A/B Medicare Administrative Contractors (MACs), and DME MACs for items or services that they furnished as the result of an order or a referral, and
- Part A Home Health Agency (HHA) services who submit claims to Regional Home Health Intermediaries (RHHIs), Fiscal Intermediaries (FIs, who still maintain an HHA workload), and Part A/B MACs.
- Optometrists may only order and refer DMEPOS products/services and laboratory and X-Ray services payable under Medicare Part B.

Provider Action Needed

If you order or refer items or services for Medicare beneficiaries and you do not have a Medicare enrollment record, you need to submit an enrollment application to Medicare. You can do this using the Internet-based Provider Enrollment, Chain, and Ownership System (PEcos) or by completing the paper enrollment application (CMS-8550). Review the background and additional information below and make sure that your billing staff is aware of these updates.

What Providers Need to Know

Phase 1: Informational messaging: Began October 5, 2009, to alert the billing provider that the identification of the ordering/referring provider is missing, incomplete, or invalid, or that the ordering/referring provider is not eligible to order or refer. The informational message on an adjustment claim that did not pass the edits indicated the claim/service lacked information that was needed for adjudication.

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Phase 2: Effective January 6, 2014, CMS will turn on the edits to deny Part B clinical laboratory and imaging, DME, and Part A HHA claims that fail the ordering/referring provider edits.

Claims submitted identifying an ordering/referring provider and the required matching NPI is missing will continue to be rejected. Claims from billing providers and suppliers that are denied because they failed the ordering/referring edit will not expose a Medicare beneficiary to liability. Therefore, **an Advance Beneficiary Notice is not appropriate in this situation**. This is consistent with the preamble to the final rule which implements the Affordable Care Act requirement that physicians and eligible professionals enroll in Medicare to order and certify certain Medicare covered items and services, including home health, DMEPOS, imaging and clinical laboratory.

Physicians and others who are eligible to order and refer items or services need to establish their Medicare enrollment record and must be of a specialty that is eligible to order and refer. Physicians and others who are eligible to order and refer items or services need to establish their Medicare enrollment record with a valid NPI and must be of a specialty that is eligible to order and refer. If the ordering/referring provider is listed on the claim, the edits will verify that the provider is enrolled in Medicare. The edits will compare the first four letters of the last name. **When submitting the CMS-1500 or the CMS-1450, please only include the first and last name as it appears on the ordering and referring file found on <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/MedicareOrderingandReferring.html> on the CMS website. Middle names (initials) and suffixes (such as MD, RPNA etc.) should not be listed in the ordering/referring fields.**

All enrollment applications, including those submitted over the Internet, require verification of the information reported. Sometimes, Medicare enrollment contractors may request additional information in order to process the enrollment application. Waiting too long to begin this process could mean that your enrollment application may not be processed prior to the implementation date of the ordering/referring Phase 2 provider edits.

Background

The Affordable Care Act, Section 6405, "Physicians Who Order Items or Services are required to be Medicare Enrolled Physicians or Eligible Professionals," requires physicians or other eligible professionals to be enrolled in the Medicare Program to order or refer items or services for Medicare beneficiaries. Some physicians or other eligible professionals do not and will not send claims to a Medicare contractor for the services they furnish and therefore may not be enrolled in the Medicare program. Also, effective January 1, 1992, a physician or supplier that bills Medicare for a service or item must show the name and unique identifier of the attending physician on the claim if that service or item was the result of an order or referral. Effective May 23, 2008, the unique identifier was determined to be the NPI. The Centers for Medicare & Medicaid Services (CMS) has implemented edits on ordering and referring providers when they are required to be identified in Part B clinical laboratory and imaging, DME, and Part A HHA claims from Medicare providers or suppliers who furnished items or services as a result of orders or referrals.

Below are examples of some of these types of claims:

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- Claims from clinical laboratories for ordered tests;
- Claims from imaging centers for ordered imaging procedures;
- Claims from suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) for ordered DMEPOS; and
- Claims from Part A Home Health Agencies (HHA).

Only physicians and certain types of non-physician practitioners are eligible to order or refer items or services for Medicare beneficiaries. They are as follows:

- Physicians (doctor of medicine or osteopathy, doctor of dental medicine, doctor of dental surgery, doctor of podiatric medicine, doctor of optometry, optometrists may only order and refer DMEPOS products/services and laboratory and X-Ray services payable under Medicare Part B.)
- Physician Assistants,
- Clinical Nurse Specialists,
- Nurse Practitioners,
- Clinical Psychologists,
- Interns, Residents, and Fellows,
- Certified Nurse Midwives, and
- Clinical Social Workers.

CMS emphasizes that generally Medicare will only reimburse for specific items or services when those items or services are ordered or referred by providers or suppliers authorized by Medicare statute and regulation to do so. Claims that a billing provider or supplier submits in which the ordering/referring provider or supplier is not authorized by statute and regulation will be denied as a non-covered service. The denial will be based on the fact that neither statute nor regulation allows coverage of certain services when ordered or referred by the identified supplier or provider specialty.

CMS would like to highlight the following limitations:

- Chiropractors are not eligible to order or refer supplies or services for Medicare beneficiaries. All services ordered or referred by a chiropractor will be denied.
- Home Health Agency (HHA) services may only be ordered or referred by a Doctor of Medicine (M.D.), Doctor of Osteopathy (D.O.), or Doctor of Podiatric Medicine (DPM). Claims for HHA services ordered by any other practitioner specialty will be denied.
- Optometrists may only order and refer DMEPOS products/services, and laboratory and X-Ray services payable under Medicare Part B.

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Questions and Answers Relating to the Edits

1. What are the ordering and referring edits?

The edits will determine if the Ordering/Referring Provider (when required to be identified in Part B clinical laboratory and imaging, DME, and Part A HHA claims) (1) has a current Medicare enrollment record and contains a valid NPI (the name and NPI must match), and (2) is of a provider type that is eligible to order or refer for Medicare beneficiaries (see list above).

2. Why did Medicare implement these edits?

These edits help protect Medicare beneficiaries and the integrity of the Medicare program.

3. How and when will these edits be implemented?

These edits were implemented in two phases:

Phase 1 -Informational messaging: Began October 5, 2009, to alert the billing provider that the identification of the ordering/referring provider is missing, incomplete, or invalid, or that the ordering/referring provider is not eligible to order or refer. The informational message on an adjustment claim that did not pass the edits indicated the claim/service lacked information that was needed for adjudication. The informational messages used are identified below:

For Part B providers and suppliers who submit claims to carriers:

N264	Missing/incomplete/invalid ordering provider name
N265	Missing/incomplete/invalid ordering provider primary identifier

For adjusted claims, the Claims Adjustment Reason Code (CARC) code 16 (Claim/service lacks information which is needed for adjudication.) is used.

DME suppliers who submit claims to carriers (applicable to 5010 edits):

N544	Alert: Although this was paid, you have billed with a referring/ordering provider that does not match our system record. Unless, corrected, this will not be paid in the future
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For Part A HHA providers who order and refer, the claims system initially processed the claim and added the following remark message:

N272	Missing/incomplete/invalid other payer attending provider identifier
------	----------------------------------------------------------------------

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For adjusted claims the CARC code 16 and/or the RARC code N272 was used.

CMS has taken actions to reduce the number of informational messages.

In December 2009, CMS added the NPIs to more than 200,000 PECOS enrollment records of physicians and non-physician practitioners who are eligible to order and refer but who had not updated their PECOS enrollment records with their NPIs.¹

On January 28, 2010, CMS made available to the public, via the Downloads section of the "Ordering Referring Report" page on the Medicare provider/supplier enrollment website, a file containing the NPIs and the names of physicians and non-physician practitioners who have current enrollment records in PECOS and are of a type/specialty that is eligible to order and refer. The file, called the Ordering Referring Report, lists, in alphabetical order based on last name, the NPI and the name (last name, first name) of the physician or non-physician practitioner. To keep the available information up to date, CMS will replace the Report twice a week. At any given time, only one Report (the most current) will be available for downloading. To learn more about the Report and to download it, go to <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html>; click on "Ordering & Referring Information" (on the left). Information about the Report will be displayed.

Phase 2: Effective January 6, 2014, CMS will turn on the Phase 2 edits. In Phase 2, if the ordering/referring provider does not pass the edits, the claim will be denied. This means that the billing provider will not be paid for the items or services that were furnished based on the order or referral.

Below are the denial edits for Part B providers and suppliers who submit claims to Part A/B MACs, including DME MACs:

254D or 001L	Referring/Ordering Provider Not Allowed To Refer/Order
255D or 002L	Referring/Ordering Provider Mismatch

CARC code 16 or 183 and/or the RARC code N264, N574, N575 and MA13 shall be used for denied or adjusted claims.

Claims submitted identifying an ordering/referring provider and the required matching NPI is missing (edit 289D) will continue to be rejected. CARC code 16 and/or the RARC code N265, N276 and MA13 shall be used for rejected claims due to the missing required matching NPI.

¹ NPIs were added only when the matching criteria verified the NPI.

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Below are the denial edits for Part A HHA providers who submit claims:

37236 This reason code will assign when:	<ul style="list-style-type: none"> • The statement "From" date on the claim is on or after the date the phase 2 edits are turned on • The type of bill is '32' or '33' • Covered charges or provider reimbursement is greater than zero but the attending physician NPI on the claim is not present in the eligible attending physician file from PECOS or the attending physician NPI on the claim is present in the eligible attending physician files from PECOS but the name does not match the NPI record in the eligible attending physician files from EPCOS or the specialty code is not a valid eligible code
37237 This reason code will assign when:	<ul style="list-style-type: none"> • The statement "From" date on the claim is on or after the date the phase 2 edits are turned on • The type of bill is '32' or '33' • The type of bill frequency code is '7' or 'F-P' • Covered charges or provider reimbursement is greater than zero but the attending physician NPI on the claim is not present in the eligible attending physician file from PECOS or the attending physician NPI on the claims is present in the eligible attending physician files from PECOS but the name does not match the NPI record in the eligible attending physician files from PECOS or the specialty code is not a valid eligible code

Effect of Edits on Providers

I order and refer. How will I know if I need to take any sort of action with respect to these two edits?

In order for the claim from the billing provider (the provider who furnished the item or service) to be paid by Medicare for furnishing the item or service that you ordered or referred, **you, the ordering/referring provider, need to ensure that:**

- a. You have a current Medicare enrollment record.
- If you are not sure you are enrolled in Medicare, you may:
 - i. Check the Ordering Referring Report and if you are on that report, you have a current enrollment record in Medicare and it contains your NPI;
 - ii. Contact your designated Medicare enrollment contractor and ask if you have an enrollment record in Medicare and it contains the NPI; or
 - iii. Use Internet-based PECOS to look for your Medicare enrollment record (if no record is displayed, you do not have an enrollment record in Medicare).

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- iv. If you choose iii, please read the information on the Medicare provider/supplier enrollment web page about Internet-based PECOS before you begin.
- b. **If you do not have an enrollment record in Medicare.**
- You need to submit either an electronic application through the use of internet-based PECOS or a paper enrollment application to Medicare.
 - i. **For paper applications** - fill it out, sign and date it, and mail it, along with any required supporting paper documentation, to your designated Medicare enrollment contractor.
 - ii. **For electronic applications** – complete the online submittal process and either e-sign or mail a printed, signed, and dated Certification Statement and digitally submit any required supporting paper documentation to your designated Medicare enrollment contractor.
 - iii. In either case, the designated enrollment contractor cannot begin working on your application until it has received the signed and dated Certification Statement.
 - iv. If you will be using Internet-based PECOS, please visit the Medicare provider/supplier enrollment web page to learn more about the web-based system before you attempt to use it. Go to <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html>, click on “Internet-based PECOS” on the left-hand side, and read the information that has been posted there. Download and read the documents in the Downloads Section on that page that relate to physicians and non-physician practitioners. A link to Internet-based PECOS is included on that web page.
 - v. If you order or refer items or services for Medicare beneficiaries and you do not have a Medicare enrollment record, you need to submit an enrollment application to Medicare. You can do this using Internet-based PECOS or by completing the paper enrollment application (CMS-855O). Enrollment applications are available via internet-based PECOS or .pdf for downloading from the CMS forms page (<http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/index.html>).
- c. **You are an opt-out physician and would like to order and refer services. What should you do?**
- If you are a physician who has opted out of Medicare, you may order items or services for Medicare beneficiaries by submitting an opt-out affidavit to a Medicare contractor within your specific jurisdiction. Your opt-out information must be current (an affidavit must be completed every 2 years, and the NPI is required on the affidavit).
- d. **You are of a type/specialty that can order or refer items or services for Medicare beneficiaries.** When you enrolled in Medicare, you indicated your Medicare specialty. **Any** physician specialty (Chiropractors are excluded) and **only** the non-physician practitioner specialties listed above in this article are eligible to order or refer in the Medicare program.
- e. **I bill Medicare for items and services that were ordered or referred. How can I be sure that my claims for these items and services will pass the Ordering/Referring Provider edits?**
- You need to ensure that the physicians and non-physician practitioners from whom you accept orders and referrals have current Medicare enrollment records and are of a type/specialty that is

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eligible to order or refer in the Medicare program. If you are not sure that the physician or non-physician practitioner who is ordering or referring items or services meets those criteria, it is recommended that you check the Ordering Referring Report described earlier in this article.

- Ensure you are correctly spelling the Ordering/Referring Provider's name.
- If you furnished items or services from an order or referral from someone on the Ordering Referring Report, your claim should pass the Ordering/Referring Provider edits.
- The Ordering Referring Report will be replaced twice a week to ensure it is current. It is possible that you may receive an order or a referral from a physician or non-physician practitioner who is not listed in the Ordering Referring Report but who may be listed on the next Report.

f. **Make sure your claims are properly completed.**

- On paper claims (CMS-1500), in item 17, only include the first and last name as it appears on the Ordering and Referring file found on CMS.gov.
- On paper claims (CMS-1450), you would capture the attending physician's last name, first name and NPI on that form in the applicable sections. On the most recent form it would be fields in FL 76.
- On paper claims (CMS-1500 and CMS-1450), do not enter "nicknames", credentials (e.g., "Dr.", "MD", "RPNA", etc.) or middle names (initials) in the Ordering/Referring name field, as their use could cause the claim to fail the edits.
- Ensure that the name and the NPI you enter for the Ordering/Referring Provider belong to a physician or non-physician practitioner and not to an organization, such as a group practice that employs the physician or non-physician practitioner who generated the order or referral.
- Make sure that the qualifier in the electronic claim (X12N 837P 4010A1) 2310A NM102 loop is a 1 (person). Organizations (qualifier 2) cannot order and refer.

If there are additional questions about the informational messages, Billing Providers should contact their local A/B MAC, or DME MAC.

Claims from billing providers and suppliers that are denied because they failed the ordering/referring edit shall not expose a Medicare beneficiary to liability. Therefore, **an Advance Beneficiary Notice is not appropriate in this situation.** This is consistent with the preamble to the final rule which implements the Affordable Care Act requirement that physicians and eligible professionals enroll in Medicare to order and certify certain Medicare covered items and services including home health, DMEPOS, imaging and clinical laboratory.

g. **What if my claim is denied inappropriately?**

If your claim did not initially pass the Ordering/Referring provider edits, you may file an appeal through the standard claims appeals process or work through your A/B MAC or DME MAC.

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h. How will the technical vs. professional components of imaging services be affected by the edits?

Consistent with the Affordable Care Act and 42 CFR 424.507, suppliers submitting claims for imaging services must identify the ordering or referring physician or practitioner. Imaging suppliers covered by this requirement include the following: IDTFs, mammography centers, portable x-ray facilities and radiation therapy centers. The rule applies to the technical component of imaging services, and the professional component will be excluded from the edits. However, if billing globally, both components will be impacted by the edits and the entire claim will deny if it doesn't meet the ordering and referring requirements. It is recommended that providers and suppliers bill the global claims separately to prevent a denial for the professional component.

i. Are the Phase 2 edits based on date of service or date of claim receipt?

The Phase 2 edits are effective for claims with dates of service on or after January 6, 2014.

j. A Medicare beneficiary was ordered a 13-month DME capped rental item. Medicare has paid claims for rental months 1 and 2. The equipment is in the 3rd rental month at the time the Phase 2 denial edits are implemented. The provider who ordered the item has been deactivated. How will the remaining claims be handled?

Claims for capped rental items will continue to be paid for up to 13 months from the physician's date of deactivation to allow coverage for the duration of the capped rental period.

Additional Guidance

- 1. Terminology:** Part B claims use the term "ordering/referring provider" to denote the person who ordered, referred, or certified an item or service reported in that claim. The final rule uses technically correct terms: 1) a provider "orders" non-physician items or services for the beneficiary, such as DMEPOS, clinical laboratory services, or imaging services and 2) a provider "certifies" home health services to a beneficiary. The terms "ordered" "referred" and "certified" are often used interchangeably within the health care industry. Since it would be cumbersome to be technically correct, CMS will continue to use the term "ordered/referred" in materials directed to a broad provider audience.
- 2. Orders or referrals by interns or residents:** The IFC mandated that all interns and residents who order and refer specify the name and NPI of a teaching physician (i.e., the name and NPI of the teaching physician would have been required on the claim for service(s)). The final rule states that State-licensed residents may enroll to order and/or refer and may be listed on claims. Claims for covered items and services from un-licensed interns and residents must still specify the name and NPI of the teaching physician. However, if States provide provisional licenses or otherwise permit residents to order and refer services, CMS will allow interns and residents to enroll to order and refer, consistent with State law.

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3. Orders or referrals by physicians and non-physician practitioners who are of a type/specialty that is eligible to order and refer who work for the Department of Veterans Affairs (DVA), the Public Health Service (PHS), or the Department of Defense (DoD)/Tricare: These physicians and non-physician practitioners will need to enroll in Medicare in order to continue to order or refer items or services for Medicare beneficiaries. They may do so by filling out the paper CMS-855O or they may use Internet-based PECOS. They will not be submitting claims to Medicare for services they furnish to Medicare beneficiaries.
4. Orders or referrals by dentists: Most dental services are not covered by Medicare; therefore, most dentists do not enroll in Medicare. Dentists are a specialty that is eligible to order and refer items or services for Medicare beneficiaries (e.g., to send specimens to a laboratory for testing). To do so, they must be enrolled in Medicare. They may enroll by filling out the paper CMS-855O or they may use Internet-based PECOS. They will not be submitting claims to Medicare for services they furnish to Medicare beneficiaries.

Additional Information

For more information about the Medicare enrollment process, visit

<http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html> or contact the designated Medicare contractor for your State. Medicare provider enrollment contact information for each State can be found at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/Contact_list.pdf on the CMS website.

The Medicare Learning Network® (MLN) fact sheet titled, "Medicare Enrollment Guidelines for Ordering/Referring Provider," is available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedEnroll_OrderReferProv_factSheet_ICN906223.pdf on the CMS website.

Note: You must obtain a National Provider Identifier (NPI) prior to enrolling in Medicare. Your NPI is a required field on your enrollment application. Applying for the NPI is a separate process from Medicare enrollment. To obtain an NPI, you may apply online at <https://nppes.cms.hhs.gov/NPPES/Welcome.do> on the CMS website. For more information about NPI enumeration, visit <http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/NationalProvIdentStand/index.html> on the CMS website.

Additional Article Updates

MLN Matters® Article MM7097, "Eligible Physicians and Non-Physician Practitioners Who Need to Enroll in the Medicare Program for the Sole Purpose of Ordering and Referring Items and Services for Medicare Beneficiaries," is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM7097.pdf> on the CMS website.

MLN Matters® Article MM6417, "Expansion of the Current Scope of Editing for Ordering/Referring Providers for Claims Processed by Medicare Carriers and Part B Medicare Administrative Contractors

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(MACs)," is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6417.pdf> on the CMS website.

MLN Matters® Article MM6421, "Expansion of the Current Scope of Editing for Ordering/Referring Providers for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Suppliers' Claims Processed by Durable Medical Equipment Medicare Administrative Contractors (DME MACs)," is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6421.pdf> on the CMS website;

MLN Matters® Article MM6129, "New Requirement for Ordering/Referring Information on Ambulatory Surgical Center (ASC) Claims for Diagnostic Services," is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM6129.pdf> on the CMS website.

MLN Matters Article MM6856, "Expansion of the Current Scope for Attending Physician Providers for free-standing and provider-based Home Health Agency (HHA) Claims processed by Medicare Regional Home Health Intermediaries (RHHIs), is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6856.pdf> on the CMS website.

MLN Matters Article SE1311, " Opting out of Medicare and/or Electing to Order and Refer Services" is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1311.pdf> informs ordering and referring providers about the information they must provide in a written affidavit to their Medicare contractor when they opt-out of Medicare.

If you have questions, please contact your Medicare Carrier, Part A/B MAC, or DME MAC, at their toll-free numbers, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Office of the Secretary**

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Office of the Chief Judge
1700 North Moore Street, Suite 1800
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(703) 235-0700 Facsimile

Memorandum to OMHA Medicare Appellants

Re: Administrative Law Judge Hearings for Medicare Claim and Entitlement Appeals

Based on a number of recent inquiries regarding delays in the processing of Medicare claim and entitlement appeals, I want to apprise you of some recent operational changes that may impact your interaction with the Office of Medicare Hearings and Appeals (OMHA). You have been chosen to receive this letter because you have a significant number of Medicare appeals currently pending before OMHA.

Due to the rapid and overwhelming increase in claim appeals, effective July 15, 2013, OMHA temporarily suspended the assignment of most new requests for an Administrative Law Judge hearing to allow OMHA to adjudicate appeals involving almost 357,000 claims for Medicare services and entitlements already assigned to its 65 Administrative Law Judges. This temporary measure was necessitated by a dramatic increase in the number of decisions being appealed to OMHA, the third level of administrative review in the Medicare claim and entitlement appeals process.

From 2010 to 2013, OMHA's claims and entitlement workload grew by 184% while the resources to adjudicate the appeals remained relatively constant, and more recently were reduced due to budgetary sequestration. Even with increased productivity from our dedicated Administrative Law Judges and their support staff, we have been unable to keep pace with the exponential growth in requests for hearing. Consequently, a substantial backlog in the number of cases pending an ALJ hearing, as well as cases pending assignment has resulted.

In just under two years, the OMHA backlog has grown from pending appeals involving 92,000 claims for services and entitlement to appeals involving over 460,000 claims for services and entitlement, and the receipt level of new appeals is continuing to rise. In January 2012, the number of weekly receipts in our Central Operations Division averaged around 1,250. This past month, the number of receipts was over 15,000 per week. Due to this rapidly increasing workload, OMHA's average wait time for a hearing before an Administrative Law Judge has risen to 16 months and is expected to continue to increase as the backlog grows.

Although assignment of most new requests for hearing will be temporarily suspended, OMHA will continue to assign and process requests filed directly by Medicare beneficiaries, to ensure their health and safety is protected. Assignment of all other new requests for hearing will resume as Administrative Law Judges are able to accommodate additional workload on their dockets. However, with the current backlog we do not expect general assignments to resume for at least 24 months and we expect post-assignment hearing wait times will continue to exceed 6 months.

We remain committed to providing a forum for the fair and timely adjudication of Medicare claim and entitlement appeals; however, we are facing significant challenges which reduce our ability to meet the timeliness component of our mission. To address this challenge, OMHA is working closely with our colleagues within the Centers for Medicare and Medicaid Services (CMS) and the Departmental Appeals Board (DAB). We are committed to finding new ways to work smartly and more efficiently, in order to better utilize resources to address the increased demand for hearings.

In order to keep you apprised concerning our workload and to facilitate your interaction with OMHA, we will host an OMHA Medicare Appellant Forum on February 12, 2013, from 10:00 am to 5:00 pm. The event will take place in the Wilbur J. Cohen building located at 330 Independence Ave. SW, Washington DC 20024. The purpose of this event is to provide further information to OMHA appellants and providers on a number of initiatives underway and to provide information on measures we can take to make the appeals process work more efficiently. You can obtain further information and register for the event by visiting the OMHA website; <http://www.hhs.gov/omha/index.html>. We are pleased to offer this opportunity and hope you will be able to join us.

Although we know that this information will not alleviate your concerns with regard to delays in processing appeals, we hope that we have at least provided a backdrop for the environment in which OMHA currently processes appeals. We ask for your indulgence as we work to address these challenges and thank you in advance for your patience as we continue our efforts to serve the Medicare appellant and beneficiary communities. For additional information and updates on OMHA's adjudication timeframes, or to register for our OMHA Medicare Appellant Forum, please visit the OMHA website at: <http://www.hhs.gov/omha/index.html>.

Sincerely,



Nancy J. Griswold
Chief Administrative Law Judge

Hospital - DMEPOS supplier arrangements and the Anti-kickback Statute

By Richard Rifenbark, Esq. and Nathaniel Lacktman, Esq., CCEP

Editor's note: Richard (Rick) Rifenbark and Nathaniel (Nate) Lacktman are Senior Counsel with Foley & Lardner LLP and members of Health Care Industry Team. They both advise DMEPOS suppliers, hospitals, and other health care clients on a range of business and regulatory issues, including health care compliance and contractual arrangements. Rick is located in the Los Angeles office and may be contacted by telephone at 213/972-4813 and by e-mail at rrifernbark@foley.com. Nate is located in the Tampa office and may be contacted by telephone at 813/225-4127 and by e-mail at nlacktman@foley.com.

This article is the fifth in a series on DMEPOS compliance issues by Foley & Lardner LLP published in Compliance Today. In the September 2011 issue of Compliance Today, the authors discussed the HIPAA implications for DMEPOS supplier marketing arrangements and provided a sample marketing authorization form as a supplier tool. This month, the authors discuss hospital-DMEPOS supplier arrangements under the Anti-kickback Statute.

Subsequent articles will discuss strategies for DMEPOS promotions and arrangements with manufacturers and DMEPOS reimbursement compliance.

Most owners and operators by now recognize that durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers are a frequent target of government enforcement actions. One segment of the DMEPOS industry—the provision of DMEPOS items to hospital patients—has also received the attention of federal regulators. Indeed, the US Department of Health and Human Services (DHHS) Office of Inspector General (OIG) considers arrangements under which DMEPOS suppliers have opportunities to access hospital patients as susceptible to problematic marketing schemes.¹ Given the increasing level of government interest in DMEPOS compliance, DMEPOS suppliers and hospitals should take care to structure their arrangements in a manner to comply with these fraud and abuse laws.

DMEPOS suppliers use a variety of structures to collaborate with hospitals to deliver items to hospital patients. This article provides an overview of three models used by DMEPOS suppliers and hospitals, along with the compliance concerns for the parties attendant to those arrangements.

The models are:

- DMEPOS suppliers operating as hospital affiliates;
- Independent DMEPOS suppliers that provide items to hospitals for inpatient use; and
- Independent DMEPOS suppliers that provide items to patients through convenience or consignment closets at hospitals.

By understanding how to implement these models in accordance with existing laws, DMEPOS suppliers and hospitals can explore new opportunities to deliver quality care to patients.

Overview of applicable laws

The primary federal fraud and abuse laws implicated by these arrangements include the Anti-kickback Statute (AKS) and the Civil Monetary Penalties Law (CMPL). Of course, DMEPOS suppliers and hospitals must comply with other applicable federal and state health care laws and regulations as well.

The AKS prohibits any person from knowingly and willfully

paying, offering, soliciting, or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce the referral of any item or service covered by a federal health care program, or in exchange for arranging for or recommending purchasing, leasing, or ordering any good, facility, service or item covered by a federal health care program, including Medicare and Medicaid.² A violation is punishable by a \$25,000 fine or imprisonment, may subject a violator to civil monetary penalties, and is grounds for exclusion from participation in the Medicare and Medicaid programs. There are various statutory and regulatory exceptions and safe harbors to the AKS available to protect certain arrangements. Violations of the AKS may also trigger a violation of the False Claims Act, which can result in substantial monetary penalties.³

The CMPL prohibits any person from offering or giving remuneration to any individual eligible for benefits under Medicare or Medicaid whom that person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under Medicare or Medicaid.⁴ Violation of the CMPL is

punishable by a \$10,000 penalty per item or service, treble damages, and potential exclusion from Medicare. Similar to the AKS, there are several exceptions to the CMPL that, if met, can protect the arrangement.

DMEPOS suppliers as hospital affiliates

One arrangement DMEPOS suppliers and hospitals use is for a hospital to create its own DMEPOS company as a subsidiary or affiliate. This is often achieved by creating a separate corporate entity whose stock is owned by the hospital or the hospital's parent company, or by creating a limited liability company in which the hospital is a sole member, or by creating a non-profit affiliate of which the hospital is the sole corporate member. In some cases, a hospital may joint venture with a third party, such as an existing DMEPOS company, to create the affiliated entity. Under that structure, the subsidiary DMEPOS supplier hires its own employees to operate the DMEPOS business or leases the employees (as well as certain administrative services) from the hospital. The subsidiary entity then enrolls in Medicare Part B and obtains its own National Provider Identifier (NPI) number. Although some states exempt hospitals from DMEPOS licensing requirements, many do not exempt

DMEPOS suppliers from licensure, even if the supplier is a division, subsidiary, or affiliate of the licensed hospital.

Compliance concerns and potential safeguards

The advantage to hospitals of the DMEPOS subsidiary structure is that it allows the hospital to direct its charity care policy and provides an increased amount of control over the DMEPOS supplier's operations and an opportunity to participate in the revenue. Given the alignment of the hospital's and supplier's financial incentives, the parties must be sure to structure the arrangement in a manner that complies with state and federal fraud and abuse laws. Although the AKS does not apply to divisions within a company, OIG has in the past contended that the statute does apply to affiliates that are separate corporate entities.⁵ Many health care law practitioners would conclude that a wholly-owned subsidiary is at low risk for an AKS violation in this scenario. However, hospitals can look to certain safeguards commonly employed by hospital discharge planners when referring patients to DMEPOS suppliers.

Overall, the hospital should not engage in conduct—whether through the discharge planning process or otherwise—that could be viewed as improperly

Continued on page 48

steering patients to the affiliated DMEPOS supplier in return for unpermitted financial gain. For example, hospitals could consider providing patients with a list of alternate DMEPOS suppliers available to provide the necessary items for patients, and not to require that the hospital's patients only use the hospital-affiliated DMEPOS supplier. Safeguards such as these were viewed favorably by OIG in Advisory Opinion No. 02-04, which involved a consignment closet arrangement between a DMEPOS supplier and a hospital.⁶ As additional safeguards, the hospital might consider disclosing to patients its ownership of the DMEPOS supplier and avoiding any improper contact between the DMEPOS supplier's personnel and the hospital's patients before the patients select the DMEPOS supplier.

Hospitals that joint venture with third parties to create a DMEPOS affiliate should attempt to structure the joint venture to comply with the AKS safe harbor for small entity investments. To qualify for the small entity investment safe harbor, no more than 40% of the value the investment interests may be held by an investor that is a referral source, nor may more than 40% of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period come from

referrals or business otherwise generated from investors.⁷ In other words, if a hospital (which is a potential referral source to the DMEPOS supplier) owns 40% or more of the joint venture, or if 40% or more of the revenues of the DMEPOS supplier are attributable to referrals from the hospital owner, the DMEPOS supplier joint venture will not qualify for safe harbor treatment. Because many of the referrals to a hospital-affiliated DMEPOS supplier will typically come from the hospital, and the hospital will likely want to own at least 40% of the joint venture, many DMEPOS joint ventures cannot be structured to meet every element of the small entity safe harbor.

Those joint ventures that do not fit within a safe harbor should take care to comply with the OIG's published guidance regarding joint ventures, such as its 1989 Special Fraud Alert on Joint Venture Arrangements.⁸ Among other things, the OIG guidance emphasizes that the parties' ownership interests in the joint venture should reflect their capital contributions, and that investors should not be targeted or rewarded based on referrals. In the context of a DMEPOS supplier joint venture, the non-hospital joint venture may not allow the hospital to own a higher percentage of the joint venture

simply because the hospital may be in a position to generate business for the DMEPOS supplier through its existing patient base. OIG also cautions against certain "shell" joint ventures in which one joint venture partner owns the majority of the DMEPOS items and capital equipment and provides all of the day-to-day management of the DMEPOS supplier, and teams with the other entity as a joint venture partner simply because of the other entity's referral base.⁹

DMEPOS suppliers that provide items to hospital patients

Many independent DMEPOS suppliers have arrangements with hospitals where the supplier provides DMEPOS items to the hospital's patients. In this scenario, there is no ownership of the DMEPOS supplier by the hospital, but rather a contractual relationship between the parties under which the DMEPOS supplier provides items to the hospital for inpatient use. The hospital directly pays the DMEPOS supplier and then the hospital bills for the item. In this respect, the DMEPOS supplier is acting more like a vendor of items for the hospital's use; the DMEPOS supplier does not bill Medicare for the items.

The contract between the parties typically includes, among other provisions:

- Representations and warranties regarding the DMEPOS supplier's compliance with Medicare Supplier Standards and all other relevant federal and state laws;
- A requirement that the DMEPOS supplier not bill the patient, Medicare, Medicaid, and/or any other third party payor for the items; and
- A description of the items covered by the agreement.

Compliance concerns and potential safeguards

Under this arrangement, the primary concern would be compliance with the AKS's regulatory discount safe harbor or the statutory discount exception, if the items are sold to the hospital with any sort of discount. Not only does the Centers for Medicare and Medicaid Services (CMS) require the hospital to accurately report all such discounts, compliance with the discount safe harbor is important, because a sale of DMEPOS items at below market value, by itself, could be considered an inducement to buy the items or could also be considered an inducement for the hospital to direct its discharge planners to refer patients to that particular DMEPOS supplier.

In order for the regulatory discount safe harbor to apply to a buyer who submits cost reports,

the following requirements must be met:

- The buyer is an entity which reports its costs on a cost report required by the DHHS or a state Medicaid program;
- The discount must be earned based on purchases of that same good or service bought within a single fiscal year of the buyer;
- The buyer must claim the benefit of the discount in the fiscal year in which the discount is earned or the following year;
- The buyer must fully and accurately report the discount in the applicable cost report;
- The buyer must provide, upon request by the Secretary of the DHHS or a state agency, a copy of the discount disclosure information the seller is required to provide the buyer; and
- The seller must fully and accurately report such discount on the invoice, coupon, or statement submitted to the buyer; inform the buyer of its obligations to report such discount and to provide information upon request; and refrain from doing anything that would impede the buyer from meeting its obligations.¹⁰

Not all contractual arrangements with discounts qualify for the regulatory discount safe harbor. However, such arrangements may meet the statutory discount exception to the AKS.¹¹ The statutory discount exception protects "a

discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program."

Generally, it is easier to meet the statutory discount exception than the regulatory discount safe harbor. The statutory discount exception does not require all the specific procedures and provisions in the discount safe harbor. Unlike the discount safe harbor, the statutory exemption simply requires that the discount be "properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program." The statutory discount exception reflects Congress' intent to encourage price competition that benefits the federal health care programs.

In addition, the DMEPOS supplier should be careful not to provide any items of value to the hospital's patients or the hospital employees that may influence the selection of a DMEPOS supplier. The CMPL imposes a \$10,000 fine per item or service (plus treble damages and potential exclusion from Medicare) for

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payments made in violation of the law's patient inducement prohibition. Thus, gifts and other items of value provided by the DMEPOS supplier to patients or referral sources are problematic under the CMPL, if they are likely to influence the selection of a DMEPOS supplier. Note, there is an exception to this prohibition for non-cash items of nominal value, which has been interpreted as \$10 per item per patient, and no more than \$50 in the aggregate annually per patient.¹²

DMEPOS supplier convenience and consignment closet arrangements

A third model used by DMEPOS suppliers and hospitals is to store items on-site at hospitals for use by the hospital's patients. This model is used at physician offices as well.¹³ These arrangements are referred to as convenience or consignment closets. Under this model, the hospital and its patients enjoy the benefit of immediate access to the items. Under the convenience closet model, the DMEPOS supplier retains title to the items and is the entity that bills the patients or payors for the items. Under the consignment closet model, the hospital bills the patients or payors for the items and then makes payment to the DMEPOS supplier. Under both models, the parties typically enter into a written agreement under which

the hospital agrees to provide space for the DMEPOS supplier's items, and the DMEPOS supplier agrees to sell to those patients who request the items. Under some arrangements, the DMEPOS supplier pays rent to the hospital for the use of the closet space.

Compliance concerns and potential safeguards

A primary concern with convenience or consignment closet arrangements is compliance with the AKS. Although OIG has issued Advisory Opinions in which it approved certain consignment closet arrangements, it has also identified a number of risk areas that should be addressed when structuring consignment closet arrangements.¹⁴ Key to the analysis of convenience or consignment closets is understanding the flow of the remuneration between the parties. Specifically, remuneration from a hospital to a DMEPOS supplier (e.g., use of hospital desks and telephones by the DMEPOS supplier) is likely not problematic, because the remuneration and referrals flow in the same direction (i.e., there is no remuneration from the DMEPOS supplier to the hospital in exchange for hospital referrals).¹⁵ In contrast, OIG views with greater suspicion payments made by a DMEPOS supplier to a hospital in connection with a consignment closet arrangement, noting that "[i]n general, payments for rent for of

consignment closets in physicians' offices are suspect."¹⁶

To the extent a convenience or consignment closet arrangement does involve rental payments by the DMEPOS supplier to the hospital, the arrangement should be at fair market value and structured to comply with the space lease safe harbor and the OIG guidance in the February 2000 Special Fraud Alert. Of course, payment of fair market value rent, under a written lease for a term of one year or more is a requirement for meeting the space lease safe harbor. Ironically, then, attempting to meet the safe harbor appears to place these arrangements under greater OIG scrutiny, because remuneration (in the form of fair market value rent, but remuneration nonetheless) is flowing from the DMEPOS supplier to the hospital landlord.

CMS has also addressed convenience and consignment closet arrangements and flirted with guidance that would have limited many common features of consignment closets (at least those used in physician offices). In August 2009, CMS issued a change request to the Medicare Program Integrity Manual that would have permitted such closets only where the following requirements are met:

- Title to the item transfers to the physician at the time the item is furnished to the beneficiary;

- The item is billed by the physician using his or her own DMEPOS billing number;
- Fitting or other services related to the item are performed by individuals associated with the physician and not by the DMEPOS supplier; and
- Beneficiaries are instructed to contact the physician and not the DMEPOS supplier for problems or questions regarding the item.¹⁷

Yet, soon after issuing the provision, CMS rescinded it.

DMEPOS suppliers should keep in mind that consignment closets are potentially an area of CMS concern. CMS has not issued any recent guidance prohibiting consignment closet arrangements and, during the January 19, 2010 Open Door Forum, stated that the updated DMEPOS Supplier Standards do not address consignment closet arrangements. Parties that enter into consignment closet arrangements should consider inserting jeopardy clauses into their agreements in case the laws affecting consignment closets (or the government's interpretation of those laws) change.

Conclusion

DMEPOS suppliers must ensure their arrangements with hospitals, whether contractual or joint venture, comply with applicable health care fraud and abuse laws,

including the AKS and CMPL. Maintaining compliant contractual relationships will help ensure that the needs of hospital patients can be met without presenting legal risk to the hospital or the DMEPOS supplier. ■

The authors wish to thank their colleagues at Foley & Lardner LLP who reviewed and commented on this article, including Lawrence Vernaglia and Lawrence Conn. All errors or omissions in this article are the authors' alone.

1. OIG Adv. Op. 08-20 (Nov. 19, 2008).
2. 42 U.S.C. § 1320a-7b(b).
3. 42 U.S.C. § 1320a-7b(g).
4. 42 U.S.C. § 1320a-7a(5).
5. 56 Fed. Reg. 35952 (Jul. 29, 1991).
6. See OIG Adv. Op. 02-04 (Apr. 19, 2002).
7. 42 C.F.R. § 1001.952(a)(2)(vi).
8. Reprinted at 59 Fed. Reg. 65372 (Dec. 19, 1994).
9. Contractual Joint Ventures, OIG Special Advisory Bulletin (Apr. 2003).
10. 42 C.F.R. § 1001.952(h).
11. 42 U.S.C. § 1320a-7b(b)(3)(A); Section 1128B(b)(3)(A) of the Social Security Act.
12. 65 Fed. Reg. 24400, 24411 (Apr. 26, 2000); Offering Gifts and Other Inducements to Beneficiaries, OIG Special Advisory Bulletin (Aug. 2002).
13. Note, the legal and compliance issues affecting such arrangements in physician offices differ from hospitals and this article does not analyze convenience and consignment closet arrangements in physician office settings.
14. See OIG Adv. Op. 06-02 (Mar. 21, 2006); OIG Adv. Op. 08-20 (Nov. 19, 2008). Although OIG Advisory Opinions are useful guidance for the health care industry, they are only binding authority for the parties who submitted the Advisory Opinion request. Other parties are not entitled to rely on the Advisory Opinions.
15. See OIG Adv. Op. 08-20, *supra*.
16. Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer, OIG Special Fraud Alert (Feb. 2000).
17. CMS, Medicare Program Integrity Manual, Transmittal 297 (Aug. 7, 2009) and Transmittal 300 (Sept. 1, 2009).

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by Natarsha Nesbitt, Esq. and Nathaniel Lacktman, Esq., CCEP

DMEPOS reimbursement appeals and the compliance officer

- » DMEPOS suppliers have five levels of Medicare claims appeals.
- » DME MACs sometimes differ when interpreting the same Medicare rule.
- » Suppliers should consider involving the Compliance department in claims appeals.
- » Suppliers can draw on the Compliance department for reimbursement advice.
- » Cooperation between Compliance and Reimbursement personnel can be a win-win.

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This article is the sixth in a series on DMEPOS compliance issues published in *Compliance Today*.

Among the many compliance concerns facing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, perhaps one of the most important is Medicare reimbursement and claims denials. After all, a well-developed referral network and satisfied patient base is of little value if the claims generated by those patients' orders do not get paid. With that in mind, DMEPOS suppliers should understand the levels of appeal available to challenge Medicare claim denials. Although the Medicare tiered appeals structure may at first seem intimidating, many DMEPOS suppliers are able to handle the first two levels of appeal in-house, drawing on outside legal counsel for those challenges that proceed to the third level of appeal and beyond.

Of particular benefit is when DMEPOS suppliers involve their compliance officer in the reimbursement appeals process. This

involvement need not be extensive or significantly time-consuming. Simply by communicating with the Compliance department, suppliers can enjoy the resources of a subject matter expert on the pending appeals, while simultaneously keeping the Compliance department abreast of key claims denial areas. The compliance officer can use that information when conducting targeted audits and developing the supplier's annual compliance plan.

Hot reimbursement issues

In the current enforcement environment, DMEPOS suppliers face a seemingly endless barrage of reimbursement challenges on state and federal levels. A significant hot issue regarding Medicare reimbursement denials is how to meet the medical documentation requirements for claim submissions. One approach suppliers can use to help decrease their denial rate is to employ staff with clinical backgrounds who can reinforce on appeal the reasons why a claim should be paid by Medicare, if the claim is denied. Another approach suppliers can consider to improve documentation of medical



Nesbitt



Lacktman

necessity is to educate their referral sources on the Medicare documentation requirements so the referral sources can better document medical necessity in the patient records, thereby improving the supplier's chance of a clean claim submission and prompt reimbursement.

Another hot button challenge currently faced by DMEPOS suppliers is the inconsistent interpretation and application of Medicare regulations across the four Durable Medical Equipment Medicare Administrative Contractors (DME MACs). Each DME MAC has an ability to issue its own rules or Local Coverage Determinations, but the DME MACs must also follow the CMS-issued rules applicable to all DMEPOS suppliers nationwide. However, there are times when the four DME MACs differently interpret the same CMS-issued rules, which results in inconsistency across the four jurisdictions. This challenge is more significant for suppliers operating nationwide and who must interact with multiple DME MACs.

An example of this challenge arises in medical necessity documentation and proof of delivery documentation. Some DME MACs adopt a narrow interpretation of the requirements, while others have slightly differing positions. For example, some DME MACs accept a download from mail carriers such as the United States Postal Service, whereas other DME MACs do not. As a result of regional inconsistencies, DMEPOS suppliers must create separate and unique processes to satisfy the requirements for each of the four DME MACs. A supplier's compliance officer can play an integral part to help the supplier's reimbursement personnel understand and coordinate among the varying interpretations across the DME MACs.

DMEPOS claims appeals process

Medicare uses a tiered appeals process, affording DMEPOS suppliers five levels of appeal

to challenge denied claims. Each level has its own unique characteristics and requirements. Overall, once a DME MAC makes an initial determination to deny a claim, a supplier has the right to an appeal. All appeals must be made in writing. For most levels, the supplier can itself file the appeal, but many choose to retain legal counsel around the third or fourth level. Below is a brief description of the five levels of appeal.

First level — Redetermination

The first level of appeal is conducted by the DME MAC itself (but by a person other than the one who made the initial determination to deny the claim). A supplier must file the redetermination request within 120 days from the date of receipt of the initial determination. Suppliers can use form CMS-20027 to request the redetermination in writing, and should attach all supporting documentation to that request. The DME MAC will issue its decision within 30 days of receiving the supplier's reconsideration request.

Second level — Reconsideration

The second level of appeal is conducted by the qualified independent contractor (QIC). The QIC for DMEPOS suppliers is RiverTrust Solutions. A supplier that wants to appeal an unfavorable redetermination must file the reconsideration request within 180 days from the date of receipt of the unfavorable Medicare redetermination notice. Suppliers can use form CMS-20033 to request the reconsideration in writing and should attach all supporting documentation to that request, including the unfavorable Medicare redetermination notice. It is particularly important to include all supporting documentation at the reconsideration level because, without good cause, a supplier will not be able to provide any additional documents for review at subsequent levels of appeal. (This rule does not apply to witness oral testimony

given at the third level of appeal.) Generally, the QIC will issue its decision within 60 days of receiving the supplier's reconsideration request. If the QIC cannot complete the decision in that timeframe, the supplier may escalate the appeal to the third level.

Third level — Administrative law judge

The third level of appeal is a hearing before an administrative law judge (ALJ) in the Office of Medicare Hearings

and Appeals. If at least \$130 remains in controversy, a supplier may seek an ALJ hearing by filing a written appeal using form CMS-20034A/B (and may also file supplemental legal briefs). A sup-

plier that wants to appeal an unfavorable reconsideration decision must file the request for an ALJ hearing within 60 days from the date of receipt of the unfavorable reconsideration decision. A sup-

plier can request an in-person hearing, but hearings typically occur by videoconference or telephone. Suppliers can also forgo a hearing and instead ask the ALJ to issue a decision on the written record. Generally, the ALJ will issue its decision within 90 days of receiving the supplier's hearing request, but this deadline is often extended. If the ALJ does not issue a decision in that timeframe, the supplier may escalate the appeal to the fourth level.

Fourth level — Medicare Appeals Council

The fourth level of appeal is a review by the Medicare Appeals Council (MAC). There are no requirements regarding the amount in controversy. A supplier may seek MAC review by filing a written appeal using form DAB-101

and may also file supplemental legal briefs. A supplier that wants MAC review of an unfavorable ALJ decision must file the request within 60 days from the date of receipt of the unfavorable ALJ decision. Generally, the MAC will issue its decision within 90 days of receiving the supplier's request, but this deadline may be extended. If the MAC does not issue a decision in that timeframe, the supplier may escalate the appeal to the fifth level.

The knowledge, experience, and ability of compliance officers to understand and interpret Medicare regulations allows them not only to highlight the hot Medicare reimbursement issues, but also to recommend solutions.

Fifth level — Judicial review in federal district court

The fifth and final level of appeal is judicial review by a federal district court judge. If at least \$1,350 remains in contro-

versy (for calendar year 2012), a supplier may seek judicial review by filing a written request in federal district court. The amount-in-controversy requirement increases each year. A supplier that wants judicial review of an unfavorable MAC decision must file the request within 60 days from the date of receipt of the unfavorable MAC decision.

Benefits of compliance officer involvement

Not all compliance officers of DMEPOS suppliers are involved with the claims appeal process, but those suppliers that do involve their compliance officers can realize some additional benefits. For example, by making the compliance officer aware of the types of claims being denied (and the reasons therefor), the compliance officer can integrate those denials into the supplier's annual compliance plan and compliance audits. In addition, the compliance officer can serve as a resource to

the reimbursement team on specific subject matter expertise. This is particularly useful to address rule inconsistencies across the four regional DME MACs.

The knowledge, experience, and ability of compliance officers to understand and interpret Medicare regulations allows them not only to highlight the hot Medicare reimbursement issues, but also to recommend solutions. In this manner, the compliance officer can serve as a bridge of communication between the organization, Medicare, and the DME MACs.

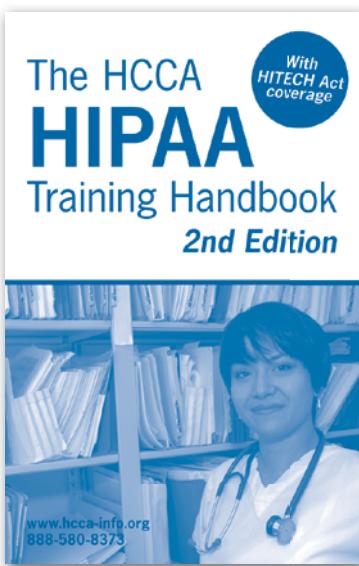
It is important that suppliers keep their compliance officers involved in the appeals process because compliance officers can track and trend claim denials and assist in efforts to demonstrate the frequency of the varying interpretations of Medicare regulations across the four DME MACs. By doing so, the compliance officer can align the supplier's

focus with that of Medicare, allowing the organization to react proactively to any issues that may arise.

Conclusion

For some DMEPOS suppliers, the Medicare appeals process may seem to be an impenetrable, confusing morass. For other suppliers, the appeals process may appear routine, mundane, and simply a cost of doing business. Whatever a supplier's comfort level with the appeals process itself, suppliers who involve their Compliance department in the appeals process (at least to a degree), may reap some useful rewards in enhanced communication, reduced claim denial rates, and improved appeal success rates. Ultimately, this cooperation between the supplier's Compliance and Reimbursement departments can be a win-win for everyone at the organization. ☐

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by Nathaniel Lacktman, Esq., CCEP; Lawrence W. Vernaglia, Esq.; and Judith A. Waltz, Esq.

Proposed overpayment regulations issued for 60-day refund rule

- » Overpayments must be returned within 60 days of when identified.
- » “Identified” means actual knowledge or reckless disregard of the overpayment.
- » Providers may conduct a “reasonable inquiry” before the clock starts.
- » CMS proposes a 10-year look back period for overpayment reviews.
- » Organizations must create a viable, flexible policy for overpayments.

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On February 13, 2012, CMS issued a set of proposed regulations under the 60-day refund rule (the proposed rule). CMS's proposed rule is responsive to industry concerns, but also opens up a significant amount of new liability. The 60-day refund rule, enacted under the Patient Protection and Affordable Care Act (PPACA) and codified at 42 U.S.C. section 1320a-7k(d), requires Medicare or Medicaid participating providers, suppliers, and plans to report and refund known overpayments by the later of 60 days from the date the overpayment is identified or the date the corresponding cost report is due.

The 60-day refund rule created significant burdens for providers, suppliers, and affected health plans attempting to meet this short window. Regulatory guidance is lacking for a number of definitions, including when an overpayment is actually “identified” and when the 60-day clock starts to run. The proposed

rule attempts to answer some of these important questions. An analysis of the proposed rule offers providers and suppliers some interpretive guidance and a preview of what they can expect when the final regulations are issued.



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Background

Prior to the enactment of the 60-day refund rule, there was a long history of disagreement between the health care bar, regulators, prosecutors, and the industry regarding whether or not there was a duty to affirmatively disclose overpayments. Some providers argued there was no duty to refund innocent overpayments, but the government disagreed and made efforts to pursue *qui tam* cases and settlements on the reverse false claim theory (i.e., where an obligation to pay or transmit money to the government is fraudulently evaded).

Much of this debate was settled with the enactment of Section 1320a-7k(d) on March 23, 2010. Specific to overpayments, PPACA included the following three interrelated provisions:

- ▶ Providers have an obligation under the False Claims Act (FCA), including an express duty to refund and report Medicare and Medicaid overpayments by the later of 60 days after the overpayment is identified or the date the corresponding cost report is due. Failure to report and return the overpayment is an obligation for purposes of the FCA.
- ▶ Enhancements to the Civil Monetary Penalties (CMP) Law now provide CMPs for failing to report and return known overpayments within 60 days or when the cost report is due.
- ▶ Expanded exclusion authority under the Medicaid program for failure to report and return known overpayments.

Section 1320a-7k(d) itself states, in pertinent part, as follows:

(d) REPORTING AND RETURNING OF OVERPAYMENTS.—

- (1) IN GENERAL. — If a person has received an overpayment, the person shall —
 - (A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
 - (B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
- (2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS. — An overpayment must be reported and returned under paragraph (1) by the later of —
 - (A) the date which is 60 days after the date on which the overpayment was identified; or
 - (B) the date any corresponding cost report is due, if applicable.

(3) ENFORCEMENT.—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.

(4) DEFINITIONS. — In this subsection:

(A) KNOWING AND KNOWINGLY. — The terms ‘knowing’ and ‘knowingly’ have the meaning given those terms in section 3729(b) of title 31, United States Code.

(B) OVERPAYMENT. — The term “overpayment” means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.

(C) PERSON. —

(i) IN GENERAL. — The term ‘person’ means a provider of services, supplier, Medicaid managed care organization (as defined in section 1903(m)(1)(A)), Medicare Advantage organization (as defined in section 1859(a)(1)), or PDP sponsor (as defined in section 1860D-41(a)(13)).

(ii) EXCLUSION. — Such term does not include a beneficiary.

As can be seen from the statutory language, a number of important definitions are omitted and the statute leaves open the critical question of when the 60-day period commences. Prior to the issuance of the proposed rule, organizations were required to interpret and apply the statute as best they could within their existing compliance structure. This is because the 60-day refund rule is currently in effect and a provider that fails to meet the reporting deadline faces damages and penalties under the FCA, CMPs, and potential

exclusion from participation in federal health care programs.

Highlights of the CMS proposed rule

CMS's proposed rule explains when an overpayment is "identified" and how overpayments are to be reported and refunded. CMS's position on those two issues is largely consistent with the statutory language of Section 1320a-7k(d). CMS interpreted the statutory language in two important material ways:

- ▶ a "reasonable inquiry" principle offering a reasonable and measured approach to determining when the 60-day clock starts running; and
- ▶ a proposed 10-year look back period for retrospective overpayment reviews that significantly expands the potential liability of providers when refunding overpayments.

The proposed rule only applies to traditional Medicare Parts A and B, even though Section 1320a-7k(d) also includes Medicaid, managed care organizations, Medicare Advantage and Part D programs. The statutory 60-day refund rule with respect to those programs remains in effect, even without regulatory guidance, although health plans and Medicaid providers likely will look to the proposed rule and any final regulations for guidance as to how to apply the statutory requirements.

When is an overpayment identified?

Under the proposed rule, an overpayment is "identified" when a person has actual knowledge of the existence of an overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. CMS acknowledged that the 60-day clock does not start running (i.e., an overpayment is not "identified") until after the provider has an opportunity to undertake a "reasonable inquiry" into the basis of the alleged overpayment.

Reasonable inquiry

CMS did not detail what constitutes a "reasonable inquiry," but clearly CMS will allow some flexibility in light of the different levels of review needed to address the wide variety of potential overpayments—ranging from simple claims issues to complex regulatory analyses. CMS did not propose the 60-day clock start running on the first mere allegation or suspicion of an overpayment. CMS appeared to recognize that many sophisticated reimbursement questions require significant use of internal and external resources, due diligence, and document review. These important steps often cannot be completed within 60 days of the initial allegation of the overpayment.

Although the reasonable inquiry rule affords greater flexibility regarding the timing of refunds, CMS balanced it against the concept that providers or suppliers have a duty to promptly conduct this reasonable inquiry upon receipt of information of a potential overpayment. If a provider fails to make any reasonable inquiry, it may be found to have acted in reckless disregard or deliberate ignorance of the overpayment. In many respects, this is consistent with the practices of providers with effective compliance plans even prior to the implementation of PPACA.

According to CMS, defining "identification" in this way gives providers and suppliers an incentive to exercise due diligence to determine whether an overpayment exists. Without such a principle, CMS believes some providers and suppliers might avoid performing activities to determine whether an overpayment exists, such as self-audits, compliance checks, and other additional research.

CMS also stated that when a government agency informs a provider or supplier of a potential overpayment, the provider or supplier has an obligation to accept the finding or make a reasonable inquiry. At this point, the legal authority for such an obligation seems

unclear at best, as does what sort of government agency notice may trigger this obligation (e.g., remittance advice, general provider alert, RAC audits, informal letter to specific provider, preliminary audit report, or formal letter).

10-year look back period

The most dramatic change proposed by CMS is an expansion of the look back period for overpayments to 10 years. CMS chose this period to parallel the outside statute of limitations under the False Claims Act, but current Medicare reopening regulations permit look back periods of only 3 or 4 years for most situations (i.e., when there is no fraud, provider integrity issue, or similar fault). The proposed requirement to report and refund overpayments received during the prior 10 years represents a significant change to current overpayment and refund practices. Should the proposed rule go into effect as drafted, this change would result in materially increased liability for providers and suppliers.

Many providers and suppliers will find a 10-year look back period not viable, if only because that period extends beyond the current record retention rules and requirements under Medicare Conditions of Participation, Supplier Standards, and state laws on medical record retention (typically ranging from 5 to 7 years). The 10-year period represents a dramatic expansion of CMS's authority and reach into retrospective claims reviews.

Self-reporting process

Under the proposed rule, the existing voluntary refund process in Chapter 4 of the Medicare Financial Management Manual will be renamed the "self-reported overpayment refund process." This is the process providers and suppliers will use to effectuate refunds. Self-reporting should be made in accordance with the protocols of the local fiscal intermediary, carrier, or contractor. CMS contemplates a standardized form to be used for repayments, but has not yet created one.

If an overpayment is claims-related, and would not be impacted by reconciliation of the cost report, the refund should not be delayed (according to CMS) until reconciliation of a cost report. For example, issues involving upcoding must be reported and returned within 60 days of identification, because the upcoded claims for payment are not submitted to Medicare as "costs" in the form of cost reports.

On a related note, CMS explained that the CMS Stark Self-Referral Disclosure Protocol (SRDP) tolls the obligation to refund the overpayment, but does not toll the obligation to report it. The OIG Self-Disclosure Protocol (SDP) also tolls the refund obligation, and a timely report to OIG under the SDP satisfies the reporting requirements under the 60-day refund rule.

Drafting a policy and procedure on overpayments

Many organizations have already created policies and procedures on self-reporting of known overpayments. With the issuance of the proposed rule (and the eventual enactment of a final rule), those organizations will need to tweak their existing policies and procedures to conform to the new regulations. But for those organizations without any policy and procedure on overpayments, it is due time to start considering how to create such a policy (whether formally-promulgated or a well-designed guideline). Again, the proposed rule has not been finalized and it would be reasonable to commence work, but not publish a policy, until the regulations are final.

When drafting a policy on overpayments, it is important to acknowledge the legal requirements, but also properly balance competing duties, apply the law fairly, and mitigate risk. In connection with that, an organization should evaluate the following considerations:

- ▶ Develop a standard form to document an internal report of an alleged overpayment. Many of the elements on that form can

mirror the required elements of the official reporting form.

- ▶ Consider whether the overpayment investigation should be conducted under attorney-client and work product privileges. The organization should have a policy and procedure to assist in these determinations.
- ▶ Conduct and document employee interviews.
- ▶ Collect evidence and document the methodology used to determine if the alleged overpayment is a credible concern.
- ▶ Assess and analyze the causes of the overpayment as well as any defenses to the overpayment or limitations on the amount of overpayment calculated.
- ▶ Determine the amount of overpayment to report and return, and determine to whom the refund should be made. Document the methodology of how the refund amount was calculated.
- ▶ Determine what corrective action is necessary to address the root cause of the overpayment and prevent its future recurrence.

Consider those cases where the “reasonable inquiry” period is anticipated to continue for such a length of time that filing some preliminary “holding statement” with the Fiscal Intermediary/Carrier/MAC may be prudent.

When drafting an overpayments policy, the organization should also keep in mind the following considerations:

- ▶ Don’t create a policy that requires an unworkable bureaucracy or over-complicated process. It should be nimble, clear, and easy to complete in a timely manner.

- ▶ Do create a policy that allows for flexibility when information changes/develops during the investigation.
- ▶ Do create a policy that demonstrates the effectiveness of the organization’s compliance plan.
- ▶ Do include in the policy any necessary internal approvals which are required for processing of the refund, and build in time for securing these approvals.
- ▶ Don’t create a policy that conflicts with the organization’s internal accounting policies without first getting input from auditors and legal counsel.
- ▶ Do implement robust training and education around the policy, how to spot overpayments, the requirements for internal (or external) reporting, and the organization’s commitment against retaliation for whistleblowers and reporters.

Conclusion

In light of the ambitious changes in the proposed rule, particularly the significant expansion of potential liability associated with a 10-year look back period, health care organizations need to understand the consequences of the 60-day refund rule and how to meet its requirements. A first step is to create and implement an appropriate policy and procedure for reporting and refunding identified overpayments. Organizations must currently meet the 60-day requirements already in place under Section 1320a-7k(d), even though the proposed rule is not finalized. Organizations that draw on the guidance in the proposed rule to create a viable policy for reporting and refunding overpayments should find themselves well-positioned when the final rule is issued. ☐

DMEPOS supplier marketing arrangements and HIPAA compliance

By Nathaniel Lacktman, Esq., CCEP; and Leeann Habte, Esq., CIPP

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*This article is the fourth in a series on DMEPOS compliance issues by Foley & Lardner LLP published in **Compliance Today**. Last month, the authors provided insight and strategic advice on DMEPOS supplier standards and the False Claims Act.*

This month, the authors discuss the HIPAA implications for DMEPOS supplier marketing arrangements and provide a sample marketing authorization form as a supplier tool. Subsequent articles will discuss hospital-DMEPOS supplier arrangements under the Anti-kickback Statute; strategies for DMEPOS promotions and arrangements with manufacturers; and DMEPOS reimbursement compliance.

Suppliers of durable medical equipment, prosthetics, and orthotics supplies (DMEPOS) play an essential role in the spectrum of patient care, particularly for a medically-fragile patient population seeking greater independence. The lifeblood of a DMEPOS supplier's business is its customer base—the patients. Motivated suppliers continue to seek out new ways to promote their items and services to customers, and rightly so. In addition, many established suppliers are exploring cross-promotional arrangements with other companies as a means to obtain additional revenue and expand their

footprint by tapping into other companies' customer bases.

Although such marketing strategies can offer significant benefits, they also present particular compliance risks in the health care context.

DMEPOS suppliers interested in exploring collaborative or cross-promotional arrangements with other businesses must take time to understand the contours of the Health Insurance Portability and Accountability Act (HIPAA) and other applicable rules, because they affect the scope and terms of such cross-promotional arrangements. For purposes of this article and all the examples contained herein, the DMEPOS supplier is assumed to be a HIPAA covered entity (as would be the case in the vast majority of retailer DMEPOS suppliers).

HIPAA marketing rules and restrictions

DMEPOS suppliers that plan to implement marketing or promotional arrangements should keep in mind that the HIPAA Privacy Rule restricts both the disclosure and use of protected health information (PHI) for marketing purposes.¹ With certain important exceptions, the Privacy Rule requires an individual's written authorization before his/her protected health information can be disclosed or used for any

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communication that meets the definition of marketing.²

Definition of marketing

Under HIPAA, a communication is considered to be marketing if the supplier makes “a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.”³ Generally, if a communication meets the definition of marketing, the supplier may make that communication to a patient only if it first obtains the patient’s express written authorization. An example of a marketing communication requiring patient authorization is a letter sent from the supplier to its former patients, informing them about a special promotion from a local fitness center that is offering discounts to the general public on new workout memberships, when the communication is not for the purpose of providing treatment advice.⁴ However, if a communication that otherwise meets the definition of marketing falls within one of the following three exceptions and does not involve direct or indirect payment for making such communication, an authorization will not be required.⁵

Exceptions to HIPAA definition of marketing

The three exceptions below fall under the definitions of treatment and/or health care operations, and use or disclosure of PHI for these

purposes is permissible without written authorization.

1. Supplier’s own health-related items or services

Under the first exception, a communication is not considered marketing if it describes a health-related product or service provided by the supplier making the communication.⁶ Among other things, this exception permits communications by a supplier about products or services “provided by” the supplier to its clients. For example, it would not be marketing for a supplier that has added a new anti-snoring device to its product supply catalog to send a flyer describing it to the supplier’s patients (whether or not each patient has actually previously sought treatment for snoring).

2. Supplier’s treatment communications

Under the second exception, a communication is not considered marketing if it is made for treatment of the individual and for the purpose of furthering the treatment of that individual.⁷ For example, under this exception, it is not marketing when a supplier mails refill reminders to patients, or contracts with a mailing house to do so.⁸

3. Coordination of care and recommendation of alternative treatments

Under the third exception, a communication is not considered

marketing if it is made for “case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.”⁹ For example, under this exception, it is not marketing when an endocrinologist shares a patient’s medical record with several behavior management programs to determine which program best suits the ongoing needs of the individual patient.¹⁰ This exception is less frequently utilized in the DMEPOS supplier context, because the supplier commonly fills the orders issued by the patient’s treating physician, and the supplier does not independently offer its own treatment recommendations.

Marketing and the sale of health information

HIPAA also has a second definition of marketing, under which a communication is considered marketing if the supplier enters into an arrangement with another entity whereby the supplier:

...discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.¹¹

This type of marketing has no exceptions under the current HIPAA Privacy Rule. In other words, a supplier may not sell the PHI or names of its patients to a business associate or any third party without first obtaining express written authorization from each patient.¹² A valid authorization must state that such remuneration is involved.¹³

When are HIPAA authorizations for marketing not required?

Even if a communication falls within the definition of marketing, there are certain situations where an authorization is not required. The HIPAA Privacy Rule provides an exception if the marketing communication is in the form of either a face-to-face communication made by the supplier to an individual, or a promotional gift of nominal value provided by the supplier.¹⁴ This provision permits a supplier to discuss any services and products, including those of a third-party, during a face-to-face communication. The supplier could also give the patient sample products or other information in this setting (subject to other restrictions, such as the Anti-kickback Statute, Civil Monetary Penalties Law, and other laws not discussed in this article). From a HIPAA perspective, no written authorization is necessary when, for example, a supplier provides a free package of formula and other baby products

to new mothers as they leave the maternity ward.

Effective February 18, 2010, the Health Information Technology for Economic and Clinical Health (HITECH) Act revised the framework for the HIPAA exceptions to marketing communications. Under these changes, even if remuneration is involved, certain communications are considered health care operations and not marketing:

- if the communication is for treatment purposes; or
- if the communication only describes a drug or biologic that has been previously prescribed or administered, provided that the amount of the remuneration to the supplier is reasonable.¹⁵

For uses or disclosures other than these exceptions, a valid authorization from the patient is required.

Intersection of HIPAA marketing rules and DMEPOS Supplier Standards

When marketing items and services, Medicare-participating DMEPOS suppliers must not only comply with HIPAA marketing restrictions, they must also comply with the Medicare DMEPOS Supplier Standards for marketing to beneficiaries. Although both sets of rules govern marketing communications, they

differ in how they restrict such communications.

Marketing your own DMEPOS items or services

The HIPAA Privacy Rule makes clear that certain activities, such as communications made by a supplier for the purpose of describing the products and services it provides, do not constitute marketing. Under HIPAA's marketing rules, a DMEPOS supplier may freely market its own products and services to its own patients, and may use its patients' health information for such purpose without authorization. This is also allowed under the Medicare DMEPOS Supplier Standards.

Cross-promoting products or services of other companies

Under the Privacy Rule, a DMEPOS supplier may not use its patients' PHI to promote the products and services of other businesses (i.e., products and services not offered by the DMEPOS supplier itself) unless it meets one of the exceptions. When a supplier sends another business's marketing materials to the supplier's patients and such communication is not for the treatment of an individual, the supplier would be using its patients' PHI. It matters not if the supplier does not actually disclose any PHI to the other business, because the

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Privacy Rule restricts both the disclosure and the use of PHI.

In this situation, none of the HIPAA marketing exceptions apply. The supplier is not marketing its own product or service. The supplier is not making a recommendation regarding treatment of an individual patient's medical condition. And, the supplier is not likely to be considered to be in a position to make specific medical treatment recommendations regarding alternative treatments to patients (as might a physician or hospital). Therefore, the supplier must obtain the authorization of its clients before sending those marketing materials. If the cross-promotion activities involve direct or indirect remuneration to the supplier from the third party, the patient authorization form must state that such remuneration is involved.¹⁶

Selling customer health information

Likewise, if a supplier discloses PHI to the other entity, in exchange for direct or indirect remuneration so that the other entity may send marketing materials to the supplier's patients, the supplier must obtain a valid authorization from its patients. The authorization must expressly state that remuneration is involved.¹⁷ For example, a supplier cannot, without authorization, sell a list of patients to a

pharmaceutical company so the pharmaceutical company can directly market its own products to the individuals on the list.

DMEPOS companies with multiple subsidiaries or sister suppliers

Under HIPAA, legally separate but affiliated covered entities, such as subsidiaries or sister companies, may designate themselves as a single covered entity for purposes of HIPAA, as long as all the covered entities designated are under common ownership or control.¹⁸ If designated as a single covered entity, the sharing of PHI among sister companies or subsidiaries within the same covered entity does not constitute a use or disclosure for which authorization is required.

Despite the fact that HIPAA allows multiple subsidiaries or sister companies to be deemed a single covered entity, CMS has stated that it considers each subsidiary to be a separate supplier.¹⁹ Under DMEPOS Supplier Standard No. 11, CMS stated that the affiliated suppliers may not "reach out to" each other's Medicare beneficiaries for marketing (or at least, telemarketing) purposes. This means that a DMEPOS company with multiple subsidiary suppliers should take caution when implementing marketing endeavors to promote products and services to its own patients.

Such activities are not impossible, but require planning on how to execute them in compliance with both HIPAA and the Medicare supplier standards.

Obtaining authorization for marketing purposes

One approach to permit broad marketing communications is for the supplier to obtain written authorization from its patients where the patients would consent, in advance, to receive marketing materials. The supplier could send its patients an authorization form. For those patients who sign and return the authorization, the supplier would then send those patients marketing materials, including marketing materials of other companies (assuming the scope of the authorization covered the intended marketing activities). Alternately, the supplier could include the marketing authorization in its patient welcome package. A third approach would be to place the authorization form online to obtain and track patient consent. Suppliers with multiple subsidiaries or sister companies should consider creating a master authorization, under which the patient would authorize marketing activities for the entire family of related suppliers, as well as the supplier's business partners.

Suppliers should note that HIPAA also imposes certain restrictions

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on the scope, content, and duration of marketing authorizations.²⁰ The marketing authorization may not be combined with another type of authorization (so-called “compound authorizations”).²¹

In addition, certain state laws impose further restrictions on the disclosure and use of PHI for marketing purposes. When state law is more restrictive than HIPAA, the state law governs. If a supplier plans to distribute marketing materials to patients in various states, the authorization form must comply with the corresponding state law. See figure 1 on page 59 for a sample marketing authorization form.

Of course, different approaches present different logistical and operational challenges, such as time and expense, online capabilities, a system to track authorization forms, and patient preferences. Suppliers need to determine what approach is most cost-effective and feasible for their needs.

Practical compliance advice

When drafting, reviewing and revising their written policies and procedures on marketing, suppliers should ensure the policies and procedures are current with the recent HIPAA developments and changes. The rules and regulations have undergone significant change as a result of amendments made by the HITECH Act.

New proposed regulations implementing the HITECH Act were published on July 14, 2010. The final regulations have not yet been issued, but are expected to be released soon. Suppliers will need to review these regulations and comply with them when they become effective.

When examining policies for HIPAA marketing compliance, suppliers should consider the following sample questions (by no means an exhaustive list):

- Does the supplier have a marketing authorization form? Does it meet current federal and state requirements? Is the form translated into other languages?
- What is the supplier's process for a patient to opt out of receiving marketing communications?
- Does the supplier identify the specific marketing uses and disclosures for which an authorization is not required?
- How does the supplier document patient authorization to receive marketing materials?

In addition to the written procedures, suppliers should verify that their actual marketing practices correspond with the expectations set forth in their policies and procedures. The marketing staff should be periodically trained and educated on relevant marketing rules under federal and state law.

The supplier's Notice of Privacy Practices should be current and accurate and its authorization form should be proper in scope and content.

Conclusion

Marketing activities are integral to the continued growth of nearly any business, including DMEPOS suppliers. Given the regulatory environment and the intersection of HIPAA rules and the Medicare Supplier Standards, suppliers should implement—and adhere to—a framework of safeguards designed to allow robust marketing efforts while maintaining high levels of compliance. ■

1. 45 C.F.R. Part 160 and Part 164, Subparts A and E.
2. See 45 C.F.R. § 164.508(a)(3).
3. 45 C.F.R. § 164.501.
4. See Marketing FAQ at p. 1, Office of Civil Rights, HIPAA Privacy (April 3, 2003).
5. 42 U.S.C. § 17936(a)(2).
6. 45 C.F.R. § 164.501.
7. 45 C.F.R. §§ 164.501; 164.506(c)(1).
8. See Marketing FAQ, *supra*, at p. 3.
9. 45 C.F.R. § 164.501.
10. See Marketing FAQ, *supra*, at p. 3.
11. 45 C.F.R. § 164.501.
12. See Marketing FAQ, *supra*, at p. 2.
13. 45 C.F.R. § 164.508(a)(3)(ii).
14. 45 C.F.R. § 164.508(3)(i).
15. 42 U.S.C. § 17936(a)(2).
16. See 45 C.F.R. § 164.508(3)(ii).
17. 45 C.F.R. 164.105(b).
18. 45 C.F.R. 164.508(a)(3)(ii).
19. See 42 C.F.R. § 424.57(c)(11); “CMS FAQ Concerning the Revised Standards for DMEPOS Suppliers,” CMS-6036-F (Feb. 16, 2011).
20. See 45 C.F.R. § 164.508(c).
21. See 45 C.F.R. § 164.508(b)(3).

Figure 1: Authorization For Use And Disclosure Of Health Information*

Name	Date of Birth		
Street Address	City	State	Zip
Phone	Email		

I hereby authorize ABC DMEPOS Supplier, Inc. to use and/or disclose my health information specifically [identify nature of information that would be used or disclosed for DMEPOS marketing purposes] for the specific purposes of informing me about new products and services, and for ABC's marketing, promotions and advertising activities. ABC's use and/or disclosure will result in the disclosure of such health information among and between [identify entities that will receive the information]. ABC may receive direct or indirect remuneration (payment) from these third parties as a result of health information obtained and shared with those business partners pursuant to this Authorization. Health information disclosed pursuant to this Authorization may be subject to redisclosure and no longer protected by federal health care privacy laws.

- You have the right to inspect or copy the health information authorized to be used and/or disclosed by this Authorization.
- You have a right to receive a copy of this signed Authorization and ABC will provide you with a copy, should you choose to sign it.
- This Authorization is voluntary and you do not have to sign it. Your refusal to sign this Authorization will not affect your ability to obtain treatment, payment, health plan enrollment, or eligibility for benefits.
- You may revoke this Authorization at any time. To revoke this Authorization, notify ABC in writing at: [insert address]. Additional information may be found in ABC's Notice of Privacy Practices at [insert website].
- This Authorization is valid for five (5) years from the date signed below.

I have had an opportunity to review and understand the content of this Authorization. By signing this Authorization, I am confirming that it accurately reflects my wishes.

Signature: _____ Date: _____

* *This form is for sample educational purposes only. Suppliers should not rely solely on this form and are advised to seek input from legal counsel to comply with all applicable federal and state laws, rules and regulations.*

Cold calls, hot lines: DMEPOS telemarketing and beneficiary contact

By Nathaniel Lackman, Esq., CCEP; and Heidi Sorensen, Esq.

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*This article is the first in a series on DMEPOS marketing compliance by Foley & Lardner published in **Compliance Today**. Next month, the authors will develop this topic by providing a practical summary of the various telemarketing rules, strategic advice for DMEPOS telemarketing, and guidelines for applying the rules to real-world situations. Subsequent articles will discuss DMEPOS marketing arrangements under the Anti-kickback Statute, HIPAA, practical solutions for obtaining beneficiary consent to marketing, and strategies for allowable cross-promotion and co-promotion of DMEPOS items.*

Suppliers of durable medical equipment, prosthetics, and orthotic supplies (DMEPOS), whether home care

companies, mail-order suppliers, or manufacturers, provide an important service to a medically-frail group of people. The Medicare population, in particular, constitutes an important customer base and a significant source of revenue for DMEPOS suppliers. Understandably, suppliers continue to seek new ways to reach out to Medicare beneficiaries and grow their customer base. However, agencies such as the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) have announced new restrictions on how DMEPOS suppliers can conduct telemarketing activities and solicit beneficiaries.

The Telemarketing Statute

The Telemarketing Statute¹ prohibits suppliers from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of covered DMEPOS items unless one of three exceptions apply. The statute does not apply if:

- the beneficiary has given the supplier written permission to contact him/her by telephone;
- the supplier has already furnished a covered item to the beneficiary and the supplier is contacting the beneficiary regarding the furnishing of that item; or
- the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months, in which case the supplier may discuss or promote other covered items with the beneficiary.

A point of caution: a supplier cannot avoid application of the statute by contracting with a third-party vendor or telemarketing company. The statute also applies to vendors or agents working on the supplier's behalf. If the vendor violates the telemarketing statute, both the vendor and the supplier can be held responsible.

The penalties for violating the statute can be severe. If a supplier knowingly submits a claim for an item in violation of the statute, CMS must deny payment. Violations of the statute, particularly a pattern of violations, can expose suppliers to potential civil, criminal, and administrative penalties, including exclusion from participation in federal health care programs.

OIG Guidance and Updated Special Fraud Alert

OIG has long cautioned suppliers against improper telemarketing practices and noted, in its DMEPOS Compliance Program Guidance,² that suppliers are prohibited from making unsolicited telephone contact to Medicare beneficiaries. OIG also issued a 2003 Special Fraud Alert³ reiterating the prohibition on unsolicited telemarketing. Both publications reference the Telemarketing Statute but do not expand on the scope of the statutory language.

In 2010, OIG issued an Updated Special Fraud Alert on DMEPOS telemarketing, drawing attention to the telemarketing activities of independent marketing firms that make unsolicited telephone calls on behalf of suppliers to Medicare beneficiaries to market the suppliers' products.⁴ In the updated alert, OIG explained that the practice violates the Telemarketing Statute because "suppliers cannot do indirectly what they are prohibited from doing directly." OIG has indicated that the need for the Special Fraud Alert grew directly out of ongoing enforcement activities

it was undertaking in conjunction with the Department of Justice (DOJ).

The updated alert took the position that, when a physician sends a supplier the written or verbal order for a beneficiary, and the supplier calls the beneficiary regarding that order, such telephone contact is a violation of the Telemarketing Statute. OIG reasoned that “a physician’s preliminary written or verbal order is not a substitute for the requisite written consent of a Medicare beneficiary.”

A number of industry representatives criticized the OIG’s position, because it is common practice for physicians to send orders directly to the supplier. Requiring physicians to obtain a beneficiary’s written consent for each new patient could be a challenging task, particularly because the already busy physicians have no incentive to add this step to their paperwork process. It would be similarly challenging to require the supplier to obtain the written consent. For example, it would be impractical, costly, and inefficient for a supplier, after receiving the physician order, to then mail a written authorization card to the new patient and wait for a signed response before contacting the patient by telephone to arrange for delivery of the ordered item.

From a legal perspective, it is unclear whether the OIG’s expanded interpretation is adequately rooted in the language of the Telemarketing Statute and, at the time the updated alert was issued, no regulations were in place. From an operational perspective, the OIG’s interpretation would likely result in significant delays before patients could receive their prescribed items, thereby limiting beneficiary access to essential Medicare-covered items.

CMS response to Updated Special Fraud Alert

A month after the OIG released its updated alert, CMS responded by issuing Frequently

Asked Questions (FAQs) regarding telemarketing.⁵ The CMS FAQs differed from the OIG alert, and many believed CMS took a more reasonable interpretation consistent with how the DMEPOS industry operates. The fact that CMS responded with differing guidance so quickly after the OIG’s release of the Updated Special Fraud Alert suggests that OIG and CMS did not coordinate prior to the OIG release. The CMS FAQs included the following guidance:

- If a supplier returns a beneficiary’s phone call, the supplier’s contact is not unsolicited.
- If a physician contacts a supplier on behalf of a beneficiary and with the beneficiary’s knowledge, and a supplier then calls the beneficiary to confirm or gather information needed to provide that particular covered item (including delivery and billing information), then that contact is *not* unsolicited. The beneficiary need only be aware that a supplier will be calling him/her regarding the covered item, recognizing that the appropriate supplier might not be identified at the time of the physician’s consultation. This guidance provided flexibility, because the physician need not inform the patient that a specific supplier will call the patient. It also did not require a physician to obtain the beneficiary’s written consent.
- If a supplier calls a beneficiary based solely on the physician order, but the beneficiary did not know a supplier would call him/her, that call would be unsolicited contact. The physician must let the beneficiary know the physician will send the order to a DMEPOS supplier and a supplier will call the beneficiary.
- A supplier is not required to collect and maintain documentation from the physician reflecting that the physician informed the beneficiary that a supplier will call. CMS stated “It would be a business decision on

the part of the supplier whether to collect and obtain such documentation for their records.”

- If a supplier makes solicited contact with a beneficiary for a particular covered item, the supplier cannot speak with the beneficiary about other covered items during that same contact. This generally applies to new customers because, after the supplier has provided a covered item to the beneficiary, the supplier may then subsequently contact the beneficiary to offer other covered items in accordance with the exceptions in the Telemarketing Statute.

The CMS FAQs elucidated a reasonable position consistent with existing business practices and the Telemarketing Statute, and provided useful and practical guidance to DMEPOS suppliers. OIG indicated both informally, and through a cover letter distributing the FAQs to suppliers that it would defer to these interpretations by CMS. However, the CMS FAQs differed from the OIG’s published position and, moreover, CMS continued to change its position in the regulations and a second set of FAQs, as discussed in detail below.

New regulations and Preamble commentary

In August, 2010, CMS released final regulations updating the DMEPOS supplier enrollment standards.⁶ The regulations introduced new telemarketing rules, imposed stricter program standards for suppliers, and implemented many of the standards in CMS’ 2008 proposed regulations.⁷ The regulations took effect on September 27, 2010 and all suppliers must meet these standards.

The Preamble to the regulations contains twelve comments regarding telemarketing and beneficiary contact. CMS’s comments in the Preamble are consistent with its FAQs;

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namely, while a Medicare beneficiary must know that a supplier will be contacting him/her, nowhere did CMS state that the referring physician must obtain the beneficiary's written permission. For example, CMS stated:

[A] supplier may contact a beneficiary if a physician contacts a DMEPOS supplier on behalf of a beneficiary with the beneficiary's knowledge, and then a supplier contacts the beneficiary to confirm or gather information needed to provide that particular covered item (including delivery and billing information). In that instance, the contact would not be considered a direct solicitation and therefore, would not implicate [the Telemarketing Statute].

However, CMS also stated it considers the Telemarketing Statute to apply not only to solicitation by telephone, but also by "e-mail, instant messaging, or in-person contact." That position represented a significant expansion on the statutory language. Although e-mail and instant messaging may arguably be sufficiently similar to telephone calls to be a reasonable extension of the statute, CMS offered no basis to support its position that the prohibition on *telephone contact* would also ban in-person contact. OIG has previously expressed concerns with in-person direct marketing, but that OIG position cannot serve as the basis for expanding the statute.

In addition, the regulation required that a referring physician obtain *written permission* before the supplier may contact the beneficiary. It required that "[t]he individual has given written permission to the supplier or the ordering physician or non-physician practitioner to contact them concerning the furnishing of a Medicare-covered item that is to be rented or purchased." (emphasis added)

Yet, the Telemarketing Statute has always held that if a beneficiary gives written permission to a supplier, the supplier may contact that beneficiary. It seemed to many that the language "or the ordering physician or non-physician practitioner" was misplaced and did not belong in the regulation because it meant a physician must obtain written permission (not simply inform the beneficiary) before the supplier could contact the beneficiary.

CMS could have expressed a more consistent position by deleting the language "or the ordering physician or non-physician practitioner." Suppliers could then refer to the Preamble to understand that the beneficiary must know that a supplier will contact him/her. This approach would have remedied the inconsistency between the regulations and the FAQs and Preamble, and provided clear instruction to suppliers who receive orders from referring physicians. This approach would also have been also consistent with current industry practices and standards. Instead, the regulation triggered the same concerns as the OIG's Updated Special Fraud Alert, and suppliers were concerned that a requirement for written permission would be burdensome, costly, and cause potential delays for Medicare beneficiaries.

CMS 2011 FAQs

CMS received a number of critical responses to the regulations and, in January 2011, issued updated FAQs addressing the industry queries.⁸ For suppliers, these 2011 FAQs were even more problematic than the regulations. CMS seemed to take some inexplicable and highly unfavorable positions regarding telemarketing and beneficiary contacts, including:

- The 2011 FAQs expanded telephone contact to include mailings made through the US Post Office. The 2011 FAQs prohibit "targeted mailings to specific

beneficiaries," although "general mass advertising" is allowed. CMS offered no explanation of what those terms mean or how the Telemarketing Statute could apply to direct mail.

- A supplier may not contact a beneficiary based solely on a physician order unless the physician obtains the beneficiary's written permission. This position is consistent with the language of the regulation, but differs from the guidance in CMS' previous FAQs.
- If a supplier makes solicited contact with a beneficiary for a particular covered item, the supplier cannot speak with the beneficiary about other covered items during that same contact. This position is largely consistent with CMS' previous FAQs.
- For companies with multiple subsidiaries, if one subsidiary is permitted to contact a beneficiary (e.g., by written permission or by previously providing covered items), a related company under the same parent corporation may not make contact without separately meeting one of the exceptions in the Telemarketing Statute. Even if all the subsidiaries are enrolled DMEPOS suppliers, CMS seems to view each as a separate entity and require each to meet an exception to the Telemarketing Statute in order to contact beneficiaries.

Rather than providing clarity, the 2011 FAQs served to increase confusion about CMS' restrictions on telemarketing and beneficiary solicitation.

Revised regulations

On April 4, 2011, CMS released a proposed rule revising supplier standards, particularly supplier standard 11.⁹ CMS acknowledged that its expanded interpretation had been criticized as overly broad and prohibited marketing activities in a manner that would be unfeasible for DMEPOS suppliers to

implement. CMS indicated that it will further investigate how to address its concerns of abusive DMEPOS marketing practices. In the interim, CMS will instruct its contractors to apply the restrictions on telephone solicitation that were in effect prior to the August 2010 regulations (rather than all types of beneficiary solicitation and contact).

The current proposed rule deletes the reference to direct solicitation and instead focuses on telemarketing, tracking the exceptions under the Telemarketing Statute. It also deletes the language that requires a referring physician to obtain the beneficiary's written permission. CMS did not include any comments regarding its 2010 or 2011 FAQs, nor how suppliers should interpret the proposed regulations in light of those FAQs, nor which FAQs still remain in effect.

Conclusion

The changing landscape and conflicting guidance has led to much confusion among DMEPOS suppliers regarding telemarketing

and beneficiary solicitation. Penalties for failing to comply with the telemarketing rules are severe. Because these rule changes have a significant impact on suppliers' business operations and marketing efforts, it is imperative for suppliers that serve Medicare beneficiaries to be aware of the restrictions. Despite the confusion, the various guidance can be boiled down into a manageable set of practical rules suppliers can use in their marketing activities, particularly as new communication technologies and marketing approaches change these activities. Next month's article will set forth those practical rules, apply them to a series of real-world DMEPOS marketing situations, and highlight key opportunities and approaches suppliers can take while still complying with the telemarketing and beneficiary solicitation rules. ■

1. Section 1843(a)(17)(A) of the Social Security Act; 42 U.S.C. § 1395m(a)(17)(A).
2. 64 FR 36368, 36380 (July 6, 1999).
3. 68 FR 10254 (Mar. 4, 2003).
4. 75 FR 2105 (Jan. 14, 2010).
5. Available at www.cms.gov/MedicareProviderSupEnroll/Downloads/DME%20Supplier%20Telemarketing%20FAQ.pdf.
6. 75 Fed. Reg. 52629 (Aug. 27, 2010).
7. 73 Fed. Reg. 4503 (January 25, 2008) (proposed rules); 42 C.F.R. § 424.57(c) (supplier standards).
8. Available at [www.palmettoga.com/Palmetto/Providers.Nsf/files/FAQS6036FINAL.pdf?\\$File/FAQS6036FINAL.pdf](http://www.palmettoga.com/Palmetto/Providers.Nsf/files/FAQS6036FINAL.pdf?$File/FAQS6036FINAL.pdf).
9. 76 Fed. Reg. 18472 (April 4, 2011)

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Compliant DMEPOS telemarketing: Strategic approaches and practical tips

By Nathaniel Lacktman, Esq., CCEP; and Heidi Sorenson

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*This article is the second in a series on DMEPOS marketing compliance by Foley & Lardner LLP published in **Compliance Today**. This month, the authors provide a practical summary of the Medicare DMEPOS telemarketing rules, offer strategic advice and opportunities regarding DMEPOS telemarketing,*

and apply the rules to real-world situations. Subsequent articles will discuss marketing arrangements under the Anti-kickback Statute and HIPAA; practical solutions for obtaining beneficiary consent to marketing; and strategies for allowable cross-promotion and co-promotion of DMEPOS items.

Part 1 of this series (published in the May 2011 issue of **Compliance Today**) explained the statutory and regulatory requirements relating to durable medical equipment, prosthetics and orthotics supplies (DMEPOS) telemarketing and beneficiary solicitation under the Medicare regulations and guidance. This article covers how that guidance is transformed into a manageable set of rules and applied to a number of real-world DMEPOS marketing situations. Suppliers will learn: (1) what is allowed and prohibited under the telemarketing and beneficiary contact rules; (2) advice to ensure compliance with these rules; (3) strategic marketing opportunities for suppliers; and (4) practical

solutions and real-world examples of permissible telemarketing and beneficiary contact activities.

Enforcement of telemarketing rules

Complaints about telemarketing practices filter into a number of different regulators and law enforcement agencies. We are aware of criminal investigations by the Department of Justice (DOJ) of some suppliers and their marketing vendors related to allegations of cold-calling Medicare beneficiaries. The Office of the Inspector General (OIG) settled a Civil Monetary Penalties case in 2009 with Matrix Diabetics, Inc., a Florida distributor of blood glucose testing supplies. The former owners and officers of the DMEPOS company agreed to pay \$260,000 for allegedly paying telemarketing firms to make unsolicited telephone calls to beneficiaries to market DMEPOS items on behalf of the company. The company in turn submitted claims for these items for Medicare reimbursement.¹

Medicare's Zone Program Integrity Contractors (ZPICs) have also made outreach through letters to suppliers alerting them to complaints of violations of the Telemarketing Statute. The volume of these enforcement activities and the number of different agencies involved highlight that the risk to suppliers who violate the Anti-kickback Statute is real, not hypothetical.

Rules for DMEPOS telemarketing and beneficiary solicitation

DMEPOS suppliers may not make unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of covered items, unless:

- the beneficiary first calls the supplier or initiates contact, and the supplier is responding to that contact;
- the beneficiary gave the supplier written permission to contact the beneficiary;
- the supplier has already furnished a covered item to the beneficiary and the supplier is contacting the beneficiary regarding the furnishing of that same item; or
- the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months, in which case the supplier may discuss or promote other covered items with the beneficiary.²

Although these summarized rules may seem simple enough, they can become complicated and nuanced when applied to real-world DMEPOS marketing situations. The table on page 56 applies the telemarketing rules to a number of DMEPOS situations.

Suppliers should keep in mind, however, there are a number of other federal and state laws that impose restrictions on telemarketing in general (e.g.,

the Federal Trade Commission's Telemarketing Sales Rule and state restrictions on telemarketing) and to Medicare beneficiaries in particular (e.g., HIPAA, the Anti-kickback Statute, and the Civil Monetary Penalties Law, including the provisions on beneficiary inducements). Those laws intersect with DMEPOS marketing and must also be considered, but the scope of this article is limited to the Medicare rules on telemarketing and beneficiary solicitation.

Contracting with third-party vendors and telemarkers

Third-party vendors and telemarketing companies are commonly used vehicles for marketing and customer outreach. DMEPOS suppliers may engage these vendors, but should understand that if the vendor violates the Telemarketing Statute, the supplier can be held responsible and face severe sanctions for the vendor's conduct. For this reason, suppliers who choose to contract with these vendors should include oversight provisions in their vendor contracts, under which the vendor agrees to adhere to the telemarketing rules applied to Medicare beneficiaries and patients in general. This is important because many vendors, particularly those who deal with a broad spectrum of customers beyond solely Medicare beneficiaries, are unaccustomed to these restrictions. In addition to the contractual language, suppliers should be diligent in ensuring the

vendor is complying with those restrictions.

Written policies and procedures

Suppliers should have written policies and procedures in place to delineate the steps the supplier will take to promote compliance with the Medicare supplier standards and the Telemarketing Statute. The written policy should clearly state that the supplier's employees, as well as individuals and entities working on the supplier's behalf, are prohibited from making unsolicited contact with Medicare beneficiaries unless one of the statutory exceptions apply. The written procedure should include a step-by-step process for contacting current and prospective customers. It should be written in a manner employees can easily understand and follow, and should be tailored to the supplier's specific business practices. As with all compliance policies and procedures, it should be reviewed periodically and updated as needed to comply with changes in the law and the supplier's operational requirements.

Documentation advice and approaches

The original Centers for Medicare and Medicaid Services (CMS) Frequently Asked Questions (FAQs) took the position that a supplier need not collect and maintain documentation from the physician reflecting that the

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Table 1: DMEPOS Medicare Telemarketing and Beneficiary Solicitation

Telemarketing Situation	Allowed Under Telemarketing Rules?
A physician sends the supplier a work order for a new patient. The patient is informed that a supplier will contact him, but does not sign a written permission form. The supplier then calls the patient.	No, because the current regulations require the beneficiary's written permission. Under the proposed rule, this would be allowed.
A physician sends the supplier a work order for a new patient and checks a box attesting that the patient has given written permission to contact. The supplier then calls the patient.	Yes, but only if the beneficiary actually gave written permission. Because the supplier does not know whether or not the beneficiary actually gave written permission, this situation presents a high level of risk and is not recommended. Under the proposed rule, this would be allowed, but the proposed rule does not require the patient to give written permission.
A physician sends the supplier a work order for a new patient, along with the patient's signed written permission to contact. The supplier then calls the patient.	Yes, because the beneficiary gave written permission. Under the proposed rule, this would be allowed, but the proposed rule does not require the patient to give written permission.
A physician sends the supplier a work order for a new patient, along with the patient's signed written permission to contact. The order is for home oxygen equipment. The supplier calls the customer and promotes/discusses other items (e.g., ventilator or respiratory assist devices).	No, because the scope of consent was limited only to those items in the physician order. If this is the first contact ever made by the supplier to the beneficiary, the supplier may not attempt to solicit the purchase of additional covered items. After the supplier provides the covered items to the beneficiary, the supplier may then promote additional products.
A potential customer sees the supplier's television commercial and places a call to a third-party vendor handling responses to the commercial. The vendor then transfers the patient to the supplier (i.e., a warm transfer).	Yes, because the beneficiary initiated contact.
A potential customer finds the supplier's Internet site and completes an online form asking the supplier to contact him. The supplier then calls the customer.	Yes, because the beneficiary initiated contact. The supplier should verify that the language of the online consent is adequate. Also a two-step process (e.g., two clicks to submit) is advised to guarantee the customer's willful consent and to serve as an online signature.
A potential customer finds the supplier's Internet site and completes an online form asking the supplier to contact him. Although there are a number of possible areas of interest, the customer only checks the "wound care" box as his interest. The supplier calls the customer and promotes/discusses other non-wound care items (e.g., crutches and ambulatory equipment).	No, because the beneficiary gave consent only to wound care supplies. If this is the first contact ever made by the supplier to the beneficiary, the supplier may not attempt to solicit the purchase of additional covered items because the supplier only had permission to contact the beneficiary regarding the particular covered items ordered. After the supplier provides the covered item to the beneficiary, the supplier may then promote additional products.
A potential customer sees the supplier's television commercial and places a call to the supplier, leaving a voicemail message. The supplier then calls the customer the next day.	Yes, because the beneficiary initiated contact.
A hospital care coordinator sends the supplier an enrollment form for the patient to coordinate the patient's discharge orders. The patient previously gave the hospital written permission or the patient signs the form to give permission for a supplier to contact him. The supplier then calls the patient.	Yes, because the beneficiary gave written permission. Under the proposed rule, this would be allowed, but the proposed rule does not require the patient to give written permission.

Table 1 continued

Telemarketing Situation	Allowed Under Telemarketing Rules?
A hospital care coordinator sends the supplier an enrollment form for the patient to coordinate the patient's discharge orders. The patient is informed that his care is being coordinated through the supplier, but has not given any written permission. The supplier then calls the patient.	No, because the current regulations require the beneficiary's written permission. The Preamble to the regulations explains that, if hospital staff obtain a patient's written consent, the hospital may order supplies on the patient's behalf. The patient's written permission need not be on the enrollment form itself, but could be on another document. Under the proposed rule, this would be allowed because the proposed rule does not require the patient to give written permission.
A DMEPOS manufacturer receives an order from a physician, with the proper patient written permission. After calling the patient, the manufacturer determines it does not provide the items directly to patients, so the manufacturer sends the order to the supplier. The supplier then calls the patient.	Yes, this is potentially allowed because the beneficiary gave written permission. However, it depends on the scope of that permission. If the permission form allows phone contact by "a supplier," it is probably acceptable. If the permission form allows a call only by the particular manufacturer, the supplier should not call the patient.
A DMEPOS manufacturer receives a call from a patient asking about how to get the manufacturer's DMEPOS supplies. The manufacturer then transfers the patient to the supplier (i.e., a warm transfer).	Yes, because the beneficiary initiated contact.
The supplier hosts a health fair or community event. A potential customer visits the event and gives his information on a written card, giving permission for the supplier to contact him. After the event, the supplier calls the customer.	Yes, because the beneficiary gave written permission. In addition, health fairs and community events are permissible methods of beneficiary contact.
The supplier hires a third-party vendor to use door-to-door salespeople to reach out to beneficiaries.	No, because under the current regulations, CMS expanded the telemarketing and beneficiary contact restrictions to include in-person contact. The proposed rule deletes this restriction.
The supplier mails a card to a large number of potential customers who are Medicare beneficiaries. After receiving the card, a potential customer places a call to the supplier.	Yes, this is probably allowed because the beneficiary initiated contact and the supplier's contact was sent by mail to a large number of customers. CMS' 2011 FAQs state that "targeted mailings to specific beneficiaries are prohibited," but that "general mass advertising through the post office" is allowed." However, neither the regulation nor the statute expressly encompass direct mail and CMS has not explained the basis for its authority to expand the Telemarketing Statute into direct mailings. There are arguments that the telemarketing rules should not apply to direct mailings. The proposed rule deletes this restriction.
The supplier mails cards to a group of potential customers who are Medicare beneficiaries. A potential customer fills in his phone number and mails back the card, indicating his interest in being contacted about the supplier's services. The supplier then calls the customer.	Yes, this is probably allowed because the beneficiary initiated contact and the supplier's contact was sent by mail. A customer signature field on the card, if not per se required, is a best practice and the recommended approach. The supplier should ensure the customer signed the card before telephoning the customer.

physician contacted the supplier with the beneficiary's knowledge. CMS stated "it would be a business decision on the part of the supplier whether to collect and obtain such documentation for their records." Even if it is not *per se* required that a supplier collect and maintain a copy of that documentation, the compliance risks are too high for a supplier not to take steps to ensure the beneficiaries gave their written permission (under the current regulation) or were made aware that a supplier would be contacting them (under the proposed rule).³

However, deciding to collect the documents is a far easier task than actually doing so, and suppliers understandably face a challenge in operationalizing this documentation requirement. One approach might be to build it into the supplier's physician work order. The revised work order would include a check box where the physician affirms he or she has obtained the patient's written permission for the supplier to contact the patient. This alone is likely not adequate under the current regulations, but it can serve as a reminder to the physician that he or she must obtain the beneficiary's written permission (or inform the beneficiary, under the proposed rule). The check box represents an affirmative effort by the supplier to help ensure compliance with the Telemarketing Statute and

supplier standard number 11. This is a beneficial tool designed to protect the supplier in the event a patient complains that the supplier violated the Telemarketing Statute. On the other hand, if the physician submits a work order without checking the box, it might suggest the patient did not give permission, and could require additional back-and-forth with the physician to obtain such.

Another approach would be to update the existing physician work order to include a signature portion where the patient authorizes the supplier to contact him/her. The patient would sign that portion in the physician's office. This approach allows the supplier to obtain the beneficiary's explicit written permission in accordance with the current regulations. But, having a patient sign a physician work order is very unusual, and the same risks apply if the physician forgets to have the patient sign the work order. Moreover, under the proposed rule, the patient is not required to give his or her written permission.

A third approach would be to create an authorization form/response card and mail it to the beneficiary immediately upon receipt of the written order for a new patient. Once the beneficiary signs and returns the authorization card, the supplier can telephone the patient. The response

card could also ask the patient to call the supplier and discuss the order. This approach could be a potential fail-safe in the event a supplier receives a work order without the beneficiary's written permission (or physician attestation that the beneficiary knows a supplier will call him or her). But, from an operational perspective, mailing a card and waiting for the response would likely cause unacceptable delays in sending the patient his/her medically-necessary items.

A fourth approach would be to create a complete authorization form and provide it to the supplier's referring physicians. The physician would have the patient review and sign the form during the office visit. The physician would then send the signed authorization form along with the work order. Once the supplier receives the signed authorization form, the supplier could contact the patient.

This approach imposes the greatest operational burden on suppliers and physicians, because it requires a separate document in addition to the existing paperwork physicians must send to suppliers. However, it is probably the most comprehensive practice because it most clearly satisfies the current regulations (though this should not be necessary under the proposed rule).

DMEPOS advertisements in Internet, television, and new media

Although the current regulations and guidance purport to restrict communications through certain new technologies such as e-mail, instant messaging, and text messages, the Internet remains—at least to a certain degree—fair game. In 2008, CMS drafted a proposed prohibition on “coercive Internet advertising,” but did not include it in the 2010 final regulations. The revised DMEPOS supplier standards do not prohibit television, radio, or Internet advertisements, or advertisements at health fairs, community events, or the supplier’s own website.⁴ Implementing and enforcing a restriction on Internet advertising might be (for the time being) too difficult and costly for CMS or the OIG to manage. In addition, media such as television and the Internet can be considered advertisements to the public or to Medicare beneficiaries generally.

The fact that the Telemarketing Statute does not apply to Internet advertisements may potentially open some opportunities for savvy suppliers who are interested in using social media tools to promote their products. For example, a supplier might consider using Google’s sponsored searches so their website appears at the top when someone enters a search for “Medicare prosthetic arm.” Sponsored searches are not new,

and are permitted under the new regulation. But, for something more cutting-edge, suppliers might consider other Internet advertising methods, such as Facebook.

The Facebook advertisement tool allows someone to publish their advertisement to a certain segment of Facebook users, narrowed by the users’ demographics and stated interests. For example, a diabetes supplier might want to place a Facebook advertisement, requesting that the advertisement only be displayed to Facebook users who are over 65 years old and who have an interest in diabetes or who “like” the American Diabetes Association. New Internet advertising approaches such as these can potentially pose a higher level of compliance risk, because the advertisements are targeted toward a specific group of people, rather than Medicare beneficiaries generally. The more specific and targeted the advertisement, the more likely CMS or OIG will find it objectionable. And yet, the Facebook advertising tool is still a “passive” advertisement in that it is placed on a webpage and not directly sent to a beneficiary by telephone, e-mail, instant messaging, or in-person contact (the four CMS-defined methods of direct solicitation). Unless and until CMS issues further guidelines on Internet advertising, the landscape of opportunities and risk remains largely uncharted.

Conclusion

The telemarketing and beneficiary contact rules have a significant impact on a DMEPOS supplier’s operations because the restrictions go to the lifeline of a supplier’s business: the customers. The April 4, 2011 proposed rule helps to make these restrictions more workable and better reflect industry practices. Yet, it remains essential for DMEPOS suppliers to understand the applicable restrictions and build operational and procedural safeguards to promote compliance, while also having a keen knowledge of the marketing opportunities that can be pursued. ■

1 See www.oig.hhs.gov/fraud/enforcement/cmp/false_claims.asp.

2 As explained in the previous article, John Spiegel, Director of CMS’ Program Integrity Group, stated on January 19, 2011 that CMS “does not intend to instruct Medicare contractors to implement the expanded provision” of the telemarketing regulations. The telemarketing rules may change depending on CMS’ subsequent actions.

3 The differences between the current regulation and the proposed rule were discussed in last month’s issue, particularly the proposed change in the written permission requirement. See also 76 Fed. Reg. 18472 (Apr. 4, 2011).

4 75 Fed. Reg. 52629, 52638-9 (Aug. 27, 2010).

DMEPOS and the False Claims Act: Compliance and litigation strategies

By Nathaniel Lacktman, CCEP and Michael McCollum

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*This article is the third in a series on DMEPOS compliance issues by Foley & Lardner LLP published in **Compliance Today**. In the June issue of **Compliance Today**, the authors provided practical tips and compliance advice regarding DMEPOS telemarketing and beneficiary contact. This month, the authors discuss the Medicare*

DMEPOS supplier standards, liability under the False Claims Act, and strategic approaches to limiting damages in whistleblower lawsuits.

Suppliers of durable medical equipment, prosthetics, and orthotic supplies (DMEPOS) face increasing scrutiny and oversight from federal agencies such as the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG). In order to obtain and maintain Medicare billing privileges, DMEPOS suppliers need to meet the Medicare supplier standards. Late in 2010, CMS expanded the supplier standards and imposed significant new burdens on DMEPOS suppliers. The industry opposed many of these changes, but it remains likely that the government will continue to argue in the appropriate cases that failure to comply with the supplier standards not only exposes DMEPOS suppliers to administrative sanctions, but also creates False Claims Act liability. DMEPOS suppliers should understand the supplier standards and the enforcement implications, both to ensure

compliance going forward, and, if necessary, to effectively defend past conduct in the event of an enforcement action, government investigation, or False Claims Act litigation.

Medicare has strict guidelines and standards that DMEPOS suppliers must meet to establish and maintain Medicare billing privileges. Among these rules is the set of federal regulations known as the Medicare DMEPOS supplier standards.¹ The supplier standards apply to all Medicare-participating DMEPOS suppliers and set forth the minimum operational requirements suppliers are asked to follow. First introduced in 1992, the supplier standards have expanded, and currently there are 30 standards.

New supplier standards and proposed revisions

In August 2010, CMS released a final rule that added four new DMEPOS supplier standards and made the existing standards more onerous. In response to significant backlash from the DMEPOS industry, CMS issued a proposed rule in April 2011, relaxing some of the standards introduced in the August 2010 final rule. When this article went to press, the April 2011 proposed rules had not been finalized.

DMEPOS supplier standards and Medicare enrollment

The National Supplier Clearinghouse (NSC) processes DMEPOS

supplier applications for Medicare, oversees the enrollment process, and with CMS is responsible for oversight of compliance with the supplier standards. Effective March 2011, new DMEPOS suppliers are now classified by the government as a “high risk” category for fraud, waste, and abuse and are subject to more stringent enrollment screening and oversight controls.

Generally, the Medicare DMEPOS supplier enrollment process is as follows. First, the applicant submits the CMS 855S enrollment application and supporting documentation to the NSC. In the application, the DMEPOS supplier certifies that it meets and will continue to meet the supplier standards. The NSC reviews the application and conducts a site visit to verify compliance with all DMEPOS supplier standards. After completing its review, the NSC notifies the applicant in writing of the enrollment decision. After enrollment, a DMEPOS supplier must maintain compliance with the supplier standards.

Implications of failure to comply

DMEPOS suppliers can face severe penalties for failing to comply, at least in material respects, with the supplier standards. From the government’s perspective, all deviations from the black letter standards are material and require sanctions, including administrative penalties,

billing revocation, Medicare recoupment, potential criminal liability, and potential liability under the False Claims Act. But, there are limits. Understanding the contours and limits of these potential penalties—and the issues and arguments that typically arise—is essential for a DMEPOS supplier to effectively position itself to avoid scrutiny by maintaining an effective compliance program and, if necessary, to respond to a regulatory or False Claims Act action.

Administrative penalties

If a DMEPOS supplier is found to not meet the supplier standards, CMS may revoke the supplier’s billing privileges. The revocation is effective within 15 or 30 days of the notice of revocation, depending on the standard violated.

The new DMEPOS regulations also allow CMS to attempt recoupment of payments as of the date of certain final adverse actions:

- Revocation of Medicare billing privileges
- Suspension or revocation of a state license
- Conviction of a felony
- Exclusion from participation in a state or federal health care program
- Revocation for failure to meet DMEPOS quality standards

Under this rule, CMS is authorized to assess and collect Medicare

overpayments back to the date of the final adverse action. This means that all funds received by a DMEPOS supplier subject to one of the adverse actions can potentially be deemed an overpayment. This rule strengthens CMS’ view that when a DMEPOS supplier is not allowed to participate in Medicare, funds the supplier receives are deemed to be overpayments.

However, the new regulations do not contain a provision authorizing recoupment retroactive to the date of the DMEPOS supplier’s non-compliance—only to the date of the final adverse action. The lack of a retroactive recoupment provision benefits DMEPOS suppliers significantly, because it limits the potential overpayment liability for non-compliance with certain supplier standards. Moreover, a DMEPOS supplier who is assessed an overpayment under this provision has administrative appeal rights. Given the current regulatory environment and the new 60-day overpayment rule, DMEPOS suppliers should develop a thoughtful approach for determining how overpayments are identified and potentially reported and refunded.²

Potential liability under the False Claims Act

Of potentially even greater concern than the possible administrative sanctions is the potential for False

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Claims Act liability. Given the current enforcement environment, government scrutiny and *qui tam* whistleblowers are a reality for DMEPOS suppliers. The supplier standards have been considered a hybrid between the Medicare conditions of participation and the conditions for payment. Whereas a violation of Medicare conditions for payment is generally considered grounds for a False Claims Act violation, some courts have ruled that a violation of Medicare conditions of participation does not necessarily give rise to a False Claims Act violation. In some recent cases in the DMEPOS industry, the government has taken a more aggressive position that the supplier standards are conditions for payment. The good news for DMEPOS suppliers is that at least one recent court ruling held that a violation of the supplier standards does not necessarily trigger a false claim.³

Supplier standards as conditions of participation or conditions for payment

The vast majority of courts that have examined the issue have held that False Claims Act liability does not arise simply by virtue of a violation of an underlying Medicare rule or regulation.⁴ Rather, one of two conditions must exist:

- The supplier expressly certified compliance with the standards when submitting a claim; or

■ Compliance with the standards is written into the regulation as a condition for payment, rather than simply a condition of participation, in the Medicare program.

The issue of Medicare conditions of participation versus conditions for payment is more complicated for DMEPOS suppliers than for other providers, such as hospitals. This is largely due to the nature of the supplier standards. The government has pointed to some characteristics of the supplier standards to support its argument that the supplier standards are conditions for payment. For example, the supplier standards are contained under the regulatory section titled "Conditions for Medicare Payment." The payment regulations require that certain conditions be met "as a basis for Medicare payment," including, among other things, conditions regarding the source of services.⁵ The "source of services" category includes the requirement that services must have been furnished by a provider, nonparticipating hospital, or supplier that was qualified to have payment made for the services at the time it furnished them. Under the government's argument, these payment regulations can and should be interpreted to mean that compliance with the supplier standards is a condition for payment.⁶

However, DMEPOS suppliers can identify other aspects of the supplier standards to refute the government's argument, and instead demonstrate that the supplier standards are simply conditions of eligibility that afford the DMEPOS supplier the privilege to prospectively bill the Medicare program. The regulatory subsection titled "Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges" sets forth several conditions that a DMEPOS supplier must meet "in order to be eligible to receive payment for a Medicare-covered item." One of those conditions is listed as "CMS has not revoked or excluded the DMEPOS supplier's privileges during the period which the item was furnished."⁷ The 30 supplier standards are listed thereafter as standards "the supplier must meet and must certify in its application for billing privileges." As noted above, there is no provision for retroactive recoupment, only recoupment following actual revocation. These aspects make the supplier standards akin to conditions of participation.

No appellate court has opined on this issue. However, in examining the interplay between these regulatory provisions, at least one court clearly held that the supplier standards are conditions of participation and not payment,

concluding that “proper redress for violations of the standards established therein is not the denial of payment, but the revocation of the supplier’s billing privileges.”⁸ Case law continues to evolve and DMEPOS suppliers—and their legal counsel—should stay attuned to new developments on this issue.

Falsity, knowledge, and limits on damages

If a DMEPOS supplier is facing a False Claims Act investigation or lawsuit that alleges liability based on noncompliance with the supplier standards, the supplier should articulate several reasons why key elements of False Claims Act liability cannot be met. This is because alleged violations of the supplier standards may bear little-to-no relation to the core elements of False Claims Act liability, namely the knowing submission of a false or fraudulent claim or statement that is material to the government’s payment of a claim. A DMEPOS supplier will want to be familiar, in particular, with the legal elements of falsity and knowledge, and how damages are to be measured under the False Claims Act.

Regarding falsity, obviously, if no supplier standard has been violated, no false claim or statement can be predicated on noncompliance with the supplier standards. Yet, the government can, and sometimes does, interpret a standard

in a manner unsupported by the regulatory language itself. Further, compliance with the supplier standards can sometimes be unclear, particularly where the regulations are vague or complicated. A recent court ruling lends support to the argument that lack of clarity alone may undermine the ability of the government or a private litigant to satisfy the “falsity” element of the False Claims Act.⁹

By that same token, courts have held that even if a claim is technically false, a sufficiently high level of uncertainty and vagueness in the regulations will undermine the knowledge element of False Claims Act liability. Under the same court’s opinion noted above, it was noted that a defendant cannot have knowingly submitted a false claim if the regulations are thoroughly unclear (i.e., where there are legitimate grounds for disagreement over the scope of the regulatory provisions) or if CMS actually knows and approves of the facts surrounding the supplier’s conduct before the challenged claims for payment are submitted, upon which conduct the supplier relies.

Beyond the issue of liability, DMEPOS suppliers should further seek to limit the amount of damages by arguing that damages are to be calculated not as the full amount of the Medicare payment, but instead according to a benefit-of-the-bargain analysis. Under that

approach, damages are measured by the difference between the value of what Medicare paid for the item and the value of what the beneficiary actually received. This concept is increasingly being applied by courts in False Claims Act cases.¹⁰

This methodology does not apply to actions under the Civil Monetary Penalties Law because that statute fixes damages as the full value of the claims improperly made. There is also some authority holding that a Medicare regulatory violation demands full repayment of the Medicare payments, because Medicare would not have paid any funds without the false claims, and Medicare does not actually receive any direct benefit from the supply of covered items.¹¹ But, that ignores the fact that beneficiaries are the true recipients of the covered items, as well as the Medicare funds to pay for those items. Therefore, DMEPOS suppliers may find success with courts recognizing that the government receives a benefit from the provision of covered items to beneficiaries, and the courts may apply the benefit-of-the-bargain rule in the Medicare context to limit the damages in DMEPOS supplier False Claims Act lawsuits.¹²

Practical compliance advice for future conduct

DMEPOS suppliers should carefully review the existing supplier

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standards to ensure they understand all the rules and requirements for Medicare participation. In addition to the regulations, DMEPOS suppliers should review the preambles to the 2010 final rule and the 2011 proposed rule. That will help DMEPOS suppliers understand CMS' purpose in issuing the rules, as well as give additional detail on how CMS interprets the regulatory language. CMS and NSC have also published FAQs on the new supplier standards and DMEPOS suppliers should read them to help answer any additional questions on how to interpret the regulations.¹³

(Note: These FAQs have been revised, so be certain to obtain a copy of the most current version.) DMEPOS suppliers will also find a wealth of information in Chapter 15 of the *Medicare Program Integrity Manual*, as well as the supplier manuals issued by each of the four regional DME Medicare Administrative Contractors.

Using these materials, as well as the regulations themselves, DMEPOS suppliers can create and tailor risk assessment tools specific to their company's compliance needs on a going forward basis. Certainly, DMEPOS suppliers should address key risk areas, such as accreditation compliance, billing and documentation, medical necessity of items ordered, state licensure and Medicaid requirements, referral relationships and contracting,

and marketing to beneficiaries. DMEPOS suppliers should also ensure their compliance program policies and procedures are current with the recent changes to the supplier standards, keeping in mind the relaxed rules contained in the recent proposed rule. DMEPOS suppliers should then verify that their actual practices regarding the supplier standards match up with the expectations set forth in their written policies and procedures. Staff should be periodically trained and educated on relevant requirements under the supplier standards and related state law rules (e.g., licensure and contracting).

Responding to an investigation of past conduct

Once the foundation has been built for an effective compliance program, DMEPOS suppliers should also be aware of the various legal arguments and strategies to defend against a CMS administrative action or a False Claims Act lawsuit regarding past conduct. Suppliers should not assume the government's informal interpretation of a standard is the only interpretation or even the correct interpretation, nor should suppliers assume that any and every violation of the supplier standards is of equal materiality or significance. Suppliers should recognize that CMS may only try to recoup funds paid after a formal adverse action, not before. Suppliers should be able

to articulate why a particular violation of a supplier standard may not give rise to a false claim (e.g., the standard may not be a condition for payment) and why the government or a litigant cannot prove the other elements of False Claims Act liability. Suppliers should be able to articulate how the regulations or previous government conduct might have been overly vague or confusing and how that uncertainty might have contributed to the suppliers' past conduct in reliance thereon. Finally, suppliers should understand how to argue for a proper measure of damages based on the benefit-of-the-bargain approach.

Conclusion

DMEPOS suppliers can look to the supplier standards as the cornerstone of their operational compliance concerns. The supplier standards can serve as the framework for risk assessments and proactive compliance reviews as part of an overall effective compliance program. In the unfortunate event of an administrative enforcement action or a whistleblower lawsuit under the False Claims Act, DMEPOS suppliers should be certain their legal counsel understands and takes full advantage of the various defenses they can raise in such litigation. ■

1 42 C.F.R. § 424.57(c).

2 J. Gresko, M. McCollum, H. Sorensen, L. Noller: "A Reasoned Approach to Identify-

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DMEPOS and the False Claims Act: Compliance and litigation strategies ...continued from page 47

- ing Federal Health Care Program Overpayments." *Compliance Today Magazine*, vol. 13, no. 2, February 2011, pp 8-11,19.
- 3 *United States ex rel. Cooper v. Gentiva Health Serv's, Inc.*, 2003 WL 22495607 * 9 (W.D. Pa., Nov. 4, 2003). See also *United States ex. rel. Jamison v. McKesson Corp.*, 2011 WL 1158945 * 1 (N.D. Miss., March 28, 2011)
- 4 See e.g., *United States America ex rel. Williams v. Renal Care Group*, 2010 WL 1062634 *10 (M.D. Tenn., March 22, 2010) (listing similar holdings from courts in the 2nd, 5th, 6th, and 7th Circuits); *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 997-1001 (9th Cir. 2010); *United States ex rel. Conner v. Salina Reg'l Health Ctr.*, 543 F.3d 1211, 1217 (10th Cir. 2008); *United States ex rel. Freedman v. Suarez-Hoyos*, 2011 WL 972585 * 8 (M.D. Fla., March 18, 2011); *United States ex rel. Landers v. Baptist Memorial Health Care Corp.*, 25 F. Supp. 2d 972 (W.D. Tenn., 2007).
- 5 42 C.F.R. § 424.5.
- 6 See e.g., *United States ex. rel. Jamison v. McKesson Corp.*, 2011 WL 1158945 * 1 (N.D. Miss., March 28, 2011); *United States ex. rel. Jamison v. McKesson Corp.*, 2009 WL 3176168 (M. D. Miss., Sept. 29, 2009) (supplier standards are a condition for payment based on the three-year enrollment certification).
- 7 42 C.F.R. § 424.57(b)(3).
- 8 *United States ex rel. Cooper v. Gentiva Health Serv's, Inc.*, 2003 WL 22495607 * 9 (W.D. Pa., Nov. 4, 2003).
- 9 *United States ex rel. Jamison*, supra, at *11, 13.
- 10 See, e.g., *United States ex rel. Science Applications Int'l Corp.*, 626 F.3d 1257 (Dec. 3, 2010).
- 11 See, e.g., *United States v. Rogan*, 459 F.Supp.2d 692, 726 (N.D.Ill. 2006), affirmed at 517 F.3d 449 (7th Cir. 2008).
- 12 See, e.g., *United States of America ex rel. Williams v. Renal Care Group*, 2010 WL 1062634 *10 (M.D. Tenn. (March 22, 2010) (calculating government's recovery to be the difference between more expensive rate for home-provision of dialysis equipment and less expensive rate for equipment provided at facilities).
- 13 N. Lacktman, H. Sorensen: "Cold calls, hot lines: DMEPOS telemarketing and beneficiary contact. *HCCA Compliance Today Magazine*, vol. 13, no. 5, May 2011, pp 42-45.

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CORPORATE RESPONSIBILITY AND CORPORATE COMPLIANCE:

*A Resource for Health Care
Boards of Directors*



**THE OFFICE OF INSPECTOR GENERAL OF THE
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**
AND
THE AMERICAN HEALTH LAWYERS ASSOCIATION

ACKNOWLEDGEMENT

This educational resource represents a unique collaboration between the American Health Lawyers Association and the Office of the Inspector General of the United States Department of Health and Human Services. This publication would have not been possible without the dedicated effort of numerous individuals at both organizations. It is intended to be a useful resource for those serving on the Boards of Directors of our nation's health care institutions.

I. INTRODUCTION

As corporate responsibility issues fill the headlines, corporate directors are coming under greater scrutiny. The Sarbanes-Oxley Act, state legislation, agency pronouncements, court cases and scholarly writings offer a myriad of rules, regulations, prohibitions, and interpretations in this area. While all Boards of Directors must address these issues, directors of health care organizations also have important responsibilities that need to be met relating to corporate compliance requirements unique to the health care industry. The expansion of health care regulatory enforcement and compliance activities and the heightened attention being given to the responsibilities of corporate directors are critically important to all health care organizations. In this context, enhanced oversight of corporate compliance programs is widely viewed as consistent with and essential to ongoing federal and state corporate responsibility initiatives.

Our complex health care system needs dedicated and knowledgeable directors at the helm of both for-profit and non-profit corporations. This educational resource, co-sponsored by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services and the American Health Lawyers Association, the leading health law educational organization, seeks to assist directors of health care organizations in carrying out their important oversight responsibilities in the current challenging health care environment. Improving the knowledge base and effectiveness of those serving on health care organization boards will help to achieve the important goal of continuously improving the U.S. health care system.

Fiduciary Responsibilities

The fiduciary duties of directors reflect the expectation of corporate stakeholders regarding oversight of corporate affairs. The basic fiduciary duty of care principle, which requires a director to act in good faith with the care an ordinarily prudent person would exercise under similar circumstances, is being tested in the current corporate climate. Personal liability for directors, including removal, civil damages, and tax liability, as well as damage to reputation, appears not so far from reality as once widely believed. Accordingly, a basic understanding of the director's fiduciary obligations and how the duty of care may be exercised in overseeing the company's compliance systems has become essential.

Embedded within the duty of care is the concept of reasonable inquiry. In other words, directors should make inquiries to management to obtain information necessary

to satisfy their duty of care. Although in the *Caremark* case, also discussed later in this educational resource, the court found that the Caremark board did not breach its fiduciary duty, the court's opinion also stated the following: "[A] director's obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the Board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards." Clearly, the organization may be at risk and directors, under extreme circumstances, also may be at risk if they fail to reasonably oversee the organization's compliance program or act as mere passive recipients of information.

On the other hand, courts traditionally have been loath to second-guess Boards of Directors that have followed a careful and thoughtful process in their deliberations, even where ultimate outcomes for the corporation have been negative. Similarly, courts have consistently upheld the distinction between the duties of Boards of Directors and the duties of management. The responsibility of directors is to provide oversight, not manage day-to-day affairs. It is the process the Board follows in establishing that it had access to sufficient information and that it has asked appropriate questions that is most critical to meeting its duty of care.

Purpose of this Document

This educational resource is designed to help health care organization directors ask knowledgeable and appropriate questions related to health care corporate compliance. These questions are not intended to set forth any specific standard of care. Rather, this resource will help corporate directors to establish, and affirmatively demonstrate, that they have followed a reasonable compliance oversight process.

Of course, the circumstances of each organization differ and application of the duty of care and consequent reasonable inquiry will need to be tailored to each specific set of facts and circumstances. However, compliance with the fraud and abuse laws and other federal and state regulatory laws applicable to health care organizations is essential for the lawful behavior and corporate success of such organizations. While these laws can be complex, effective compliance is an asset for both the organization and the health care delivery system. It is hoped that this educational resource is useful to health care organization directors in exercising their oversight responsibilities and supports their ongoing efforts to promote effective corporate compliance.

II. DUTY OF CARE

Of the principal fiduciary obligations/duties owed by directors to their corporations, the one duty specifically implicated by corporate compliance programs is the *duty of care*.¹

As the name implies, the *duty of care* refers to the obligation of corporate directors to exercise the proper amount of care in their decision-making process. State statutes that create the duty of care and court cases that interpret it usually are identical for both for-profit and non-profit corporations.

In most states, duty of care involves determining whether the directors acted (1) in “good faith,” (2) with that level of care that an ordinarily prudent person would exercise in like circumstances, and (3) in a manner that they reasonably believe is in the best interest of the corporation. In analyzing whether directors have complied with this duty, it is necessary to address each of these elements separately.

The “good faith” analysis usually focuses upon whether the matter or transaction at hand involves any improper financial benefit to an individual, and/or whether any intent exists to take advantage of the corporation (a corollary to the duty of loyalty). The “reasonable inquiry” test asks whether the directors conducted the appropriate level of due diligence to allow them to make an informed decision. In other words, directors must be aware of what is going on about them in the corporate business and must in appropriate circumstances make such reasonable inquiry, as would an ordinarily prudent person under similar circumstances. And, finally, directors are obligated to act in a manner that they reasonably believe to be in the best interests of the corporation. This normally relates to the directors’ state of mind with respect to the issues at hand.

In considering directors’ fiduciary obligations, it is important to recognize that the appropriate standard of care is not “perfection.” Directors are *not* required to know everything about a topic they are asked to consider. They may, where justified, rely on the advice of management and of outside advisors.

Furthermore, many courts apply the “business judgment rule” to determine whether a director’s duty of care has been met with respect to corporate decisions. The rule

provides, in essence, that a director will not be held liable for a decision made in good faith, where the director is disinterested, reasonably informed under the circumstances, and rationally believes the decision to be in the best interest of the corporation.

Director obligations with respect to the duty of care arise in two distinct contexts:

- The *decision-making function*: The application of duty of care principles to a specific decision or a particular board action; and
- The *oversight function*: The application of duty of care principles with respect to the general activity of the board in overseeing the day-to-day business operations of the corporation; *i.e.*, the exercise of reasonable care to assure that corporate executives carry out their management responsibilities and comply with the law.

Directors’ obligations with respect to corporate compliance programs arise within the context of that oversight function. The leading case in this area, viewed as applicable to all health care organizations, provides that a director has two principal obligations with respect to the oversight function. A director has a duty to attempt in good faith to assure that (1) a corporate information and reporting system exists, and (2) this reporting system is adequate to assure the board that appropriate information as to compliance with applicable laws will come to its attention in a timely manner as a matter of ordinary operations.² In *Caremark*, the court addressed the circumstances in which corporate directors may be held liable for breach of the duty of care by failing to adequately supervise corporate employees whose misconduct caused the corporation to violate the law.

In its opinion, the *Caremark* court observed that the level of detail that is appropriate for such an information system is a matter of business judgment. The court also acknowledged that no rationally designed information and reporting system will remove the possibility that the corporation will violate applicable laws or otherwise fail to identify corporate acts potentially inconsistent with relevant law.

Under these circumstances, a director’s failure to reasonably oversee the implementation of a compliance program may put the organization at risk and, under extraordinary circumstances, expose individual directors to personal liability for losses caused by the corporate non-

1 The other two core fiduciary duty principals are the duty of loyalty and the duty of obedience to purpose.

2 *In re Caremark International Inc. Derivative Litigation*, 698 A.2d 959 (Del. Ch. 1996). A shareholder sued the Board of Directors of Caremark for breach of the fiduciary duty of care. The lawsuit followed a multi-million dollar civil settlement and criminal plea relating to the payment of kickbacks to physicians and improper billing to federal health care programs.

compliance.³ Of course, crucial to the oversight function is the fundamental principle that a director is entitled to rely, in good faith, on officers and employees as well as corporate professional experts/advisors in whom the director believes such confidence is merited. A director, however, may be viewed as not acting in good faith if he/she is aware of facts suggesting that such reliance is unwarranted.

In addition, the duty of care test involving reasonable inquiry has not been interpreted to require the director to exercise “proactive vigilance” or to “ferret out” corporate wrongdoing absent a particular warning or a “red flag.” Rather, the duty to make reasonable inquiry increases when “suspicions are aroused or *should be aroused*;” that is, when the director is presented with extraordinary facts or circumstances of a material nature (*e.g.*, indications of financial improprieties, self-dealing, or fraud) or a major governmental investigation. Absent the presence of suspicious conduct or events, directors are entitled to rely on the senior leadership team in the performance of its duties. Directors are not otherwise obligated to anticipate future problems of the corporation.

Thus, in exercising his/her duty of care, the director is obligated to exercise general supervision and control with respect to corporate officers. However, once presented (through the compliance program or otherwise) with information that causes (or should cause) concerns to be aroused, the director is then obligated to make further inquiry until such time as his/her concerns are satisfactorily addressed and favorably resolved. Thus, while the corporate director is not expected to serve as a compliance officer, he/she is expected to oversee senior management’s operation of the compliance program.

III. THE UNIQUE CHALLENGES OF HEALTH CARE ORGANIZATION DIRECTORS

The health care industry operates in a heavily regulated environment with a variety of identifiable risk areas. An effective compliance program helps mitigate those risks. In addition to the challenges associated with patient care, health care providers are subject to voluminous and sometimes complex sets of rules governing the coverage and reimbursement of medical services. Because federal and state-sponsored health care programs play such a significant role in paying for health care, material non-compliance with these rules can present substantial risks to the

health care provider. In addition to recoupment of improper payments, the Medicare, Medicaid and other government health care programs can impose a range of sanctions against health care businesses that engage in fraudulent practices.

Particularly given the current “corporate responsibility” environment, health care organization directors should be concerned with the manner in which they carry out their duty to oversee corporate compliance programs. Depending upon the nature of the corporation, there are a variety of parties that might in extreme circumstances seek to hold corporate directors personally liable for allegedly breaching the duty of oversight with respect to corporate compliance. With respect to for-profit corporations, the most likely individuals to bring a case against the directors are corporate shareholders in a derivative suit, or to a limited degree, a regulatory agency such as the Securities and Exchange Commission. With respect to non-profit corporations, the most likely person to initiate such action is the state attorney general, who may seek equitable relief against the director (*e.g.*, removal) or damages. It is also possible (depending upon state law) that a dissenting director, or the corporate member, could assert a derivative-type action against the directors allegedly responsible for the “inattention,” seeking removal or damages.

Over the last decade, the risks associated with non-compliance have grown dramatically. The government has dedicated substantial resources, including the addition of criminal investigators and prosecutors, to respond to health care fraud and abuse. In addition to government investigators and auditors, private whistleblowers play an important role in identifying allegedly fraudulent billing schemes and other abusive practices. Health care providers can be found liable for submitting claims for reimbursement in reckless disregard or deliberate ignorance of the truth, as well as for intentional fraud. Because the False Claims Act authorizes the imposition of damages of up to three times the amount of the fraud and civil monetary penalties of \$11,000 per false claim, record level fines and penalties have been imposed against individuals and health care organizations that have violated the law.

In addition to criminal and civil monetary penalties, health care providers that are found to have defrauded the federal health care programs may be excluded from participation in these programs. The effect of an exclusion can be profound because those excluded will not

³ Law is not static, and different states will have different legal developments and standards. Standards may also vary depending on whether an entity is for profit or non-profit. Boards of public health care entities may have additional statutory obligations and should be aware of state and federal statutory requirements applicable to them.

receive payment under Medicare, Medicaid or other federal health care programs for items or services provided to program beneficiaries. The authorities of the OIG provide for mandatory exclusion for a minimum of five years for a conviction with respect to the delivery of a health care item or service. The presence of aggravating circumstances in a case can lead to a lengthier period of exclusion. Of perhaps equal concern to board members, the OIG also has the discretion to exclude providers for certain conduct even absent a criminal conviction. Such conduct includes participation in a fraud scheme, the payment or receipt of kickbacks, and failing to provide services of a quality that meets professionally recognized standards. In lieu of imposing exclusion in these instances, the OIG may require an organization to implement a comprehensive compliance program, requiring independent audits, OIG oversight and annual reporting requirements, commonly referred to as a Corporate Integrity Agreement.

IV. THE DEVELOPMENT OF COMPLIANCE PROGRAMS

In light of the substantial adverse consequences that may befall an organization that has been found to have committed health care fraud, the health care industry has embraced efforts to improve compliance with federal and state health care program requirements. As a result, many health care providers have developed active compliance programs tailored to their particular circumstances. A recent survey by the Health Care Compliance Association, for example, has found that in just three years, health care organizations with active compliance programs have grown from 55 percent in 1999 to 87 percent in 2002. In support of these efforts, the OIG has developed a series of provider-specific compliance guidances. These voluntary guidelines identify risk areas and offer concrete suggestions to improve and enhance an organization's internal controls so that its billing practices and other business arrangements are in compliance with Medicare's rules and regulations.

As compliance programs have matured and new challenges have been identified, health care organization boards of directors have sought ways to help their organization's compliance program accomplish its objectives. Although health care organization directors may come from diverse backgrounds and business experiences, an individual director can make a valuable contribution toward the compliance objective by asking practical questions of management and contributing his/her experiences from other industries. While the opinion in *Caremark* established a Board's duty to oversee a compliance program, it did not enumerate a specific methodology for

doing so. It is therefore important that directors participate in the development of this process. This educational resource is designed to assist health care organization directors in exercising that responsibility.

V. SUGGESTED QUESTIONS FOR DIRECTORS

Periodic consideration of the following questions and commentary may be helpful to a health care organization's Board of Directors. The structural questions explore the Board's understanding of the scope of the organization's compliance program. The remaining questions, addressing operational issues, are directed to the operations of the compliance program and may facilitate the Board's understanding of the vitality of its compliance program.

STRUCTURAL QUESTIONS

- 1. How is the compliance program structured and who are the key employees responsible for its implementation and operation? How is the Board structured to oversee compliance issues?**

The success of a compliance program relies upon assigning high-level personnel to oversee its implementation and operations. The Board may wish as well to establish a committee or other subset of the Board to monitor compliance program operations and regularly report to the Board.

- 2. How does the organization's compliance reporting system work? How frequently does the Board receive reports about compliance issues?**

Although the frequency of reports on the status of the compliance program will depend on many circumstances, health care organization Boards should receive reports on a regular basis. Issues that are frequently addressed include (1) what the organization has done in the past with respect to the program and (2) what steps are planned for the future and why those steps are being taken.

- 3. What are the goals of the organization's compliance program? What are the inherent limitations in the compliance program? How does the organization address these limitations?**

The adoption of a corporate compliance program by an organization creates standards and processes that it should be able to rely upon and against which it may be held accountable. A solid understanding of the rationale and objectives of the compliance program, as well as its goals and inherent limitations, is essential if the Board is to evaluate the reasonableness of its design and the effectiveness of its operation. If the Board has unrealistic expectations of its compliance program, it may place undue reliance

on its ability to detect vulnerabilities. Furthermore, compliance programs will not prevent all wrongful conduct and the Board should be satisfied that there are mechanisms to ensure timely reporting of suspected violations and to evaluate and implement remedial measures.

4. Does the compliance program address the significant risks of the organization? How were those risks determined and how are new compliance risks identified and incorporated into the program?

Health care organizations operate in a highly regulated industry and must address various standards, government program conditions of participation and reimbursement, and other standards applicable to corporate citizens irrespective of industry. A comprehensive ongoing process of compliance risk assessment is important to the Board's awareness of new challenges to the organization and its evaluation of management's priorities and program resource allocation.

5. What will be the level of resources necessary to implement the compliance program as envisioned by the Board? How has management determined the adequacy of the resources dedicated to implementing and sustaining the compliance program?

From the outset, it is important to have a realistic understanding of the resources necessary to implement and sustain the compliance program as adopted by the Board. The initial investment in establishing a compliance infrastructure and training the organization's employees can be significant. With the adoption of a compliance program, the organization is making a long term commitment of resources because effective compliance systems are not static programs but instead embrace continuous improvement. Quantifying the organization's investment in compliance efforts gives the Board the ability to consider the feasibility of implementation plans against compliance program goals. Such investment may include annual budgetary commitments as well as direct and indirect human resources dedicated to compliance. To help ensure that the organization is realizing a return on its compliance investment, the Board also should consider how management intends to measure the effectiveness of its compliance program. One measure of effectiveness may be the Board's heightened sensitivity to compliance risk areas.

OPERATIONAL QUESTIONS

The following questions are suggested to assist the Board in its periodic evaluation of the effectiveness of the organization's compliance program and the sufficiency of its reporting systems.

A. Code of Conduct

How has the Code of Conduct or its equivalent been incorporated into corporate policies across the organization? How do we know that the Code is understood and accepted across the organization? Has management taken affirmative steps to publicize the importance of the Code to all of its employees?

Regardless of its title, a Code of Conduct is fundamental to a successful compliance program because it articulates the organization's commitment to ethical behavior. The Code should function in the same way as a constitution, *i.e.*, as a document that details the fundamental principles, values, and framework for action within the organization. The Code of Conduct helps define the organization's culture; all relevant operating policies are derivative of its principles. As such, codes are of real benefit only if meaningfully communicated and accepted throughout the organization.

B. Policies and Procedures

Has the organization implemented policies and procedures that address compliance risk areas and established internal controls to counter those vulnerabilities?

If the Code of Conduct reflects the organization's ethical philosophy, then its policies and procedures represent the organization's response to the day-to-day risks that it confronts while operating in the current health care system. These policies and procedures help reduce the prospect of erroneous claims, as well as fraudulent activity by identifying and responding to risk areas. Because compliance risk areas evolve with the changing reimbursement rules and enforcement climate, the organization's policies and procedures also need periodic review and, where appropriate, revision.⁴ Regular consultation with counsel, including reports to the Board, can assist the Board in its oversight responsibilities in this changing environment.

⁴ There are a variety of materials available to assist health care organizations in this regard. For example, both sponsoring organizations of this educational resource offer various materials and guidance, accessible through their web sites.

C. Compliance Infrastructure

- 1. Does the Compliance Officer have sufficient authority to implement the compliance program? Has management provided the Compliance Officer with the autonomy and sufficient resources necessary to perform assessments and respond appropriately to misconduct?**

Designating and delegating appropriate authority to a compliance officer is essential to the success of the organization's compliance program. For example, the Compliance Officer must have the authority to review all documents and other information that are relevant to compliance activities. Boards should ensure that lines of reporting within management and to the Board, and from the Compliance Officer and consultants, are sufficient to ensure timely and candid reports for those responsible for the compliance program. In addition, the Compliance Officer must have sufficient personnel and financial resources to implement fully all aspects of the compliance program.

- 2. Have compliance-related responsibilities been assigned across the appropriate levels of the organization? Are employees held accountable for meeting these compliance-related objectives during performance reviews?**

The successful implementation of a compliance program requires the distribution throughout the organization of compliance-related responsibilities. The Board should satisfy itself that management has developed a system that establishes accountability for proper implementation of the compliance program. The experience of many organizations is that program implementation lags where there is poor distribution of responsibility, authority and accountability beyond the Compliance Officer.

D. Measures to Prevent Violations

- 1. What is the scope of compliance-related education and training across the organization? Has the effectiveness of such training been assessed? What policies/measures have been developed to enforce training requirements and to provide remedial training as warranted?**

A critical element of an effective compliance program is a system of effective organization-wide training on compliance standards and procedures. In addition, there should be specific training on identified risk areas, such as claims development and submission, and marketing practices.

Because it can represent a significant commitment of resources, the Board should understand the scope and effectiveness of the educational program to assess the return on that investment.

- 2. How is the Board kept apprised of significant regulatory and industry developments affecting the organization's risk? How is the compliance program structured to address such risks?**

The Board's oversight of its compliance program occurs in the context of significant regulatory and industry developments that impact the organization not only as a health care organization but more broadly as a corporate entity. Without such information, it cannot reasonably assess the steps being taken by management to mitigate such risks and reasonably rely on management's judgment.

- 3. How are "at risk" operations assessed from a compliance perspective? Is conformance with the organization's compliance program periodically evaluated? Does the organization periodically evaluate the effectiveness of the compliance program?**

Compliance risk is further mitigated through internal review processes. Monitoring and auditing provide early identification of program or operational weaknesses and may substantially reduce exposure to government or whistleblower claims. Although many assessment techniques are available, one effective tool is the performance of regular, periodic compliance audits by internal or external auditors. In addition to evaluating the organization's conformance with reimbursement or other regulatory rules, or the legality of its business arrangements, an effective compliance program periodically reviews whether the compliance program's elements have been satisfied.

- 4. What processes are in place to ensure that appropriate remedial measures are taken in response to identified weaknesses?**

Responding appropriately to deficiencies or suspected non-compliance is essential. Failure to comply with the organization's compliance program, or violation of applicable laws and other types of misconduct, can threaten the organization's status as a reliable and trustworthy provider of health care. Moreover, failure to respond to a known deficiency may be considered an aggravating circumstance in evaluating the organization's potential liability for the underlying problem.

E. Measures to Respond to Violations

- 1. What is the process by which the organization evaluates and responds to suspected compliance violations? How are reporting systems, such as the compliance hotline, monitored to verify appropriate resolution of reported matters?**

Compliance issues may range from simple overpayments to be returned to the payor to possible criminal violations. The Board's duty of care requires that it explore whether procedures are in place to respond to credible allegations of misconduct and whether management promptly initiates corrective measures. Many organizations take disciplinary actions when a responsible employee's conduct violates the organization's Code of Conduct and policies. Disciplinary measures should be enforced consistently.

- 2. Does the organization have policies that address the appropriate protection of "whistleblowers" and those accused of misconduct?**

For a compliance program to work, employees must be able to ask questions and report problems. In its fulfillment of its duty of care, the Board should determine that the organization has a process in place to encourage such constructive communication.

- 3. What is the process by which the organization evaluates and responds to suspected compliance violations? What policies address the protection of employees and the preservation of relevant documents and information?**

Legal risk may exist based not only on the conduct under scrutiny, but also on the actions taken by the organization in response to the investigation. In addition to a potential obstruction of a government investigation, the organization may face charges by employees that it has unlawfully retaliated or otherwise violated employee rights. It is important, therefore, that organizations respond appropriately to a suspected compliance violation and, more critically, to a government investigation without damaging the corporation or the individuals involved. The Board should confirm that processes and policies for such responses have been developed in consultation with legal counsel and are well communicated and understood across the organization.

- 4. What guidelines have been established for reporting compliance violations to the Board?**

As discussed, the Board should fully understand management's process for evaluating and responding to identified violations of the organization's policies, as well as applicable federal and state laws. In addition, the Board should receive sufficient information to evaluate the appropriateness of the organization's response.

- 5. What policies govern the reporting to government authorities of probable violations of law?**

Different organizations will have various policies for investigating probable violations of law. Federal law encourages organizations to self-disclose wrongdoing to the federal government. Health care organizations and their counsel have taken varied approaches to making such disclosures. Boards may want to inquire as to whether the organization has developed a policy on when to consider such disclosures.

VI. Conclusion

The corporate director, whether voluntary or compensated, is a bedrock of the health care delivery system. The oversight activities provided by the director help form the corporate vision, and at the same time promote an environment of corporate responsibility that protects the mission of the corporation and the health care consumers it serves.

Even in this "corporate responsibility" environment, the health care corporate director who is mindful of his/her fundamental duties and obligations, and sensitive to the premises of corporate responsibility, should be confident in the knowledge that he/she can pursue governance service without needless concern about personal liability for breach of fiduciary duty and without creating an adversarial relationship with management.

The perspectives shared in this educational resource are intended to assist the health care director in performing the important and necessary service of oversight of the corporate compliance program. In so doing, it is hoped that fiduciary service will appear less daunting, and provide a greater opportunity to "make a difference" in the delivery of health care.

**BEST PRACTICES FOR MEDICARE
AND MEDICAID EMR INCENTIVE
PROGRAMS**

Regina Gurvich, MBA CHC
Chief Compliance Officer, AdvantageCare Physicians

- Monitoring compliance with Meaningful Use requirements
- ‘Audit-ready’—documentation retention to support meaningful use and Clinical Quality Measure attestations
- Risk-avoidance – pitfalls of False Claims Act liability

I CERTIFY THAT...

- ... the foregoing information is true, accurate, and complete. I understand that the Medicare EMR Incentive Program payment requested will be paid from Federal funds, and that the use of any false claims, statements, or documents, or the concealment of material fact used to obtain Medicare EMR Incentive Program payment, may be prosecuted under applicable Federal or State criminal laws and may be subject to civil penalties.”

STAGED APPROACH TO MU

- Stage I
 - 2011-2012 – EMR adoption, data capturing, and sharing
- Stage II
 - 2014 – Promoting of information sharing between providers, patient engagement, and advanced clinical processes
- Stage III
 - 2016 – Improving health outcomes

4

ELIGIBILITY, HOSPITALS

Medicare

- Hospitals paid under Inpatient Prospective Payment System (IPPS)
- Critical Access Hospitals (CAHs)
- Medicare Advantage (MA Affiliated) Hospitals

Medicaid

- *Acute care hospitals (including CAHs and cancer centers) with >10% Medicaid volume*
- *Children's Hospitals (No Medicaid volume requirement)*

5

ELIGIBILITY, PROFESSIONALS

Medicare

- Doctors of Medicine or Osteopathy
- Doctors of Dental Surgery or Dental Medicine
- Doctors of Podiatric Medicine
- Doctors of Optometry
- Chiropractors

Medicaid

- Physicians
- Nurse Practitioners
- Certified Nurse Midwives
- Dentists
- Physician Assistants

6

INCENTIVE OPPORTUNITY**Medicare**

- \$44,000
 - For eligible provider
 - Over a 5 year period
 - Maybe subject to a 2% sequestration cut

Medicaid

- \$63,750
 - For eligible Medicaid professionals
 - Over a 6 year period

7

MU MEASURES

- Percentage based measures
- Yes/ No measures
- and...Risk-Assessment

8

CMS AUDIT INITIATIVE

9

THE “5%”

- OIG criticism of lack of CMS oversight
 - CMS to audit Medicare & dual providers
 - States to audit Medicaid providers participating in Medicaid EMR program

10

CMS PRE-PAYMENT AUDITS

- Edits in place to scrub for eligibility, reporting, and payment
- Additional edits targeting last minutes submissions
 - Random
 - Targeting anomalous data
- Supporting documentation for both pre- and post-payment audits must support
 - MU eligibility criteria
 - Clinical quality

11

WHAT TO DO WHEN YOU GET AUDITED...

DO's

- Establish timeline for response
- Gather primary source documents
- Verify accuracy against original submission
- Know thy measures
- Centralize coordination of response

DON'Ts

- Re-create the documents
- Backdate/ change records
- Ignore discrepancies
- Act in silo
- Miss opportunity to appeal adverse result!

12

PRIMARY SUPPORTING DOCUMENTATION

- Numerators and denominators for the measures
- Time period under report
- Evidence to support that it was generated for eligible provider
 - NPI, CCN, Provider Name, Practice name
- Documentation demonstrating data accumulation & calculation

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MEDICARE AUDIT PROCESS

- Initial request letter
 - Figliootti & Co
 - Electronic notification from CMS email address
- Desk review or on-site review
- Audit Determination letter
 - MU criteria 'successfully met'
 - Recoupment of payment

14

CMS APPEAL CATEGORIES

- Eligibility Appeal
- Meaningful Use Appeal

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CMS APPEALS

- For general appeal questions/updates on the status of pending appeals email <https://questions.cms.gov/newrequest.php>
- For info on filing appeal and status of pending, 888-734-6433
- Timeframe
 - MU – within 30 days after the date of recoupment demand letter
 - Incentive payment calculation – within 60 days of determination

16

MEDICAID APPEAL PROCESS

- State Medicaid Agencies handle the process

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COMMON ISSUES & RISKS

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COMMON ISSUES

- Data security risk assessment
- Lack of support for yes/no MU criteria

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SECURITY RISK ASSESSMENT

- HIPAA vs. Meaningful Use requirement
- Detailed analysis
- Specific to Eligible Provider & EMR
- Stage II vs. Stage I -
 - Encryption/ security of data at rest
 - Assessment must be completed before the end of the reporting period

20

SECURITY RISK AREAS

Security Areas to Consider		Examples of Potential Security Measures
Physical Safeguards	<ul style="list-style-type: none"> • Your facility and other places where patient data is accessed • Computer access • Portable devices 	<ul style="list-style-type: none"> • Building alarm systems • Locked offices • Screens shielded from secondary viewers
Administrative Safeguards	<ul style="list-style-type: none"> • Designated security officer • Monitoring and oversight • Controlling information access • Periodic security reassessment 	<ul style="list-style-type: none"> • Staff training • Monthly review of user activities • Policy enforcement
Technical Safeguards	<ul style="list-style-type: none"> • Controls on access to EHR • Use of audit logs to monitor users and other EHR activities • Monitoring and securing electronic patient data from improper changes • Secure, authorized electronic exchanges of patient information 	<ul style="list-style-type: none"> • Secure passwords • Backing-up data • Virus checks • Data encryption
Policies & Procedures	<ul style="list-style-type: none"> • Written policies and procedures to assure HIPAA security compliance • Documentation of security measures 	<ul style="list-style-type: none"> • Written protocols on authorizing users • Record retention
Organizational Requirements	<ul style="list-style-type: none"> • Business associate agreements 	<ul style="list-style-type: none"> • Policies for identifying and managing vendors who access, create or store PHI • Agreement review and updates

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DOCUMENT RETENTION

- 6 years post-attestation retention for MU criteria
 - documents supporting MU objectives
 - clinical quality measures
- EMR contract/ service agreements
 - Clause on documentation retention by vendor

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ENFORCEMENT RISK

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ENFORCEMENT RISK OF AUDIT

- Referral of fraud cases to CMS or OIG
- Enforcement to date
- Risk associated with FCA:
 - "Knowingly"
 - "Claim"
 - "Obligation of repayment"
 - "Obligation of reporting"
- Criminal liability

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REFERENCES

- o [www.cms.gov/EHRIncentive Programs/](http://www.cms.gov/EHRIncentive%20Programs/)
- o CMS Specification Sheets
- o Federal Register
- o CMS FAQ's
- o ONC FAQ's (healthit.hhs.gov)
- o Federal advisory committee meeting minutes
- o EMR Information Center (888-734-6433)
- o EMR Incentive Programs Listserv

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CONTACT

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Care Management Can We Do It Better?

Wilma Acosta,
Associate Director
Protiviti, Inc.

Alex Robison,
Managing Director
Protiviti, Inc.

Agenda

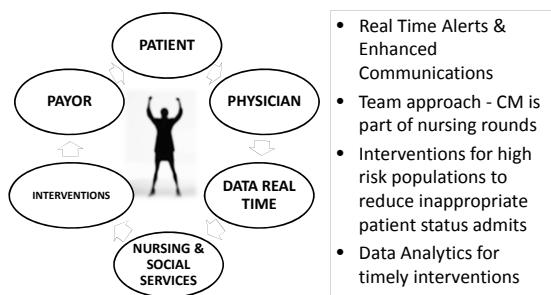
- I. Care Management Challenges
- II. Compliance Case Studies
 - Intermittently throughout Presentation
- III. Audits Methods
 - Traditional vs Innovative
- IV. Care Management – Models
 - Considerations for Future State
 - Workflows, Department Configurations
- V. Discussions – Q&A

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2

CARE MANAGEMENT

Data Analytics for New Model



- Real Time Alerts & Enhanced Communications
- Team approach - CM is part of nursing rounds
- Interventions for high risk populations to reduce inappropriate patient status admits
- Data Analytics for timely interventions

3/13/2014

3

Care Management Payors World

- Payors

- Medicare/Medicaid and other Federally Funded programs coverage and payment methods dictate patient bed status -
 - No two exact - default to **CMS Medicare Manual**

But should this be the Norm?

- What about ACOs, Managed Care and Employer Plans,?

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4

Care Management Challenges

Challenges – Clinical and Regulatory

- InterQual and Milliman Criteria
 - Local / National Coverage Determinations (LCDs) (NCDs)
 - Physician Advocate / Advisors
 - 2 midnight Rule
 - Observation
 - 1 day stays
 - Outpatient in a bed
 - Condition code 44

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5

Case Study #1

- Health system A (HS-A) with large oncology services admits a patient for inpatient chemotherapy. HS-A obtains pre-admit approval from Medicaid for 2 days inpatient chemo infusion therapy. Reason: patient had difficult time with chemo – severe reaction and requires monitoring for uncontrolled Nausea / Vomiting / Dehydration.
 - Upon external audit review, the reviewer determined this patient should not have been admitted as inpatient but instead placed in observation.

Case Denied for 1 day stay.

Which of the following do you think was the cause of the denial?

- Patient tolerated chemo, stable, no major reactions noted on next day.

□ Patient's history of difficulty with chemo therapy, and family social issues noted by physician as reason for admission.

□ Discharge patient had no unusual chemo reactions, stable and able to go home noted on same day of chemo.

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6

AUDIT METHODS TO DO OR NOT TO DO?

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7

Traditional Audit Processes

Typically, review x number of charts

- A selection of 1 day stays and observations
- Policies and procedures are reviewed
- Claims reviewed
- Findings are provided to case management – compliance not generally included

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8

Traditional Audit Processes

General Recommendations:

- Use CMS Medicare Inpatient Only List
- Know InterQual and Milliman
- Know CMS rules regarding observation criteria
- Employ physician advocate , e.g. Executive Health Resources, Accretive,
- Use Condition 44....***carefully***
- Have CMS' in Emergency Room & weekend coverage

But upon Follow-up no major changes!

Lack of Changes, Controls or Improvements

Risk of repayment and Focus review same or increased.

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Traditional Audits Revealed

- CMs do not assess potential admission within 4-6 hours of arrival to hospital
- Cases were not reviewed by payor type
- First come/ First Served – therefore an observation order may not be timely obtained
- 24 hour coverage in key patient areas, Emergency, Post-op recovery, were not supported by schedules or actual staffing
- CM performing clerical / Admin duties
- Social Service Workers were not part of the interdisciplinary team in Emergency Department, they were not handling the complex social issues

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10

Audit To Think Out Of The Box!

- Create a new audit process with compliance involved
- Identify what did not yield long term sustainable results
 - Chart to claim audit not sufficient
 - Evaluation of care management tools not sufficient
 - More forms or staffing not sufficient

Consider

- The 3 W's of Auditing Care Management
 - What to review
 - Who to review
 - When to review

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New Audit Concept

What:

- Patients in Emergency, Outpatient Surgical Areas, Cath Lab, Interventional Radiology, Pre-op
- Systems utilized for CM e.g. InterQual, Midas,
- Forms and clinical policies, orders,

Who

- Staff competencies
- Physician Advisor / Advocate process
- ED Chief, PACU Chief, Post-op Recovery Nurse Director

When

- Review the entire CM process from time patient enters system to patient final disposition / discharge
- Round / Shadow / Observe evenings, weekends with CM team

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New Audit**Concept** *cont.*

- Observe CM real time in the actual departments where patients first enter the hospital
 - Emergency Room (ED)Outpatient procedures; such as Interventional Radiology, Cath Lab, Post Op Recovery, Endoscopy, Infusion Center, Day Surgery
- Shadow the CMs during peak times - weekend and late evenings
- Interview Surgery Scheduler(s) for use of Medicare Inpatient Only List
- Interview the Physician Advisor (phone interview if external)

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Compliance Gets Involved

Compliance should have role in the development of training materials

Compliance should be the final reference source for CMS rule interpretations

- Set the definitions of observation, 2 midnight rule, etc
- Write the education for the Care Managers
- Provide interpretation of rules and regulations for consistency
- ***Do Not Let Care Management Director Interpret Medicare Language!***

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Compliance Gets Involved

- Be notified when Care Management reviews denials of patient status.
 - Approve the change / write the standards for changing the patient status to obtain payment
- Know the workflow and processes and monitor frequently
- Ensure clinical Care Management has competent staff

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Case Study #2

- Emergency room of a Trauma I center, it is Saturday morning, 8:30am, the CM is sent to 6th floor to cover med-surgical unit.
- No CM was left to cover the Emergency Dept. 2 patients in behavioral health crisis arrived 10:05am , 10 year old with severe lacerations @ 10:35, and 3 MVAs Trauma 1 arrived in ER within 10 minutes of each other around 11:30, meanwhile there were 3 patients awaiting bed placement and no observation orders.
 - Key to know that 2 of the MVAs and the 3 awaiting bed placement were Medicare and Medicaid patients.

What should hospital do, since the CM is also the UR coordinator for the day and must handle the discharges and backlog of patients in 1 and 2 day stays and those already in Observation > 48 hours?

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MODEL SOLUTIONS

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CM MODEL - Emergency Dept.

CM works from a central location in the ED assessing and reassessing all arrivals to ED focusing first on Medicare and Medicaid patients.

Emergency Room Care Manager

- Assess new arrivals to ED with 2-4 hours
- Reassess all ED patients in a bed > than 8-10 hours
- Covers outpatient surgical and interventional areas
- Discharge Plans for outpatients in a bed = < 24 hours
- 1 day Stays and Condition Code 44 & Assess Readmissions
- Manages all Medicare and Medicaid admits in first 24 hours

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UR Centralization Model

UR works remotely or from a central location in the hospital managing cases not requiring daily review/assessments, back up for CM staff and serve as super users.

Centralized Utilization Review

- OBS > 48 hrs & 10 Day LOS
- Review Readmissions
- Denials related to patient status
- Discharge Plans for inpatients > 24 hours
- Inpatient Surgeries, Pediatrics, General Medical Inpatient > 24 hours
- Condition Code 44 backup
- Super Users - Train new staff
- Coverage

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Support Centralization Model

In this model UR Support works remotely or from a central location in the hospital supporting all CM/UR staff and serve as super users.

Care Support LPN, Nurse Aid, Unit Clerk

- Transportation Arrangements (Taxis, vouchers, ambulances)
- DME/Therapy Scheduling
- Manage return calls from Insurance Companies
- Calling/Faxing/E-mails for information on available services as directed by UR/LSW
- Assist patients/families with forms and placement or discharge processes

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CM Model for Clinical Units

Care Manager

- Rounds with Medical Team in unit
- Assesses Patient Status Determinations
- Reviews Direct Admits
- Reviews Observation cases > 24, and evaluates for potential 2 night midnight admits
- Recognizes and Performs Condition Code 44 procedures
- Completes Concurrent Reviews & 1 Day Stays
- Begins Discharge Plan (Identify type, handoff to LSW)

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Use concept maps to plan CM care

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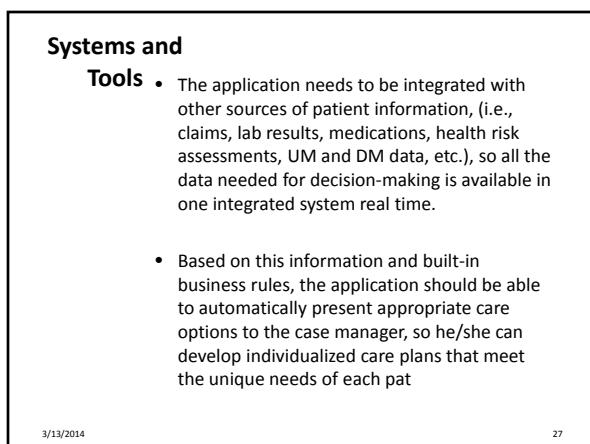
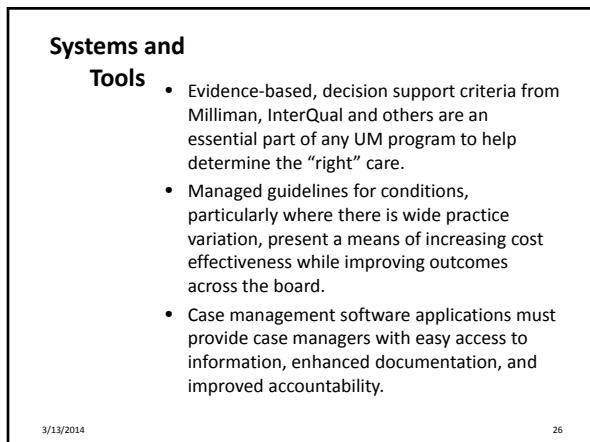
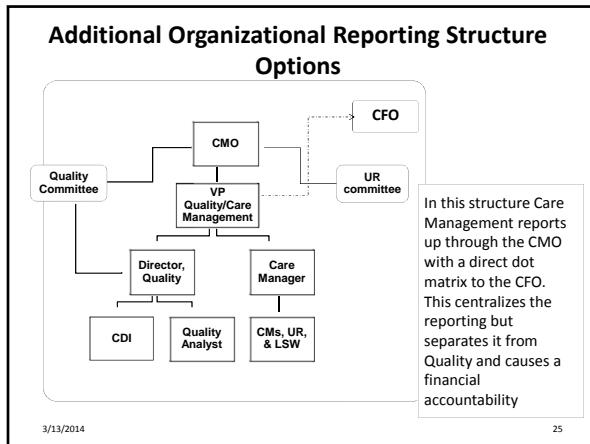
Model Reporting Structures

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Potential New Organizational Reporting Structure Options

In this structure Care Managers and UR Managers are separate and UR Managers report in to Revenue Cycle. They have a dot matrix to Quality and CM. They handle medical necessity denials, and work patient status remotely.

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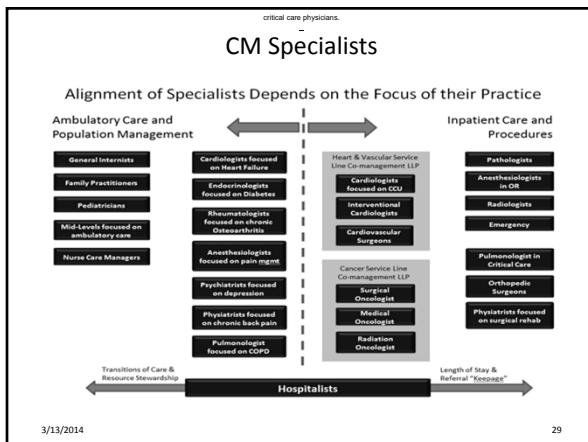


Excerpt from St. Luke's job description

- Provides clinically-based CM to support the delivery of effective and efficient patient care.
 - Has overall accountability for the UM and discharge plan for pts. ***within the assigned caseload.***
 - Collaborates with members of the health care team to identify appropriate utilization of resources and to ***ensure reimbursement.***
 - Utilizes criteria ***to confirm medical necessity*** for admission and continued stay.
 - ***With the patient, family and health care team,*** creates a discharge plan appropriate to the patient's needs and resources.

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Inform Patients of the CM Program – Web Site



St. Francis Hospital
The Heart Center®
Catholic Health Services
At the heart of health

[HOME](#)
[FOR PATIENTS & FAMILIES](#)
[Preparing for a Visit](#)
[Find a Doctor](#)
[Visitor Information](#)
[Contact Us](#)
[Care Management](#)
[Pastoral Care](#)
[Suites and Single Rooms](#)
[Room Service](#)
[Enrolling in Clinical Studies](#)
[Insurance Information](#)
[> Departments & Services](#)
[> Education + Prevention Programs](#)

Care Management

Care Management
At St. Francis Hospital, a team of nurse Care Managers and Social Workers will help plan and assess your care needs before you leave the hospital.

Social Workers

Social Workers at St. Francis provide post-hospital information and referrals, crisis intervention and supportive counseling services. Your Social Worker can help ease your transition after your hospital discharge and offer referrals for community resources to assist in finding alternative care and managing illness.

Care Managers

Care Managers at St. Francis develop and coordinate your continued care services. Such services might include referrals to home care, rehabilitation, IV home infusion, Meals on Wheels and other post-hospital resources. Your Care Manager will research your needs and insurance coverage to find the available and appropriate services for you.

For more information, call the St. Francis Care Management Department at 516-562-6040, Monday through Friday, from 8 a.m. to 6 p.m., and from 8 a.m. to 4 p.m. on weekends and holidays.

<http://www.stfrancisheartcenter.com/patients/visit/caremgmt>

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Inform Patients of the CM Program – Web Site

Care Management

- While you are a patient at Medina Hospital our primary goal is to speed your return to good health. As our experts respond to your medical needs, we know that meeting your social, financial, emotional and environmental needs can also contribute to your recovery process. Care Management is a key resource in meeting those needs.

Care Management Staff

- Our caring staff comprises the skills of nurses, social workers and insurance reviewers (utilization review) to assist the patient's needs. These individuals work closely with the patient, family, physician and healthcare team.
- Staff is assigned to specific nursing units. All inpatients and observation patients are reviewed at the time of admission to ensure they meet inpatient admission criteria. Patients are continually reviewed throughout their stay to ensure they are discharged to the appropriate setting, at the appropriate time.

Discharge Planning

- An essential part of every post-hospital care is discharge planning. Considering these plans early helps to alleviate later stress as you recover. Medina Hospital social workers have a primary role in the development of this discharge plan. We can help you design a post-hospital care plan tailored to your specific needs.

Providing Resources

Our social workers can link patients and their families to:

- Home Healthcare
- Homemaker Services
- Medical Equipment
- Day Care Programs
- Nursing Home Placement
- Counseling/Rehabilitation Services
- Support Groups
- Legal Services
- Meal Programs
- Financial Assistance Programs

http://my.clevelandclinic.org/locations_directions/regional-locations/medina-hospital/guest-services/care

Two Midnight Rule And Other New Guidance

Two-midnight rule controversy – Delayed to Oct 2014

Long-stay observation cases increased from 3% of all cases in 2006 to 8% in 2011.

1. The decision to admit a patient should be based on an expectation that the patient will require at least a two-midnight stay.

- CMS contractors will operate under the presumption that stays of at least two midnights are medically necessary, with the "clock" beginning when the patient starts receiving hospital services (including observation services).
- During the September 26 open-door forum, CMS clarified that if a patient stays one midnight in observation and the physician expects that the patient will require at least another midnight in the hospital, the patient can be appropriately admitted despite the fact that it is a one-day inpatient stay.
- If a patient is admitted but ultimately doesn't stay two midnights, clear physician documentation supporting the order and expectation of two midnights will be required.

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CMS announced an amnesty period on reviews from Oct. 1 to Dec. 31.

- CMS essentially has announced an amnesty period on reviews from October 1, 2013 to December 31, 2013.
- RACs will not review cases during this period
- Medicare administration contractors will only review cases with a length of stay less than two midnights

Opportunity to change how and when patient status is determined

Opportunity to decrease medical necessity denials due to patient status

Opportunity for compliance to insert itself in Case Management processes that would decrease observation and 1 day stay issues.

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Discussion & Questions

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Thank You!

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813-503-6491

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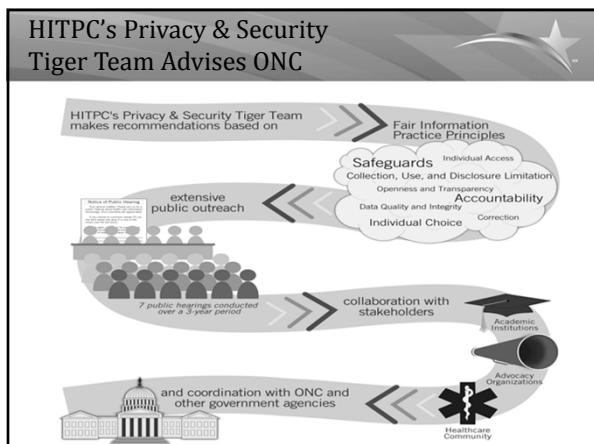
The Office of the National Coordinator for
Health Information Technology

HEALTH INFORMATION TECHNOLOGY
SERVICES

Privacy and Security Tools and Resources

Health Care Compliance Association

San Diego, California
March 31st, 2014



Privacy & Security
Tiger Team Recommendations to Date

From 2010-2013, the Tiger Team developed 160 recommendations for improving privacy and security of health information

HITPC forwarded 154 recommendations to ONC

As of September 30, 2013,
ONC has acted upon 133 of the 154 recommendations

53%	Fully or Partially Adopted
33%	In Process
14%	Action Pending

ONC Goal: Inspire Confidence and Trust

Promote the Secure Use of Health IT

- Information Assurance

Coordinate Development of Privacy and Security Policy

- Patient Direct Access to Lab Report (CLIA)

Meaningful Use

Educate and Empower Patients and Providers

- Improved Access to Health Information
- View and Download Health Records
- Patient Education
- Enhanced Understanding of Patients

Provide Technical Assistance

- Interactive Security Training
- Data Segmentation for Privacy
- Notice of Privacy Practices
- eConsent Trial

S&I FRAMEWORK

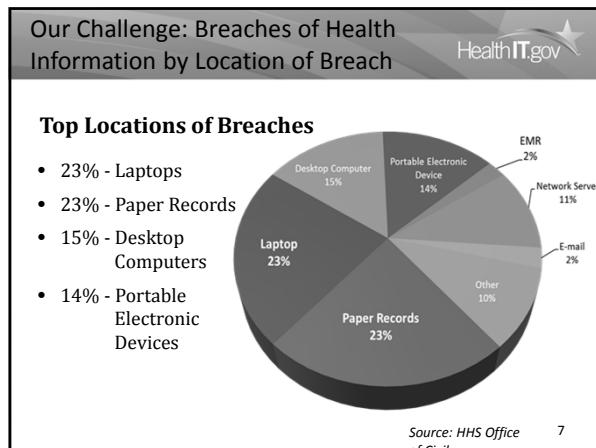
Our Challenge: Breaches of Health Information by Type of Breach

Top Types of Breaches

- 51% - Theft
- 21% - Unauthorized Access / Disclosure
- 13% - Loss

Type of Breach	Percentage
Theft	51%
Loss	13%
Unauthorized Access/Disclosure	21%
Unknown	3%
Improper Disposal	5%
Hacking/IT Incident	7%
Other	1%

Source: HHS Office of Civil Rights



Enforcement Highlights

- Continued focus on Security Rule compliance
 - Affinity Health Plan – over \$1.2 million
 - ePHI left on photocopier drives
 - Wellpoint - \$1.7 million
 - Faulty testing of programming updates left information accessible on web portal
 - Idaho State University -- \$400,000
 - Disabled firewall exposed ePHI to breach
- Privacy
 - Shasta Regional Medical Center -- \$275,000
 - Patient medical records shared with media

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Mobile Devices: Tips to Protect and Secure Health Information

HealthIT.gov
Advancing America's Health Care

Use a password or other user authentication.	Keep security software up to date.
Install and enable encryption.	Research mobile applications (apps) before downloading.
Install and activate wiping and/or remote disabling.	Maintain physical control of your mobile device.
Disable and do not install file-sharing applications.	Use adequate security to send or receive health information over public Wi-Fi networks.
Install and enable a firewall.	Delete all stored health information before discarding or reusing the mobile device.
Install and enable security software.	

9

OCR's YouTube Videos

	Your New Rights Under HIPAA 264,157 Views		The HIPAA Omnibus Rule 269,989 Views
	Your Health Information, Your Rights 113,307 Views		Su Informacion de Salud, Sus Derechos 563,831 Views
	The Right to Access Your Health Information 84,421 Views		Treatment, Payment and Health Care Operations 77,811 Views
	EHRs: Privacy and Security 5,300 Views		Communicating with Friends And Family 97,247 Views
	Explaining the Notice of Privacy Practices 124,705 Views		HIPAA Security Rule 290,615 Views

TOTAL VIEWS FROM FEBRUARY 16 2012 - DECEMBER 3, 2013: 1,831,383
 Visit us at <http://www.youtube.com/USGovHHSOCR>

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Protecting Patients Rights:
New OCR Resource Center at Medscape.org

Video Programs module imbedded into page for dynamic interest
 OCR Educational Links, Including Mobile Device Content
<http://www.medscape.org/sites/advances/patients-rights>

HIPAA/OCR Poll Question Updated Quarterly

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Cybersecure: Contingency Planning

The latest training game focuses on disaster planning, data backup and recovery and other elements of contingency planning.

<http://www.healthit.gov/providers-professionals/privacy-security-training-games>

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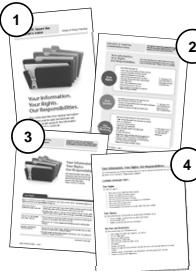
Models of Notice of Privacy Practices

The Office for Civil Rights (OCR) and Office of the National Coordinator for Health Information Technology (ONC) collaborated to develop model NPPs for covered entities to use:



5

Types of Notices Available



- Booklet** – Presents the material in booklet form with design elements
 - Layered Notice** – Presents a summary of the information on the first page, followed by the full content on the following pages
 - Full Page** – Has the design elements found in the booklet, but is formatted for full page presentation
 - Text Only** – Provides a text-only version of the notice

<http://www.hhs.gov/ocr/privacy/hipaa/modelnotices.html>

6

Meaningful Consent Website

- Geared toward providers, health information exchange organizations (HIEs), and other health IT implementers
 - Gives background on meaningful consent and ONC's eConsent Trial Project
 - Provides customizable tools and resources to help you enable patients to make meaningful consent decisions



www.HealthIT.gov/meaningfulconsent

9

Coming Soon - Security Risk Assessment Tool

- Downloadable Risk Assessment Tool designed to guide providers through the Risk Assessment process.
- The tool includes resources to
 - understand the context of the question,
 - examples of potential impacts to PHI if requirements aren't met,
 - and includes actual safeguard language from the HIPAA Security Rule

A screenshot of a web-based application titled "Security Risk Assessment Tool". The main header features the title and a star graphic. Below the header, there's a sub-header "Current User: none | Logout | www.HealthIT.gov". The main content area contains a "Security Risk Assessments" section with a sub-section "Security Risk Assessments". This section includes a photograph of two healthcare professionals (a doctor and a nurse) reviewing documents. To the right of the photograph is a detailed description of the tool's purpose, mentioning the HITECH Act, the need to identify risks and vulnerabilities, and the importance of following HIPAA risk assessment guidelines. It also describes the tool as an ongoing process for maintaining security. On the far right, there's a sidebar with links for "Users", "About Your Practice", "Business Associates", and "Asset Inventory". A "Log In" button is located at the bottom of the sidebar.

Security 101: Contingency Planning

Security 101: Security Risk Analysis



www.HealthIT.gov/security-risk-assessment

19

We're All In This Together



Everyone has a role in protecting and securing health information

Download the Full Infographic Today!



<http://www.healthit.gov/policy-researchers-implementers/everyone-has-role-protecting-and-securin>

The Top 10 Conflicts of Interest Developments Healthcare Professionals Need to Know About

Greg Radinsky, JD, MBA, CHC, CCEP
 Vice President & Chief Corporate Compliance Officer
 North Shore-LIJ Health System
 HCCA Compliance Institute
 March 31, 2014 - San Diego, California



Disclaimer

- The materials and views expressed in this presentation are the views of the presenter and not necessarily the views of the North Shore-LIJ Health System



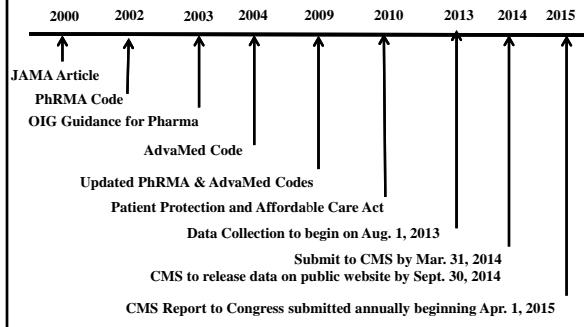
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ShoreLIJ

Goals of the Presentation

- Summary of new laws and industry guidance on COI and gifts
- Practical tips to avoid Stark and Anti-kickback issues
- Guidance on auditing and monitoring your COI and Gift Policy
- Answer your questions



Brief Timeline of Industry COI Developments



Pharmaceuticals

Glaxo will stop paying doctors to promote its products

Partly in response to new physician payment disclosure rules, U.K.-based GlaxoSmithKline said it will stop paying physicians for promoting its products at speaking engagements and for attending medical conferences. But for now, other large drugmakers say they will keep paying doctors to give



"We're seeing that companies are generally curbing the more aggressive marketing tactics that they considered business as usual in the past."

directly with doctors and other healthcare professionals who prescribe medications.

"We're seeing that companies are generally curbing the more aggressive marketing tactics that they considered business as usual in the past," said Dr. Daniel Carlat, director of the Pew Charitable Trusts' prescription project. "The Sunshine Act is a critical part of the story because the fees paid to doctors to market drugs are

paid to docs to market drugs are embarrassing to everyone involved."

But Eli Lilly & Co., Pfizer, Bristol-Myers Squibb and Shire told Bloomberg News that they won't stop

Bloomberg News that they won't stop paying doctors to talk with other physicians about their products.

physicians about their products.

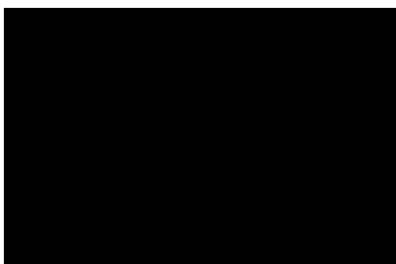
urged other drug companies to follow Glaxo's lead. "For companies that choose not to stop these practices

at companies using the more cutting tactics entered business last." These practices, they should be aware that Congress will scrutinize their actions very closely through the ACA's new report-

The Sunshine Act is not the only impetus for changing pharmaceutical regulations.

ing pharmaceutical industry marketing practices.

Conflicts of Interest Training Example



2014 Top 10 List: #10 Physician Payment Sunshine Provisions (PPACA Section 6002)



- Final regulations finally released on Feb. 1, 2013! (Official FR date Feb. 8, 2013)
 - Manufacturers to report any payments to physicians/teaching hospitals above \$10 unless an exception applies
 - Broad definition of payment
 - Manufacturers plus GPOs must report any ownership/investment interests by a physician and his/her immediate family
 - <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>

Who Paid for Your Doctor's Bagel?

ObamaCare's 'Sunshine Act' will benefit only accountants, bureaucrats and lawyers.

By THOMAS P. STOSSEL

Embedded in ObamaCare is a toxic rule called the Physician Payments Sunshine Act. The Act requires all companies that manufacture medical products purchased by the government to disclose on a public website anything they give physicians valued above \$10. Last month, the Centers for Medicare and Medicaid Services (CMS) issued draft guidance.

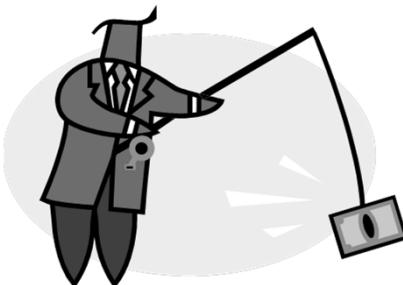
CMS justifies this legislation by citing "conflicts of interests that may influence research, education and clinical decision-making in ways that compromise clinical integrity and patient care, and may lead to increased health care costs."

This reasoning invert s reality. Medical care is incomparably better today than when I received my M.D. degree in 1967—due primarily to the availability of products developed by industry in unencumbered collaboration with physicians, and to industry's commitment to teach physicians how to use them.

Thanks to this collaboration, longevity has increased by a decade, and in my specialty, hematology, treatments for anemia, blood-clotting disorders and malignancies of the blood have improved spectacularly.

<http://online.wsj.com/article/SB10001424052970204468004577166840760748000.html>

What Will be the Real Impact of the Physician Sunshine Provisions?

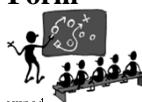


2014 Top 10 List: #9 Physician-Owned Distributorships (PODs)

- “These business ventures raise substantial concerns that a physician’s [ROI] from the venture may influence the physician’s choice of device.” – OIG Feb 2008
 - “Senators Request Probe of Surgeons” – WSJ June 9, 2011
 - PODs – Senate Finance Committee, June 2011
 - “In Small California Hospitals, The Marketing of Back Surgery – WSJ Feb. 9, 2012
 - OIG national study on spine implant PODs survey (2012/2013)
 - March 26, 2013 OIG Special Fraud Alert: Physician-Owned Entities
 - October 2013 OIG Report – Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use



Sample Procurement Screening Form Questions



- Does your company or any of its subsidiaries use any physician-owned distributorships? _____ Yes _____ No If yes, describe:
 - Is your company publicly-traded? _____ Yes _____ No

If Yes, please disregard the following:

- Do any of X's employees (full or part-time) including physicians have any ownership interests or receive any other compensation from the company itself or any distributor(s) used by the company to serve X or any of its facilities? _____ Yes _____ No



2014 Top 10 List: #8 Anti-Kickback Statute (PPACA Section 6402(f))

- PPACA section 6402(f) eases the government's requirements to bring an AKS action
 - PPACA changes:
 - "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]"
 - "a claim that includes items or services resulting from a violation of [AKS] constitutes a false or fraudulent claim for purposes of [the False Claims Act]"

2014 Top 10 List: #8 Anti-Kickback Statute (PPACA Section 6402(f))



- **RehabCare Group Inc. (Rehabilitation Services) - \$30 million**
 - Allegedly paid a nursing home a one-time payment of ~ \$600K as well as a percentage of the profit from the ongoing therapy services performed pursuant to the contract
 - **Victory Pharma Inc. (Pharmaceutical) - \$11.4 million**
 - Allegedly provided physicians tickets to sporting events, concerts, plays, along with paying for spa, golf and ski outings, dinners at expensive restaurants, other out of office events, and paid sales rep "preceptorships"
 - **Sanofi-Aventis (Pharmaceutical) - \$109 million**
 - Allegedly provided free product kickbacks to physicians to market the "value add" of these units to physicians along with expensive dinners
 - **GlaxoSmithKline (Pharmaceutical) - \$3 billion**
 - Among other issues, allegedly provided lavish vacations and "speaking fees" to doctors who agreed to promote the drugs to their colleagues
 - <http://www.justice.gov/opa/documents/gsk/us-complaint.pdf>
 - **Dr. Steve Wasserman (Physician) - \$26.1 million**
 - Dermatologist in Florida allegedly accepted kickbacks from a pathology laboratory and billed Medicare for medically unnecessary services

2014 Top 10 List: #8 Anti-Kickback Statute (PPACA Section 6402(f))



- **C.R. Bard (Medical Products) - \$48.26 million**
 - ❑ Allegedly paid physicians kickbacks in the form of grants, guaranteed minimum rebates, conference fees, marketing assistance, and/or free medical equipment to use its brachytherapy seed therapy
 - **Abbott Laboratories (Medical Device) - \$5.475 million**
 - ❑ Allegedly paid physicians for teaching assignments, speaking engagements, and conferences with the expectation to purchase vascular products
 - **CareFusion (Medical Device) - \$40.1 million**
 - ❑ Allegedly paid one physician a \$11.6 million for recommending Chloraprep products while he served as co-chair of the Safe Practices Committee of NQF
 - **Other cases related to patient referrals and patient data (home care, lab)**
 - ❑ Goodwill Home Healthcare, a home health care agency in Illinois, allegedly participated in kickbacks in exchange for referral of Medicare patients
 - ❑ Biodiagnostic Laboratory Services in New Jersey allegedly offered bribes to physicians for referring patient blood specimens
 - ❑ Sacred Heart Hospital and four physicians in Chicago allegedly received bribes to induce patient referrals and increase the patient census
 - ❑ Pharmacist charged with paying more than \$50K in kickbacks to doctor for physician referrals

Government Guidance



- **OIG – A Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse, Nov. 2010**
 - “Does the company really need my particular expertise or input?”
 - “Does the amount of money the company is offering seem fair, appropriate, and commercially reasonable for what it is asking me to do?”
 - “Is it possible the company is paying me for my loyalty so that I will prescribe its drugs or use its devices?”

2014 Top 10 List: #7 Increased Focus on Fair Market Value of Physician Compensation



- **Cooper Health System - \$12.6 million:** Allegedly paid outside physicians \$18K to serve on an advisory board and attend four meetings a year
- **HCA - \$16.5 Million:** Allegedly leased office space at a facility from diagnostic physicians at a rental rate in excess of fair market value
- **Intermountain Healthcare - \$25.5 million:** Voluntary disclosed. In addition to various technical violations, included a bonus structure that took into account the volume and value of referrals of physicians who referred patients to them
- **Adventist Health/White Memorial Medical Center - \$14.1 million:** Allegedly transferred assets to physicians who referred patients to the facility at less than fair market value and compensated physicians at above fair market value for teaching services at their family practice residency site
- **Tuomey Healthcare System - \$237 million:** Allegedly entered into part-time employment contracts with 19 physicians were for more than fair market value and were based on the volume of business generated by the physician
- **Health Management Associates:** Among other issues, allegedly paid physicians bonuses or awarded contracts to physician groups staffing HMA emergency rooms to induce physicians to admit patients unnecessarily, entered into sham medical directorship contracts, and sold physicians assets below fair market value

2014 Top 10 List: #6 Increased Focus on Technical Requirements of Stark Related to Gifts

- Non-Monetary Compensation Exception
 - \$385 limit applies to calendar year
 - Limited exception if hospital inadvertently exceeds annual limit
 - Government assumes hospitals track non-monetary compensation
 - Memorial Hospital (Ohio) voluntary disclosure
 - <http://www.cms.gov/PhysicianSelfReferral/DPS/list.asp#TopOfPage>
- Medical Staff Incidental Benefits Exception
 - Less than \$32 per occurrence
 - Item or service is provided to all members of the medical staff in the same specialty without regard to volume or value of referrals



2014 Top 10 List: #5 Co-Marketing Arrangements



- Co-Marketing Arrangements
 - Vendor/healthcare provider product/service advertisements
 - Vendor patient general education brochures
 - Community patient education events
 - Vendor training agreements
 - Preceptorships

2014 Top 10 List: #4 - Other Common Hospital/Physician Issues

- Educational Grant Activities
- Speakers' Bureaus
- Vendor FDA Related Training
- SEC Registration Disclosure Forms
- Royalty Agreements
- Establishing 501(c) (3) Foundations
- Insider Trading



2014 Top 10 List: #3 – Research

- HHS Final Rule Financial Conflict of Interest Rules for Researchers
 - More stringent Investigator disclosure requirements
 - SFI disclosure threshold lowered generally from \$10K to \$5K
 - Public disclosure requirements
 - Training requirements
- Three New York Based Researchers Conspiracy to Receive Bribes from Chinese Company and Government Supported Research Institute



2014 Top 10 List: #2 Changes to Beneficiary Inducement CMP



- 2002 OIG Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries
- PPACA Section 6402 – Adds four new exceptions to allow “charitable and other innocuous” programs
 - Access to Care
 - Coupons, Rebates and Rewards Programs
 - Financial Need
 - Waiver of Co-pays for Covered Part D Generic Drugs
- Patient recruiter inducement cases

2014 Top 10 List: #1 IRS Form 990



■ IRS Form 990

- Increases transparency and disclosure of non-profit hospitals' operations
- Highlights conflicts of interest and insider dealings
- Among other topics, requires reporting board members' and key employees' family and business relationships

IRS Form 990 – Transparency

Form 990 (2008) Page 6

Part VI Governance, Management, and Disclosure (Sections A, B, and C request information about policies not required by the Internal Revenue Code.)

Section A. Governance and Management

Section B. Policies

	Yes	No
12a Does the organization have a written conflict of interest policy? If "No", go to line 13 . . .	12a Yes	12a No
b Are officers, directors or trustees, and key employees required to disclose annually interests that could give rise to conflicts?	12b Yes	12b No
c Does the organization regularly and consistently monitor and enforce compliance with the policy? If "Yes," describe in Schedule O how this is done	12c Yes	12c No
13 Does the organization have a written whistleblower policy?	13 Yes	13 No
14 Does the organization have a written document retention and destruction policy?	14 Yes	14 No
15 Did the process for determining compensation of the following persons include a review and approval by independent persons, comparability data, and contemporaneous substantiation of the deliberation and decision?	
a The organization's CEO, Executive Director, or top management official?	15a Yes	15a No
b Other officers or key employees of the organization?	15b Yes	15b No

. Describe the process in Schedule O

Engage Clinical Leadership



Data is King! – Medical Journal Articles

<http://www.amsascorecard.org/>

Educate on the Law and Internal Policy

COI Enforcement Settlements

Recruit Champions from Unbelievers

Don't Forget to Educate the Vendors!

COI Policy Educational Tools

- Employee Gift Brochure
 - Vendor Gift Brochure
 - Employee COI Brochure
 - Frequently Asked Questions Document
 - Cartoons
 - Outside Activity Approval Form
 - Sample Gift Return Letter



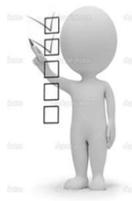
Awareness: Vendor Relations

Champ on Interactions with Vendors



COI Monitoring Mechanisms

- Conflicts of interest questionnaires
 - Certifications related to code of conduct and related policies and procedures
 - Scope of individuals who complete an annual disclosure
 - Procurement monitoring controls
 - Compliance helpline and survey benchmarking
 - Audits
 - DRA mailing
 - Contractual representations



Monitoring Control: Annual Conflicts of Interest Disclosure Form

Describe the service (e.g., consulting, speaking engagement, research, malpractice work).

List the total compensation, gift and/or meal (e.g., \$2,000.00).

Date(s) of service (e.g., 1/1/2011-12/31/2014).

Does it conform with policy 800.04 entitled "Gifts and Interactions with Industry"? For a copy of this document, please refer to Document Library.

Yes
 No

Monitoring Control: Annual Conflicts of Interest Attestation Statement

I certify that I have read and am in compliance with the Code of Ethical Conduct and the NSLIJ Health System policies entitled Conflicts of Interest and Recusal and Gifts and Interactions with Industry to the best of my knowledge. I further certify that the information contained in this Disclosure is accurate and complete to the best of my knowledge.

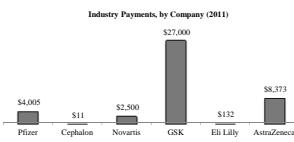
Sample Tearsheet



Joe Smith, MD
Internal Medicine, Radiology
Affiliations:
X Hospital
X Hospital

9	unique industry relationship disclosures
6	unique companies with relationships
\$42,021	in total payments

Industry Payments, by Company (2011)



Company	Bona Fide Serv.	Education	Meals	Speaker	Travel
Pfizer	\$3,798		\$207		
Cephalon			\$11		
Novartis	\$2,500				
GSK				\$27,000	
Eli Lilly				\$132	
AstraZeneca	\$1,150		\$73	\$7,150	

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Questions



Greg Radinsky, JD, MBA, CHC, CCEP
VP, Chief Corporate Compliance Officer
516.465.8327
gradinsk@nshs.edu

North Shore – LIJ Health System, Inc.

POLICY TITLE: Gifts and Interaction with Industry	ADMINISTRATIVE POLICY AND PROCEDURE MANUAL
POLICY #: 800.04	CATEGORY: Compliance and Ethics
System Approval Date: 7/18/13	Effective Date: 3/03
Site Implementation Date:	Last Revised: 11/11
Prepared by: Office Of Corporate Compliance	Superseded Policy(s)/#: N/A

GENERAL STATEMENT of PURPOSE

Over the past few years, respected professional publications and associations have cited concerns over the extent, the potential for negative influence and damage to professional integrity, and the sheer diversity and complexity of collaborations between health care providers and Industry. Accordingly, numerous respected medical schools, academic medical centers, health care providers, and trade associations, whose members include Industry, have attempted to address these concerns by revising and updating their existing policies on gifts, conflicts of interest and similar matters to further regulate their interactions with Industry.

Federal and State laws and the regulations promulgated there under (commonly referred to as the anti-kickback, Stark, and civil monetary penalty statutes and regulations) prohibit the acceptance of any item of value (remuneration) made directly or indirectly, in cash or in kind, that may induce or appear to induce the purchase, recommendation to purchase or referral of any kind of health care goods, services, or items reimbursed by a federal or state health care program such as Medicare and Medicaid. Consequently, the acceptance of any gifts or business courtesies from any third-parties with whom the Health System conducts business or who are seeking to do business with the Health System may implicate Federal and State prohibitions.

In addition, the Health System adopted a Conflicts of Interest and Recusal policy (Policy #800.03) with additional disclosure provisions to mitigate potential or actual conflicts of interest. Please be sure to consult this policy with regard to potential Industry or non-Industry conflicts of interest. Therefore, this policy is intended to provide parameters for appropriate decision-making regarding the acceptance or provision of business gratuities, gifts, activities and courtesies and other interactions between Individuals and Industry. All applicable Individuals shall receive training regarding potential conflicts of interest in interactions with Industry. Any questions as to whether a particular collaboration, interaction, relationship, gift, or social occasion would be appropriate in a specific circumstance should be directed to the Office of Corporate Compliance or the Health System Foundation.

POLICY

It is the policy of the North Shore-LIJ Health System that interactions with Industry should be conducted to avoid or minimize conflicts of interest. When conflicts of interest arise, they must be addressed appropriately as described in the Procedure section below.

SCOPE

This policy applies to faculty at any North Shore-LIJ Health System facility and all members of the North Shore – LIJ Health System workforce including, but not limited to, employees, medical staff, volunteers, students, physician office staff, and other persons performing work for or at North Shore – LIJ Health System including faculty of the Hofstra-North Shore-LIJ School of Medicine conducting research on behalf of the School of Medicine.

DEFINITIONS

Individuals: All members of the North Shore – LIJ Health System workforce including, but not limited to, employees, medical staff, volunteers, students, physician office staff, and other persons performing work for or at North Shore – LIJ Health System.

Industry: Pharmaceutical, biotechnology, medical device and other health care related entities and their employees, representatives and other agents both on and off-premises owned or leased by the Health System, except where off-premises locations are specifically noted. This policy applies to conduct with Industry whether or not the particular Industry entity actually does business with the Health System.

Gift: A “Gift” means, for the purpose of this Policy, anything of value an Individual receives from Industry for which the Individual has not paid or performed services in a manner that is routine in commercial transactions.

Gifts include, but are not limited to: cash of any amount, gift certificates, loans, trade show/office trinkets or promotional items (e.g., pens, calculators, notepads, coffee mugs), flowers, food and beverage (e.g., box of chocolate, wine), entertainment tickets, golf related items, stocks or other securities, or participation in stock offerings, Industry invitations to be their guests at charitable events sponsored by the Health System or other charitable organizations, raffle prizes, and use of a Industry’s vehicles or vacation facilities.

Gifts also include any food or beverage provided by Industry to Individuals on Health System premises except for Accreditation Council for Continuing Medical Education (ACCME) accredited programs or other events that comply with the ACCME Standards for Commercial Support. Individuals should use discretion in participating in any permissible Industry-sponsored meal off-site. Any meals should be modest in nature and provided incidental to attendance at an off-site event.

Sample or Drug Sample: means, for the purpose of this policy, free pharmaceutical products obtained from an Industry representative intended for clinical administration to a patient.

PROCEDURE/GUIDELINES

I. GIFTS FROM INDUSTRY

Gifts from Industry are prohibited regardless of any value because even gifts of a nominal value may be viewed to influence or potentially influence Individuals in the conduct of their duties or responsibilities. Gifts that are impermissible to Individuals are also impermissible when given to family members or guests of Individuals. Individuals also must consciously and actively divorce clinical care decisions (including referrals, and diagnostic or therapeutic management) from any perceived or actual benefits accrued or expected from Industry including, but not limited to, research funding, scholarships for Continuing Medical Education (“CME”) attendance, and any compensation agreement.

Patient Gifts: Although this policy’s emphasis is on interactions with Industry, Individuals also are prohibited from accepting a personal, individual Gift of any kind from patients, former patients, their friends and relatives as individuals unless:

- The Gift is a modest token of appreciation rather than intended to influence behavior;
- The Gift does not involve cash or a cash equivalent such as a gift card; and
- The circumstances are such that refusal could hurt a patient’s feelings or otherwise be counterproductive to a patient relationship.

When feasible, Individuals should direct the donor to the relevant Health System Foundation so that such Gifts can be made to the appropriate entity. Similar tokens of appreciation provided by a patient or his or her family member to a facility department or office are also permissible.

Social, Benevolence, Congratulatory Gifts, Business Courtesies: This policy does not apply to interactions between Individuals and the Health System and between Individuals and each other. Such interactions may involve a Gift as defined above. However, Individuals are reminded that the Health System’s policy #800.10 addresses Business Courtesies and certain Individuals have to report such Gifts for tracking purposes when provided to a potential referral source even when such Gifts are provided for social, benevolence, or congratulatory reasons.

Community Outreach and Education: The Health System may develop promotional items of nominal value that promote awareness of clinical programs consistent with the Health System’s mission to provide community outreach and education.

Returning Unsolicited Gifts: If unsolicited Gifts arrive via the post office or private carrier, the department head or administrator will advise on the best method for returning the Gift.

II. COMPENSATION FROM INDUSTRY FOR CONSULTING SERVICES

Individuals who are invited to speak or provide genuine consulting services can accept reimbursement from Industry in the form of honoraria or compensation for time and expenses, but must comply with the following requirements in addition to checking, prior to accepting any engagement, any relevant provision contained in a handbook, manual or contract that governs the terms and conditions of the Individual's employment such as an employee handbook, faculty manual, or employment agreement:

- a. Presentations or consultation engagements must be of scientific/academic merit and/or benefit the Health System;
- b. Individuals are prohibited from participating in Industry-sponsored Speaker's Bureaus unless academic investigators are presenting results of their research to peers and there is an opportunity for critical exchange;
- c. Individuals are prohibited from receiving compensation for listening to a sales pitch (e.g., detailing) by an Industry representative;
- d. Individuals must not receive any form of compensation for changing a patient's prescription;
- e. Individuals must only accept fair market value compensation fees for specific, legitimate services provided by him or her and for work actually performed. Payment must be commensurate with time and effort and the terms of the arrangements, services provided, and compensation must be set forth in advance and in writing. Any reimbursement for travel, lodging, and meal expenses must be reasonable and directly related to the engagement;
- f. Acceptance of any Industry honoraria or consultation engagement is contingent on the prior approval from an appropriate Administrative Director, Chairperson, or similar position. A Chairperson needs approval from the Chief Medical Officer;
- g. Any time spent on a consultation or service agreement must be performed on non-Health System work time unless approved by facility or department policy or by the Individual's manager;
- h. Industry compensation must be disclosed in accordance with the Health System's conflicts of Interest and Recusal Policy #800.03 and the Health System's Conflicts of Interest in Research Policy #GR065, as applicable;
- i. Any applicable Individuals with decision-making in a procurement role must also follow the Health System's procurement policies; and
- j. In the event Health System resources, such as work time, computers, and library, are involved in the consultation, Individuals must consult the policies of the site

where such resources may be used. It is considered improper to use Health System resources, especially computer resources for non-Health System purposes beyond incidental *de minimis* use.

III. ATTENDANCE AND/OR PARTICIPATION BY INDIVIDUALS IN INDUSTRY SPONSORED OR SUPPORTED PROFESSIONAL MEETINGS THAT ARE NOT SPONSORED BY THE HEALTH SYSTEM

Education for Professionalism

This section applies to attendance and/or participation by Individuals at Industry sponsored or supported events that are not sponsored by the Health System. Clinicians are expected to participate in meetings of professional societies as part of their CME and professional obligations. Faculty and staff with special expertise may be invited to give lectures or otherwise participate in conferences and seminars in a variety of venues outside the Health System.

However, clinicians should be aware of the potential influence of Industry at these meetings. Industry support must never compromise academic independence or be presented such that one could infer that the purpose of the support of a meeting or conference was to induce or influence any favorable business action. Discretion must be employed in determining whether to attend, based on whether the event has a legitimate educational value.

The Health System permits attendance and participation by Individuals when an event is supported in part or in whole by Industry, but only when certain requirements are met as described below.

Attendees

If an Individual is only attending an education meeting or conference, the following requirements must be followed.

- The event is offered by a professional society, academic institution or independent organization that affirmatively complies with the Accreditation Council for Continuing Medical Education (ACCME) Standards or involves either training on the safe and effective use of a medical product and/or discusses non-promotional clinical educational information to further medical care;
- Financial support by Industry is fully disclosed at the meeting by the Sponsor;
- The event, agenda and presentations include fair balance, and the content of the presentations are not determined by Industry unless FDA related or similar training is being provided or the information provided relates to either the safe and effective use of a medical product and/or non-promotional clinical education information to further medical care;
- No Gifts, compensation, travel, meals or lodging may be accepted from Industry for attending an educational meeting or conference except for modest meals provided in

compliance with the ACCME Standards (e.g., incidental to attendance of an off-site event);

- Presenters are required to disclose that their presentation consists of his or her own studies and conclusions and such studies and conclusions promote evidence based clinical care;
- Individuals must not accept any Gifts from Industry at such events;
- Industry support must not be displayed in presentation or education spaces; and
- The setting and cost of the event must be appropriate to its purpose.

Participants

Individuals who actively participate in meetings and conferences supported in part or in whole by Industry (e.g., giving a lecture, organizing the meeting, participating in FDA related training), must follow these additional requirements:

- The meeting or conference content is determined by the Individual and not the Industry Sponsor unless FDA or research related training is provided;
- The Individual must provide a fair and balanced assessment of therapeutic options and promote objective scientific and educational activities and discourse;
- The Individual is not required by an Industry Sponsor to accept advice or services concerning content, speakers, or other educational matters as a condition of the sponsor's contribution of funds or services;
- Individuals are prohibited from allowing their professional presentations of any kind, oral or written, to be ghostwritten by any party, Industry, or otherwise;
- The Individual explicitly describes all of his or her related financial interests (i.e., past, existing, or planned) to the audience or explicitly declares that he or she has no related financial interests;
- The Individual states that the content reflects the Individual's views and not the views of the Health System unless approved by their Chair and the Department of Public Affairs;
- The Individual may accept reasonable payment for travel, meals, lodging and honorarium of fair market value, but no reimbursement of family members or guests' travel expenses is allowed;
- Time spent in preparing and delivering the lectures does not impair the Individual's ability to fulfill Departmental responsibilities; and

- The use of the Health System name at a non-Health System event complies with Health System policies regarding the use of the Health System's name (Policy #500.02 – Use of Institutional Name).

In addition, participation involving speaking or similar responsibilities is subject to the requirements described in the "Compensation from Industry to Individuals" section of this Policy. Individuals uncertain about the appropriateness of a particular event or function should contact the Office of Corporate Compliance for advice.

IV. INDUSTRY SUPPORT FOR RESEARCH RELATED ACTIVITIES

All Industry support for research related activities occurring throughout the Health System must be processed through or approved by the Health System Grants Management Office, which resides in Research Administration at The Feinstein Institute for Medical Research or the Health System Foundation. Grants, awards and/or donations (collectively referred to as "Industry Support") from vendors to support research or education may be accepted by the Health System only if: (i) the Industry Support is accompanied with the vendor's certification that the Support is given to support Health System research or education and is not intended to influence purchasing decisions or research outcomes and (ii) it is approved by academic Department Chair, if health system resources are used, the facility Executive Director of the facility affected, and the Senior Vice President, Research or designee with responsibility for the supported research or educational activity.

In addition, all policies and procedures promulgated by The Feinstein Institute and the Grants Management Office relating to the submission, review, execution, and reporting of external funding for research must be followed. General grant policies may be located under the policies tab on Healthport with detailed policies and procedures available on the Grants Management Office website at:

<http://www.feinsteininstitute.org/resources-for-investigators/grants-management-office-gmo/>.

V. INDUSTRY SUPPORT FOR HEALTH SYSTEM SPONSORED CME AND OTHER HEALTH SYSTEM SPONSORED EVENTS

The Health System has centralized departments assigned to CME, which oversee all requests for Industry Support and receipt of funds for CME activity to ensure compliance with the ACCME Standards.

All Industry educational events sponsored by the Health System must be compliant with the ACCME Standards whether or not CME credit is awarded unless FDA related or similar training is provided. The Health System conducts audits to assure compliance with these standards including those with respect to content validation and meals.

Individuals should be aware of the Standards for Commercial Support established by the ACCME. A complete description of the Standards of the ACCME to ensure independence in CME activities is available at:

http://www.accme.org/dir_docs/doc_upload/68b2902a-fb73-44d1-8725-80a1504e520c_uploaddocument.pdf.

In addition to the aforementioned ACCME Standards, educational events sponsored by Industry on the Health System campus or a designated location should comply with the following provisions:

- Gifts of any type are not distributed to attendees or participants before, during, or after the meeting or lecture; and
- Funds from Industry to support the specific educational activity are provided to the Department or Program, but not to an individual faculty member.

Please contact the Office of Continuing Medical Education at (516) 465-3263 if you have any questions about CME or related Health System event.

In addition to the above broad guidelines regarding the conduct of the event itself, the following provisions apply to the planning and organization of the event:

Solicitation: Industry Support may be solicited only for charitable, educational, academic or other appropriate purposes and must be approved by the Department Chair and/or the Foundation (if applicable). Such solicitation shall be made to all companies similar in nature to the one solicited, not just those doing business or potentially doing business with the Health System. Furthermore, such solicitation must clearly indicate that Industry Support is not a factor in vendor selection. Solicitation discussions must not involve Individuals with vendor or product recommendation roles or Industry sales and marketing personnel unless no other communication option is feasible.

Permitted Uses of Industry Support: Industry is permitted to support education and other Health System projects and events, including but not limited to, research and fundraising projects that further the charitable mission of the Health System. Such Industry Support must be accompanied by a written certification from the appropriate Industry official that the support is provided to support education or a project or event that furthers the charitable mission of the Health System and that such Industry Support is not being provided to influence purchasing decisions or research outcomes.

Industry may direct its support to fully or partially fund an individual event, project or ongoing educational or charitable program of the Health System, but must indicate its request in its written certification. However, the Health System shall plan, operate and control all aspects of any such program in a manner consistent with the ACCME Standards (including, but not limited to, the provision of any food or beverages at such program, the selection of the program's content, faculty, attendees, educational methods and materials).

Product Training/Evaluation: Industry Support for a genuine, bona fide product education program or product symposium which by its nature may involve identification of an Industry name, logo or product is permitted if managed to eliminate or minimize the potential for advertising or other promotion.

Product Fairs or Similar Programs: Product fairs or similar promotional programs are allowed as long as these activities follow the ACCME Standards. Individuals who are faculty members or who are in a position to recommend products for purchase should review the above policy provisions regarding attendance and participation at such events.

Industry Financial Support: Industry Support for a Health System event or project must not be made payable to an Individual but must be made payable to the Health System and sent to the applicable Health System Finance Office, Office of Sponsored Programs (“OSP”), Office of Grants Management (“GMO”), Foundation, or Office of Continuing Medical Education.

Management, Monitoring and Oversight of Industry Support: Developing a system that properly manages and monitors Industry Support can prevent the co-mingling of Industry Support with Health System revenues and verify that Industry Support was used only for permitted uses. This system is crucial to preventing allegations that such Industry Support is an inappropriate form of support to the Health System.

Accordingly, all Industry Support funds must be allocated into Health System’s centralized accounts for accounting and oversight purposes. Checks received from Industry which by definition support temporarily restricted programmatic or research activities must be deposited into a separate Special Purpose Fund. The Health System office responsible for securing the support (GMO or Foundation) will request the Special Purpose Fund, which will be set up by the Finance Department.

Further allocation to departmental accounts may be performed using the written certification from the Industry and/or the policies and procedures of the Finance Department. In addition, persons using Industry Support for a particular project or event must be able to document: (a) the amount, source and date of the Industry Support received from Industry; (b) the project or event receiving Industry Support; (c) the amount of Industry Support applied to the project and event; (d) the use of the Industry Support; and (e) who determined the use of the Industry Support funds. Users of Industry Support must seek guidance from Finance and/or the Grants Management Office and Contracts and the Foundation concerning the best method of monitoring and oversight that meets their particular situation.

Acknowledgement: Industry may be acknowledged for its donations or grants in a manner consistent with the ACCME standards.

VI. INDUSTRY SUPPORT FOR STUDENTS OR TRAINEES

Health System facilities serve as training grounds for a variety of students and trainees. For the purposes of this section, the term “students” means persons enrolled in programs of study leading to a degree and “trainee” refers to persons enrolled in post-graduate training programs. The following requirements are designed to minimize potential influence by Industry on purchasing and referral decisions by facilities and faculty members:

- Scholarship and fellowship support by Industry is permitted, but must either be by a written grant with the Health System, through the Grants Management Office or the Health System Foundation, and placed in an account managed and directed entirely by

the Health System or be provided directly to a student or trainee from an independent medical association or similar entity in accordance with a local, regional or national competitive or recognition process;

- The Health System or the applicable educational affiliate must have complete control over the selection of recipients of scholarship or fellowship assistance;
- Industry grants to specific students or trainees are prohibited except for grants made: (a) as described above in which the Health System selects recipients; or (b) in accordance with a local, regional or national competitive or recognition process; and
- Per the “Gifts from Industry to Health System section,” Gifts from Industry at such events is prohibited; and Industry support cannot be tied to the use of Industry products or any implicit or explicit *quid pro quo* (i.e., “no strings are attached”).

VII. ROYALTIES AND PAYMENTS FROM INDUSTRY AND EMPLOYEE-OWNED ENTERPRISES.

Individuals are advised that Health System policy #GR017 governs patents and other intellectual property developed using Health System resources. This policy is not intended to contradict or restrict the provisions of #GR017.

Individuals involved in research or other activities using Health Systems resources that give rise to intellectual property shall consult the Office of Technology Transfer at the Feinstein Institute.

In the event that an Individual has an agreement with Industry for royalties based on patents or other forms of intellectual property or for the receipt of other compensation (such as payments due to ownership interests), the agreement must be structured (or re-structured, if necessary) to correspond to the policies and procedures of the Health System as well as any applicable law.

The following requirements must be followed regarding structuring or restructuring Agreements:

- The Agreement shall meet contractual standards for consulting agreements described in Section II of this policy (e.g., the agreement shall be written, fees disclosed annually, compensation at fair market value and so forth);
- The Agreement shall be entered into only when the Individual has made, or is expected to make, a contribution that is scientifically novel, innovative and significant, and the Agreement shall provide sufficient detail to ascertain the contribution;
- The Agreement shall not be conditioned on use or promotion by the Individual or the Health System of the contribution or of any other products or services of the other party or parties to the Agreement or their business affiliates; and
- To the extent practicable, all royalty-based or profit-sharing based payments to the Individual under the Agreement shall be calculated in a manner that excludes any sales of the product or service to the Health System by the other party or parties to the agreement

or their business affiliates unless there is a compelling clinical or business justification approved in writing in advance by the Office of Legal Affairs.

All such arrangements must be disclosed to the Office of Corporate Compliance prior to employment and annually thereafter in accordance with the Health System's Conflicts of Interest and Recusal Policy #800.03 and when involving research to the Office of Research Compliance in accordance with the Health System's Conflicts of Interest in Research Policy #GR065 .

Individuals also must submit to the Office of Corporate Compliance appropriate documentation to demonstrate compliance with this section of the policy.

VIII. DRUG SAMPLES TO INDIVIDUALS

“Samples” or “Drug Samples” means, for the purpose of this policy, free pharmaceutical products obtained from an Industry representative intended for administration to a patient. Many of the Health System facilities licensed under Article 28 of the New York Public Health Law prohibit or severely restrict the use of Drug Samples at their sites. In other areas, Individuals licensed to prescribe and dispense medications may accept Drug Samples from Industry for distribution to patients.

Distribution to persons other than patients carries the inference that such Drug Sample is a Gift and carries risk to an Individual’s professional reputation. Accordingly, Individuals who interact with Industry representatives concerning Drug Samples are strongly discouraged from accepting Drug Samples unless particular Samples pose significant benefits, are generally not used by the general population often, are usually needed quickly and whose benefits outweigh the regulatory, safety, security and other risks posed by such Samples.

For example, Individuals should refuse easily affordable or obtainable items that could be viewed as inappropriate (e.g., a widely used, over the counter product that one could find in a supermarket) but accept Samples for more expensive items that pose a problem for indigent clients or items that should reach the patient quickly after the patient encounter, and generally would not be viewed as inappropriate (e.g., an antibiotic).

Furthermore, to the extent that such Drug Samples are permitted, Individuals interacting with Industry representatives should cooperate with each other or with a Health System site if feasible on managing Samples in a centralized manner that ensures security, timely access and tracks the recipients of Drug Samples. In the event such a centralized system is not feasible or interferes with access, Individuals should carefully consider alternative ways to manage Drug Samples in a manner that does not pose risk to their professional reputation.

Drug Samples shall never be sold and any drug sample shall not be used by Individuals for themselves or family members or anyone other than a patient in need of the particular Sample.

IX. INDUSTRY PRODUCT EVALUATIONS AND INDUSTRY SITE VISITS

Industry Evaluation Products

Industry may offer to place a new device or piece of equipment at the Health System on a trial basis. Such offers require Office of Procurement approval prior to delivery and the issuance of a no-charge Purchase Order that describes the item and the timeframe for the evaluation. Industry will be expected to deliver and retrieve the item within the designated time period.

The number of single use products (e.g., consumable or disposable products) provided at no charge must not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances. Multiple use products provided without transfer of title for evaluation purposes must be furnished only for a period of time that is reasonable under the circumstances to allow for an adequate evaluation.

Products used in a clinical research study are governed by the terms of the agreement or award.

Individuals must not entertain or encourage such offers by Industry unless the device or equipment is of genuine interest to the Health System. Individuals must not influence the decision of the Office of Procurement in approving or disapproving an offer by Industry.

Industry Site Visits

Site visits for the evaluation of Industry products and/or services are sometimes appropriate parts of a purchasing decision. When such visits are necessary, they must be approved by the Department Chair and/or any applicable department leadership and paid with departmental funds. Industry support for such trips is prohibited.

X. SITE ACCESS BY INDUSTRY SALES AND MARKETING REPRESENTATIVES

The presence of Industry sales and marketing representatives at Health System facilities presents operational issues of patient confidentiality, security, infection control, as well as a suggestion of an inappropriate relationship with Industry. The following requirements reduce the likelihood of an inappropriate presence of Industry:

Pharmaceutical Industry

- The Health System recognizes that its interactions with representatives of pharmaceutical manufacturers differ from its interactions with representatives of medical device and other Industry manufacturers.
- All pharmaceutical industry sales and marketing representatives' access is strictly prohibited to the Health System's premises, including but not limited to hospitals, outpatient clinics, and the offices of employed physicians except as provided below.

- Pharmaceutical sales and marketing representatives with new or compelling data to present may request an appointment with the Health System Pharma Council through the Office of the Health System’s Chief Pharmacy and Medication Safety Officer or his or her designee or through the Office of Procurement -- no other appointments or invitations are acceptable.
- Pharmaceutical Medical Liaisons also may be granted limited access only by prior appointment or invitation and such individuals must be credentialed by the Health System’s vendor credentialing service described in Policy #100.22, “Company Representatives and Visitors in Patient Care Areas.”

Medical Device and Other Non-Pharmaceutical Industry Manufacturers

- For sales and marketing representatives of medical device and other Industry manufacturers such as medical product manufacturers, access must be pursuant to an appointment or invitation related to the provision of medical care, research studies, and authorized by the applicable faculty member or staff or otherwise permitted by policy 100.22, “Company Representatives and Visitors in Patient Care Areas.”
- Except as permitted by policy 100.22, sales and marketing representatives of medical device and other Industry manufacturers are prohibited from interacting with patients (including observation) unless it has been approved by Health System personnel and there has been prior disclosure to and consent by the patient and then only to provide in-service training, services or assistance on devices, equipment or other technologies.

Other Site Access Industry Requirements

All Industry representatives are also subject to policies of the Health System including, but not limited to, those concerning access and security, registering and credentialing an appropriate number of individual Industry representatives.

- All Industry representatives are to wear professional attire at all times. No “scrubs” are permitted unless provided by a Health System employee for a specific purpose that requires “scrubs” or similar work-related attire (e.g., demonstration of product in a location requiring such attire). All attire provided by the Health System must be returned to the authorized Health System employee immediately upon completion of the purpose requiring the attire (even if a repeated need for the attire is planned later in the day). Under no circumstances may Industry representatives leave the premises with any attire provided by the Health System.
- Involvement of students and trainees in such meetings shall occur only for educational purposes and under the supervision of a faculty member.
- Industry personnel are prohibited from distributing refreshments, meals, or Gifts during visits.

- Regarding access to appointments or invitations, all Industry sales and marketing representatives (pharmaceutical, medical device and other healthcare related entities and their employees, representatives and agents) are restricted to non-patient areas, non-public areas except when reasonable to access their appointment location or to provide in-service training or services on devices and other equipment as also described in Policy #100.22 and are expressly prohibited from loitering and conducting marketing and promotional activities with visitors, patients, employees, students and trainees en route to appointments.

XI. DISCLOSURE OF RELATIONSHIPS WITH INDUSTRY

Individuals are prohibited from publishing articles, scientific presentations or other related materials under their own names that are written in whole or in part by Industry or other individuals without proper attribution.

In scholarly publications, Individuals must disclose their related financial interests in accordance with the International Committee of Medical Journal Editors (<http://icmje.org/>) or if available, the requirements of the particular publication.

Individuals with supervisory responsibilities for students, trainees, residents or staff must ensure that any potential conflict of interest does not affect or appear to affect the supervision of any applicable Individual.

Any potential conflict of interest must be disclosed in accordance with the Health System's Conflicts of Interest and Recusal Policy #800.03 and the Health System's Conflict of Interest in Research Policy #GR065.

If disclosures are made from any source (including but not limited to regulatory officials such as those from CMS) of payments by Industry to physicians and teaching hospitals within the Health System and such disclosures permit review for correctness, such review shall be made by Compliance working with the Health System's Grants Management Office, Research Compliance, PAANS, and the physicians and Health System officials involved. Individuals learning of such disclosures shall notify the Office of Corporate Compliance immediately.

Any applicable Individual with decision-making or a procurement role must also follow the Health System's Conflicts of Interest and Recusal Policy and related policies. For example, Individuals may not participate in discussions or decisions on Health System purchases of products or services from a company in which they have a financial interest. The same applies to purchase of products or services of a competitor of the company in which they have a financial interest.

XII. ENFORCEMENT

Hospital and site managers and Department Chairs shall be responsible for helping to enforce this policy. All violations must be reported to the Office of Corporate Compliance for appropriate resolution.

Exceptions to this policy can only be granted by the Chief Corporate Compliance Officer.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

Administrative Policy #100.22 “Company Representatives in the Patient Care Area”

Administrative Policy #500.02 – Use of Institutional Name

Corporate Compliance Policy #800.03 - Conflicts of Interest and Recusal Policy

Corporate Compliance Policy #800.04 - Gifts, Gratuities, and Business Courtesies

Corporate Compliance Policy #800.10 - Business Courtesies to Potential Referral Sources

Research Policy #GR065 - Conflicts of Interest in Research Policy

Research Policy #GR017 – Intellectual Property

North Shore-Long Island Jewish Health System, “Policy on Conflicts of Interest and Interactions between Representatives of Certain Industries and members of the System Pharmacy and Therapeutics Committee for the North Shore –LIJ Health System” received courtesy of Office of Procurement.

Gregory E. Demske, “Examining the Relationship Between the Medical Device Industry and Physicians,” testimony to Senate Special Committee on Aging, February 27, 2008.

Liaison Committee on Medical Education, “Functions and Structure of a Medical School, Standards for Accreditation of Medical Education Programs Leading to the M.D. Degree,” June, 2008.

University of Pittsburgh Medical College, “Policy on Conflicts of Interest and Interactions between Representatives of Certain Industries and Faculty, Staff and Students of the Schools of Health Sciences and Personnel Employed by UPMC at all Domestic Locations,” February 15, 2008 (effective date).

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Association of American Medical Colleges, “Industry Funding of Medical Education: Report of an AAMC Task Force,” (June, 2008), available at www.aamc.org/publications.

Association of American Medical Colleges, "In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making," (June, 2010), available at www.aamc.org/publications.

The Office of the Inspector General and The American Health Lawyers Association, "Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors."

Advanced Medical Technology Association, "Code of Ethics on Interactions with Health Care Professionals," (published December 18, 2009, effective July 1, 2009).

Hofstra University, Conflict of Interest and Commitment Policy and Addendum (last revised 10/15/07), available at http://hofstra.edu/About/Policy/policy_cip.html.

Mt. Sinai School of Medicine, Conflicts of Interest-Interactions with Vendors and Other Commercial Entities, 2008, available at the introduction and following pages at:
http://www.mssm.edu/forfaculty/policies/conflict_interest/vendors_commercial_entities/introduction.shtml.

Stanford University, Stanford Industry Interactions Policy, effective October 1, 2006, available at <http://med.stanford.edu/coi/siip/> and Stanford Policy on Compliance with the ACCME Standards for Commercial Support and Stanford Commercial Support of CME Activities FAQs, September 22, 2008, updated December 2, 2008, available at <http://med.stanford.edu>.

Yale University, Yale University Policy on Conflict of Interest and Conflict of Commitment, Revised, May, 2004, available at www.yale.edu/provost/html/coi.html.

Bernard Lo and Marilyn J. Field, Conflict of Interest in Medical Research, Education, and Practice, Institute of Medicine (2009), summary available on the Internet at <http://www.nap.edu/catalog/12598.html>.

Partners Healthcare, Partners Commission on Interactions with Industry (April, 2009), available at: http://www.partners.org/documents/CommissionReport_PartnersHealthCare2009.pdf.

Sen. Special Comm. On Aging, *Commercial Sponsorship of Continuing Medical Education: Testimony of Lewis Morris, Chief Counsel, Office of the Inspector General, Department of Health and Human Services* (July 29, 2009), available at:
http://www.oig.hhs.gov/testimony/docs/2009/07292009_oig_testimony.pdf.

CLINICAL REFERENCES:

N/A

FORMS:

N/A

APPROVAL:

System Administrative P&P Committee	6/27/13
System PICG Committee/Clinical Operations Committee	7/18/13

Versioning History:**3/03****10/05****5/10****11/11**

North Shore-LIJ Health System

Gift-Industry Interaction Policy

Policy # 800.04

For more information,
we have available:

- The complete Gift-Industry Interaction Policy
- Frequently Asked Questions for Interactions with Industry

You can also contact us at:

North Shore-LIJ Health System
Office of Corporate Compliance

200 Community Drive
Great Neck, NY 11021
(516) 465-8097



Summary of Selected Portions of the Health System Policy on Gift and Industry Interactions

Scope: Employees, Employed and Contracted Physicians and Voluntary Physicians

- The policy applies to interactions between Industry and employees and employed and contracted physicians both on campus and off-campus.
- Voluntary Physicians are covered on-campus and also off-campus if they have faculty appointments or a connection to the Health System such as committee memberships or contract relationships.
- They are not covered off-campus if their contact with the Health System is limited to that of mere membership on the medical staff of a Health System facility.

Gifts

- Personal gifts (e.g., notepads, pens, food, wine, entertainment tickets, flowers) from Industry are prohibited on or off campus.
- Industry provided meals at professional and similar type meetings are permissible if the meal is provided in a manner consistent with ACCME guidelines (e.g., no vendor involvement, incident to the presentation, no sales materials).

Samples

- Drug samples at Health System Article 28 sites (hospitals, clinics, etc.) must adhere to the policies of that facility's pharmacy.
- Elsewhere, drug samples should be used for patients, only for products that are needed quickly, and/or cost prohibitive.

Consultation and Other Outside Engagements

- Outside engagements with Industry such as consultations and presentations are permissible if terms are in writing, compensation is at fair market value, work reflects one's own views, has scientific merit and has been approved by the appropriate Administrative Director or Chairman.
- Industry-sponsored Speaker's Bureaus are prohibited unless academic investigators are presenting results of their research to peers and there is an opportunity for critical exchange.

Vendor Relations: Representatives, Product Evaluation, Site Visits

- Pharmaceutical sales and marketing representatives with new or compelling data may make an appointment with the health system's Chief Pharmacy and Medical Safety Officer or his/her designee or through the Office of Procurement (no other appointments are acceptable).
- Pharmaceutical Medical Liaisons (pharmaceutical company employees with advanced scientific or clinical degrees whose roles are to educate clinicians on scientific or medical



advances), if credentialed with the health system's vendor credentialing system, may have limited access by prior appointment.

- Medical Device representatives may visit if the visit is related to the care of a patient and made by prior appointment. Industry representatives are permitted by invitation only and only in non-patient care areas unless to provide in-service education to clinicians. Industry representatives are permitted to interact with patients only by prior arrangement and only to provide patient education or assistance with the representative's products.
- No gifts including food provided by the representative are permitted.
- Students and trainees shall not interact with Pharmaceutical Medical Liaisons and Medical Device representatives unless faculty members are present and only for educational purposes that include an exchange of views.
- Professional dress is required at all times. Scrubs must be worn only in authorized areas and scrubs must never be removed from the premises.
- Access is limited to non-academic and non-patient care areas unless reasonably needed to access an appointment or for the education of a patient.

- Industry-provided product samples for evaluation have restrictions and Industry paid site visits are prohibited; procurement policies incorporate many of these features and can be consulted.

Research

- Industry support for research is permitted with (i) a certification that the support will not influence purchasing decisions or research outcomes, (ii) approval from the Senior VP, Research or designee, and, (iii) adherence to the policies of the Feinstein Institute and the Office of Grants and Contracts.

Industry Support for Health System Projects

- Solicitation of Industry support shall exclude Industry marketing personnel and individuals with vendor or product recommendation roles to the extent practicable.
- Industry support shall not be payable to an individual but to the Health System.
- Industry support shall be accompanied by a certification from Industry that the support is being provided to further an educational or charitable purpose of the Health System, is not intended to influence purchasing decisions or research outcomes, and an understanding that the Health System and

not Industry will control the project, event or purpose implementation.

- The Health System shall follow the ACCME guidelines in managing Industry's role, if any, in the project, event or purpose of the Industry support.

Educational Events

- All Industry educational events sponsored by the Health System must be compliant with ACCME Standards for Commercial Support regardless of whether or not CME credit is awarded unless FDA related or similar training is provided.
- Individuals may attend educational events not sponsored by the Health System only if the event is offered by a professional society, academic institution and complies with ACCME Standards or involves either training on the safe and effective use of a medical product and/or discusses non-promotional clinical educational information to further medical care.

The complete Policy and related materials are available from Corporate Compliance or visit our Department page on HealthPort



**Compliance
Helpline
(800) 894-3226
www.northshore-lij.ethicspoint.com**



Compliance
Helpline
(800) 894-3226

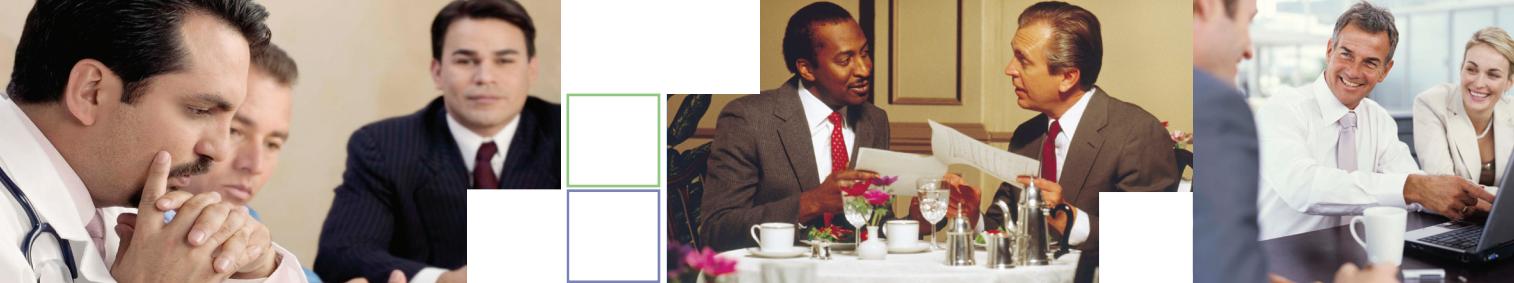
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North Shore-LIJ Health System
Office of Corporate Compliance
200 Community Drive
Great Neck, NY 11021
(516) 465-8097



Gifts and Interactions with Industry

Policy for Vendors



North Shore-LIJ

Purpose of the Policy

The Health System believes in proper relationships with its vendors and understands that, in their various roles in patient care, education and research, medical staff, employees, students, trainees, officers and trustees and other persons connected with the health system must interact with vendors and industry representatives at different levels from the marketing and purchasing of products, devices and supplies to education and research.

Such interaction can support and enhance the work of the health system in furthering its mission. However, such interaction must be properly managed in order to avoid conflicts of interest and maintain patient safety and the integrity of the health system's programs.

The purpose of this policy is to establish parameters for interactions with industry representatives for medical staff, faculty, employees, students, trainees and others connected with the North Shore-LIJ Health System.

Scope

- This policy applies to industry interactions with all health system employees, trustees, students, trainees, residents, employed and contracted clinicians and voluntary physicians as applicable (referred to as "individuals").
- Industry is defined as pharmaceutical, biotechnology, medical device and other healthcare-related entities.

Relationship to Industry Codes of Conduct

- The health system acknowledges both the *Code of Interactions with Healthcare Professionals* developed by the Pharmaceutical Research and Manufacturers Association (PhRMA) and the *Code of Ethics* developed by the Advanced Medical Technology Association (AdvaMed).
- However, due to the health system's role in education and research, its *Gifts and Interactions with Industry Policy* has features that are more rigorous than the above industry codes. Industry representatives with questions may contact the health system's Office of Procurement (516) 396-6410 or the Office of Compliance at (516) 465-8097.



Summary of Selected Portions of the Health System Policy on Gift and Industry Interactions



Gifts and Food

- Personal gifts (e.g., notepads, pens, food, wine, entertainment tickets, flowers) from Industry are prohibited on or off campus.
- Industry provided meals are prohibited both on and off campus unless the meal is provided in a manner consistent with ACCME Standards (e.g., no vendor involvement in planning the program or attendance, any food is incidental to the presentation, no sales materials).

Samples

- Drug samples provided by industry must adhere to the policies of that facility's pharmacy.
- The health system's facilities generally either prohibit or severely restrict the use of drug samples.
- If drug samples are allowed by a facility, industry drug samples should be used for patients only, for products that are needed quickly, and/or are cost prohibitive.

Health System Educational Events

All industry educational events sponsored by the health system must be compliant with ACCME Standards for Commercial Support regardless of whether or not CME credit is awarded unless FDA related or similar training is provided.

Consultation and Other Outside Engagements

- Outside engagements with industry such as consultations and presentations are permissible if terms are in writing, compensation is at fair market value, work reflects one's own views, has scientific merit and has been approved by the appropriate health system administrative director or chair.
- North Shore-LIJ individuals are prohibited from participating in industry-sponsored speaker's bureaus unless academic investigators are presenting results of their research to peers and there is an opportunity for critical exchange.
- Industry provided FDA-related training on the safe and effective operation of medical products may include modest meals and accommodations, but "lunch and learns" and similar engagements are not permissible.

Sales and Marketing Representatives

Access to North Shore-LIJ premises by industry representatives is limited to the following:

- Pharmaceutical sales and marketing representatives with new or compelling data may make an appointment with the health system's Chief Pharmacy and Medical Safety Officer or his/her designee or through the Office of Procurement (no other appointments are acceptable).
- Pharmaceutical Medical Liaisons (pharmaceutical company employees with advanced scientific or clinical degrees whose roles are to educate clinicians on scientific or medical advances in treatment of a disease entity, safe and effective use of the company's products and health outcomes), if credentialed with the health system's vendor credentialing system, may have limited access by prior appointment.

• Medical Device representatives may visit if the visit is related to the care of a patient and made by prior appointment. Industry representatives are permitted by invitation only and only in non-patient care areas unless to provide in-service education to clinicians.

- Industry representatives are permitted to interact with patients only by prior arrangement and only to provide patient education or assistance with the representative's products.
- No gifts, including food, provided by the industry representative are permitted.
- Students and trainees shall not interact with Pharmaceutical Medical Liaisons and Medical Device representatives unless faculty members are present and only for educational purposes that include an exchange of views.
- Professional dress is required at all times. Scrubs must be worn only in authorized areas and scrubs must never be removed from the premises.

- Access is limited to non-academic and non-patient care areas unless reasonably needed to access an appointment or for the education of a patient.

Industry Support for Health System Projects

- Solicitation of Industry support shall exclude industry marketing personnel and health system individuals with vendor or product recommendation roles to the extent practicable.
- Industry support shall not be payable to a health system individual, but to the health system.
- Industry support shall be accompanied by a certification from industry that the support is being provided to further an educational

or charitable purpose of the health system, and is not intended to influence purchasing decisions or research outcomes.

- North Shore-LIJ shall follow the ACCME Standards in managing industry's role, if any, in the project, event or purpose of the industry support.

Industry Support for Students or Trainees

- Scholarship and fellowship support by Industry is permitted, but must be by a written grant with the health system and placed in an account managed entirely by North Shore-LIJ.
- An independent medical association or similar entity can provide scholarship and fellowship support directly to a student or trainee in accordance with a local, regional or national competitive or recognition process.

Industry Product Evaluations and Site Visits

- Industry products left for evaluation are permissible subject to approval by the Office of Procurement and require the issuance of a no-charge purchase order that describes the timeframes for evaluation, delivery and retrieval by the Industry vendor.
- Industry support for travel by health system personnel to view products and equipment is prohibited.

For further information

Please call the Office of Corporate Compliance at (516) 465-8097 to obtain the complete policy and related educational materials.

SAMPLE

CONFLICTS OF INTEREST

2011 ANNUAL DISCLOSURE QUESTIONNAIRE

Dear Medical Chairpersons, Officers, Executive Directors, Licensed Practitioners and Key Employees:

We require all licensed practitioners, officers, key employees and trustees to disclose annually any potential conflict of interest and update any changes throughout the year in order to comply with existing and new federal and state laws.

Most recently, as part of the new health care legislation, the Physician Payments Sunshine Act will require industry manufacturers to publicly report annual payments greater than \$10 made to physicians and teaching hospitals. The Health System is being proactive in obtaining any necessary information to ensure our public reputation and perception is not implicated by any potential conflict of interest.

You have been identified to complete the Conflict of Interest questions. These questions have been assigned to you based upon your role in the Health System. Please answer each question to the best of your knowledge by **August 5, 2011**.

Please complete this form as soon as possible to ensure we comply with the IRS regulation's deadline.

Thank you for your cooperation with this important endeavor.

Very truly yours,

XXXXXX

VP, Chief Corporate Compliance Officer

Introduction

The reporting period for this annual disclosure is January 1, 2011 to the present.

Before completing this disclosure, you may find it helpful to review the Health System's Code of Ethical Conduct and the policies on "Conflicts of Interest and Recusal" and "Gifts and Interactions with Industry." These can be found on the Corporate Compliance webpage located on HealthPort. Each term that may require further clarification is underlined in each question and are included in Appendix A. If you answer "YES" to any question, you will need to provide further information.

When you complete your questionnaire, please fax it to the Office of Corporate Compliance at XXX-XXX-XXXX. Our office will manually enter your responses in the COI-SMART application then send you a PDF copy for your files.

If potential conflicts of interest arise during the year, you will need to revise and resubmit this document as soon as your situation changes. If you have any questions, please do not hesitate to contact the Office of Corporate Compliance at XXX-XXX-XXXX.

	Business Relationship with Elected Officials
1	Do you or a member of your Family have a Family or business relationship with any elected official at the local, state or federal level? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, please describe.
	Position to Influence Business Decisions
2	Are you, a <u>Family Member</u> or a <u>Related Business Interest</u> in a position to influence the business or other decisions of a <u>Health System</u> entity in a manner that could lead, or appear to lead, to the personal financial gain or advantage to you, a Family Member or Related Business Interest? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, please complete the following: List the name of the Person or Entity involved (e.g., your name, <u>Family Member</u> name, <u>Related Business</u>

<p><u>Interest name).</u></p> <p>List the <u>Health System</u> entity impacted.</p> <p>List <u>Health System</u> committee in which you participate that may influence decisions regarding the purchase or utilization of products or services for patient care (e.g., P&T Committee). If not applicable, write "Not Applicable".</p>
<p>3 Do you, a <u>Family Member</u> or a <u>Related Business Interest</u> have any <u>Financial Interest</u> in any private (i.e., not publicly-traded) corporation or enterprise with which any <u>Health System</u> entity has done or does business?</p> <p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, please complete the following:</p> <p>Owned By (e.g., employee, Family Member, Related Business Interest).</p> <p>Name of non-public corporation or enterprise.</p> <p>Description of Investment (e.g., stock, equity interest, property interest).</p> <p>Date Acquired.</p>
<p>4 Do you own stock in any publicly-traded healthcare related company (e.g., medical manufacturer, pharmaceutical company, laboratory company)? Please provide this information to help ensure our compliance with a new regulatory requirement.</p> <p>However, you do NOT have to report any shares in mutual funds or exchange-traded funds. Also, you do NOT have to disclose any stock information of family members.</p> <p><input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, please complete the following:</p> <p>List name of the Organization.</p> <p>State the estimated value of the investment (e.g. \$2,00.00)</p> <p>List name of the Organization.</p> <p>State the estimated value of the investment (e.g. \$2,00.00)</p>

	<p>List name of the Organization.</p> <p>State the estimated value of the investment (e.g. \$2,00.00)</p>
	Hold a Position with Business Entity
5	<p>Do you, a <u>Family Member</u> or a <u>Related Business Interest</u> hold a position as a director, officer, partner, trustee, employee, agent, a committee member, or consultant to, any individual, corporation, partnership or other business entity that does business with or provides products or services to any <u>Health System</u> entity?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, please complete the following:</p> <p>The name of Person or Entity involved (e.g., employee name, <u>Family Member</u> name, <u>Related Business Interest</u> name).</p> <p>List the name of organization.</p> <p>List the position held.</p> <p>Duration of position (e.g., 01/01/2011 - 12/31/2011).</p> <p>List amount of compensation (e.g., \$2,000.00. If no compensation, state \$00.00).</p>
	Business Transaction with Health System
6	<p>Have you, a <u>Family Member</u>, or a <u>Related Business Interest</u> engaged in any business transaction with any <u>Health System</u> entity?</p> <p>You do NOT have to report any compensation, benefits or reimbursement of expenses from the <u>Health System</u> or health care services or goods received as a patient.</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, please complete the following:</p> <p>List the name of the Person or Entity involved (e.g., employee name, <u>Family Member</u> name, <u>Related Business Interest</u> name).</p> <p>Description of transaction.</p> <p>List the <u>Health System</u> entity impacted.</p>

	Gifts, Gratuities, and Compensation from Health System Vendors or Malpractice
7	<p>Did you, a Family Member or a Related Business Interest receive any gifts, meals, gratuities, hospitality, or compensation including, but not limited to, consulting fees, honoraria, royalties and other payments for services from any existing or potential Health System vendor(s) or any malpractice law or consulting firm (e.g., consulting, research design, service on advisory or review committees, research, seminars, lectures, expert witness work, or teaching engagements)?</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, please complete the following:</p> <p>List the name of the Person or Entity Involved (e.g., employee name, <u>Family Member</u> name, <u>Related Business Interest</u> name).</p> <p>List the <u>Health System</u> vendor.</p> <p>Describe the service (e.g., consulting, speaking engagement, research, malpractice work).</p> <p>List the total compensation, gift and/or meal (e.g., \$2,000.00).</p> <p>Date(s) of service (e.g., 1/1/2011-12/31/2011).</p> <p>Does it conform with policy 800.04 entitled "Gifts and Interactions with Industry"? For a copy of this document, please refer to the Office of Corporate Compliance Webpage under Policies.</p> <ul style="list-style-type: none"> • <input checked="" type="checkbox"/> Yes • <input type="checkbox"/> No
	Outside Health Care Employment/Committee Memberships/Volunteer Opportunities
8	<p>Are you, a <u>Family Member</u> or a <u>Related Business Interest</u> a member of a governing board, an officer, an employee, an agent of, or have an ownership/financial interest, or receive compensation from any health care provider other than a <u>Health System</u> entity?</p> <p>Please note that clinicians do not need to list entities where they have staff privileges, but must disclose compensation received from non-<u>Health System</u> healthcare providers or any ownership interest in a non-<u>Health System</u> health care provider. For example, physicians must disclose if they are treating patients</p>

<p>outside their employment with the <u>Health System</u> and receiving any compensation.</p> <p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, please complete the following information:</p> <p>List the name of the Person or Entity involved (e.g., employee name, <u>Family Member</u> name, <u>Related Business Interest</u> name).</p> <p>Name of non-<u>Health System</u> entity.</p> <p>Description of employment, service, or ownership interest.</p> <p>Total Compensation (e.g. \$2,000.00. If no compensation, state \$0.00. If <u>Family Member</u>, type N/A).</p> <p>Date(s) of service (e.g., 1/1/2011-12/31/2011).</p>
<p>Other Matters</p>
<p>9 Are you involved with any other matter that could be perceived as a <u>Conflict of Interest</u> with the <u>Health System</u>? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If yes, please describe below.</p>

APPENDIX A

HELP DEFINITIONS FOR GENERAL FINANCIAL QUESTIONS

Associated Individuals means all individuals employed by or otherwise associated with the Health System including, but not limited to, trustees, officers, employees, agents, medical staff, volunteers and students.

Conflict of Interest may exist if an Associated Individual is in a position to influence the business or other decisions of the Health System in a manner that could lead, or appear to lead, to the personal gain or advantage of the Associated Individual, his or her Family Members, or a Related Business Interest.

Family Member means husband or wife; natural or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or

sister-in-law; grandparent or grandchild; and any other person if that person resides in the same household as the Associated Individual.

Related Business Interest means any person, organization or business entity may be considered as a Related Business Interest to an Associated Individual if such Individual or any member of his/her Family: (1) is a director, officer, employee, member, partner or trustee of such Related Business Interest; or (2) has a financial interest in such Related Business Interest, which includes any ownership, investment, income or similar right or interest which could benefit the Associated Individual or a Family member.

Financial Interest means a person has directly or indirectly through business, investment, or a Family Member:

- An ownership or investment interest in any entity with which the Health System has a transaction or arrangement; or
- A potential ownership or investment interest in any entity with which the Health System is negotiating a transaction or arrangement.

Business relationships between two persons include the following: One person is employed by, or is transacting business with, another person or with another organization in which the other person is an owner, director, officer or key employee.

Two persons are related to the same business or investment entity as directors, officers or greater than 10% owners.

Health System includes all of the hospitals, and related not-for-profit and for-profit entities. See list below.

1. XXXXXXXX
2. XXXXXXXX

	10 Did you have, or do you currently have, a <u>Family</u> relationship or a <u>Business Relationship</u> with any Trustee, officer or employee of the <u>Health System</u> ? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, please describe the relationship.
	11 Did you have, or do you currently have, a <u>Family</u> relationship or a <u>Business Relationship</u> , directly or indirectly, with the <u>Health System</u> or with any entity that has done business with the Health System?



Yes No If yes, please describe the relationship.

12 Have you, under any current or former name or business entity, ever:

a) Been convicted of, or pleaded guilty to, a felony or misdemeanor that would result in mandatory exclusion from the Medicare program or that is related to (i) a financial crime (such as theft, fraud, extortion, embezzlement, income tax evasion, breach of fiduciary duty, and insurance fraud); (ii) a crime that placed the Medicare program or its beneficiaries at immediate risk (such as a criminal neglect or misconduct conviction in a malpractice suit); (iii) the delivery of an item or service under Medicare or a State health care program, or the abuse or neglect of a patient; (iv) interference with or obstruction of any investigation into any criminal offense; or (v) the unlawful manufacture, distribution, prescription or dispensing of a controlled substance?



Yes No If yes, please complete the following:

Describe the adverse legal action for the conviction.

Date of conviction.

List the Federal or State agency or the court/administrative body that imposed the action/conviction.

b) Had a revocation or suspension of (i) a license to provide health care by any state or federal licensing authority; (ii) accreditation to provide health care or participate in a Federal or State health care program; or (iii) any Medicare billing number or Medicare payment?



Yes No If yes, please complete the following:

Describe the adverse legal action for the conviction.

Date of conviction.

List the Federal or State agency or the court/administrative body that imposed the action/conviction.

c) Had a suspension, exclusion or debarment from participation in, or sanction imposed by, any Federal or State health care program or any Federal procurement or non-procurement program?

Yes No If yes, please complete the following:

Describe the adverse legal action for the conviction.

Date of conviction.

List the Federal or State agency or the court/administrative body that imposed the action/conviction.

Attestation

I certify that I have read and am in compliance with the Code of Ethical Conduct and the NSLIJ Health System policies entitled “Conflicts of Interest and Recusal,” “Gifts and Interactions with Industry” to the best of my knowledge. I further certify that the information contained in this Disclosure is accurate and complete to the best of my knowledge.

Printed Name and Title: _____

Signature: _____

Date: _____

HELP DEFINITIONS FOR IRS and CMS RELATED QUESTIONS

Trustees and their businesses are identified on the attached List of Trustees. [Drop down list]

Family is defined to include spouses, parents and grandparents, brothers and sisters (whether whole or half blood), children (whether natural or adopted), grandchildren, great-grandchildren and spouses of any of these persons.

Business relationships between two persons include the following:

One person is employed by, or is transacting business with, another person or with another organization in which the other person is an owner, director, officer or key employee.

Two persons are related to the same business or investment entity as directors, officers or greater than 10% owners.

Below are a few examples of a **Business Relationship**.

Example 1. D and E are Health System employees. D's spouse is also a partner in an accounting firm with 300 partners, but is not an officer, director or key employee of the firm. D's accounting firm provides services to E in the ordinary course of trade or business, on terms generally available to the public, and receives \$2,000,000 in fees during the year. This relationship is not reportable both because (1) it is in the ordinary course of trade or business and (2) D does not hold a greater-than-35% interest in the firm.

Example 2. F and G are Health System employees. F's spouse is the owner and CEO of a professional hockey team. G purchased a luxury suite for all of the team's home games at the published rate of \$250,000 for the year. This relationship between F and G is not reportable because the transaction was in the ordinary course of business on terms generally offered to the public.

Example 3. H and J are Health System employees. Both employees' spouses are CEO's of publicly-traded companies and each serves on the other's board. This outside relationship is a reportable business relationship because each is an officer or director of the same business entity.

Example 4. K and L are Health System employees. L's spouse is a greater-than-35% partner in a law firm that during the year charged K a special rate of \$60,000 for legal services that were worth \$240,000. The ordinary course of business exception does not apply because the services were at rates not available to the general public. However, the attorney/client privilege exception does apply, and therefore this is not a reportable transaction.

Health System includes all of the hospitals, and related not-for-profit and for-profit entities. See list below.

1. XXXXXXXX
2. XXXXXXXX

List of Some Key Conflicts of Interest Journal Articles/Reports

- Patients' attitudes about gifts to physicians from pharmaceutical companies, *J. Am. Board Fam. Pract.* 1995 Nov.-Dec. 8(6); 457-64
- Physicians and the Pharmaceutical Industry – Is a Gift Just Ever a Gift? *JAMA* 2000; 283:373-380, Jan.19, 2000
- Of Principles and Pens: Attitudes and Practices of Medicine Housestaff toward Pharmaceutical Industry Promotions, *The American J. of Med.*, Vol. 110, 551-57, May 2001
- A Social Science Perspective on Gifts to Physicians from Industry, *JAMA* 2003; 290: 252-255, July 9, 2003
- The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest, *34 J. Legal Studies* 1-25 (The University of Chicago, January 2005)
- Health Industry Practices that Create Conflicts of Interest – A Policy Proposal for Academic Medical Centers, *JAMA* 2006; 295: 429-433, January 25, 2006
- A National Survey of Physician-Industry Relationships, *N. Engl. J. Med.* 2007; 356: 1742-1750, April 26, 2007
- Association of American Medical Colleges (AAMC), "The Scientific Basis of Influence and Reciprocity: A Symposium" (June 12, 2007)
- Academic Medical Centers and Financial Conflicts of Interest, *JAMA* 2008; 299: 695-697, Feb. 13, 2008
- AAMC, "Industry Funding of Medical Education: Report of an AAMC Task Force" (June 2008)
- Accuracy of Conflict-of-Interest Disclosures Reported by Physicians, *N. Engl. J. Med.* 2009; 361: 1466-1474, Oct. 8, 2009
- The Agenda for Continuing Medical Education – Limiting Industry's Influence, *N. Engl. J. Med.* 2009; 361: 2478-2482, December 17, 2009
- Conflict of Interest in Medical Research, Education, and Practice, *Institute of Medicine*, Apr. 2009
- Serving Two Masters – Conflicts of Interest in Academic Medicine, *N. Engl. J. Med.* 2010; 362(8), 669-671, Feb. 25, 2010
- Disclosing Industry Relationships – Toward an Improved Federal Research Policy, *N. Engl. J. Med.* 2010, 363;7, 604-606, Aug. 12, 2010
- AAMC Report: *In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making*, June 2010

Sample Conflicts of Interest Contractual Provision

- Conflicts of Interest. X represents that it has disclosed to Hospital all relationships or financial interests that may represent or could be construed as a conflict of interest with respect to X's transaction of business with Hospital. Except as may be disclosed in writing by X, X further represents that no employee, trustee or officer of Hospital is a partner, member or shareholder of, or has a financial interest in X. For purposes of this Section, the term "financial interest" shall include, but not be limited to, the following transactions or relationships between an employee, trustee or officer of Hospital and X - consulting fees, honoraria, gifts or other emoluments, or "in kind" compensation; equity interests, including stock options, of any amount in a publicly or non-publicly-traded company (or entitlement to the same); royalty income (or other income) or the right to receive future royalties (or other income); any non-royalty payments or entitlements to payments; or service as an officer, trustee, or in any other role, whether or not remuneration is received for such service. A breach of any representation under this Section shall be grounds for immediate termination of this Agreement.

North Shore-LIJ Health System Conflicts of Interest and Recusal Policy

Policy #800.03

North Shore-LIJ Health System
Corporate Compliance Office
200 Community Drive
Great Neck, NY 11021
(516) 465-8097



North Shore LIJ Hope lives here.SM

northshorelij.com

North Shore LIJ

Art: GHonaski, North Shore-LIJ Art Dept, 13125-5-10



Purpose of the Policy

Conflicts of Interest arise when a person who is in a position to influence the business or other decisions of the Health System does so in a manner that leads or appears to lead to personal gain for himself or herself, Family members or Related Business Interests.

Such conflicts interfere with that person's duty of loyalty to the Health System. Ultimately, such conflicts may lead to decisions that negatively affect cost and quality. The federal Physician Payments Sunshine Act and various state statutes reflect this concern and will require drug and medical device manufacturers and other companies to report payments to physicians.

Accordingly, it is the policy of the Health System to conduct business free from the influence of Conflicts of Interest and to properly manage and mitigate Conflicts of Interests using a system of disclosure and recusal.

This brochure discusses some of the issues regarding the Health System's policy.

For more information, we have available

- The complete Conflicts of Interest and Recusal Policy
- The Health System's Code of Ethical Conduct
- On-line disclosure reporting – <https://nshs.coi-smart.com>
- Gifts and Interactions with Industry Policy
- Business Courtesies to Potential Referral Sources Policy
- Health System's Conflict of Interest in Research Policy
- FAQ on Conflicts of Interest

You can also contact us at:
Corporate Compliance 516.465.8097



Scope: Associated Individuals, Family Members, Related Business Interests

- The policy applies to “Associated Individuals.” These are persons employed or otherwise associated with the Health System including, but not limited to Trustees, officers, employees, agents, medical staff, and students.
- Associated Individuals can have conflicts of interest if their decisions at the Health System benefit or appear to benefit themselves, Family Members or Related Business Interests. **Example:** Member of a formulary committee consults for a drug manufacturer. See Disclosure and Recusal sections.
- A Family Member of an Associated Individual means spouse, natural or adoptive parents, children, and/or siblings, stepchildren, stepsiblings, in-laws, grandparents and grandchildren of the Associated Individual, and any other person who resides in the same household of the Associated Individual. **Example:** Employed physician has in-laws who own a nursing home that may receive referrals from her hospital. See Disclosure and Recusal sections.
- A Related Business Interest means a person, organization or business entity in which an Associated Individual or Family member (a) serves as an employee, officer, director, member, partner, or trustee, or (b) has a financial interest such as ownership, investment, income or similar right or interest that can benefit the Associated Individual or Family member.

Example: An employee’s spouse is an owner of health care products company that does business with the Health System.

- Regarding ownership of outside companies, disclosure and recusal decisions can vary based on factors such as the employee’s role in the Health System, the private or public nature of the company, or its size. See Disclosure and Recusal sections, the policy’s “Frequently Asked Questions” (FAQ) document, or call the Office of Corporate Compliance for further guidance.

Examples of Conflicts

- Outside activities by the Associated Individual, Family member or Related Business Interest that actually or potentially compete with the Health System such as employment by a competitor. Please note that clinicians maintaining hospital staff privileges at a competing hospital is not an inappropriate Conflict of Interest and does not need to be disclosed.
- Outside activities by the Associated Individual, Family Member or Related Business Interest that actually or potentially compromise the Associated Individual’s work or decision-making at the Health System such as employment by a Health System vendor.
- Based on details of the Associated Individual’s role and function at the Health System, the outside activity may not be problematic.

Disclosure

- Disclosure by the Associated Individual is the best first step to avoid any potential issue.
- Associated Individuals must promptly disclose actual or potential conflicts of interest to the Office of Corporate Compliance. Any Associated Individual who intends to enter into any arrangement that could potentially generate referrals must have the arrangement approved by the Chief Compliance Officer prior to entering into it. Please contact the Office of Corporate Compliance regarding any questions about a potential conflict.
- Certain Associated Individuals designated by the Office of Corporate Compliance will complete a Conflict of Interest Disclosure Report upon employment or affiliation with the Health System and at regular times thereafter.
- The Office of Corporate Compliance will advise of next steps, if any, to manage any conflicts.

Recusal

- Following disclosure, Associated Individuals should recuse themselves from discussion or other participation in matters or transactions giving rise to the conflict.
- Recusals should be recorded in committee minutes, if applicable, or documented by supervisors.
- The Office of Corporate Compliance is available to answer questions.

Other Issues

- Associated Individuals must not disclose Health System confidential information to unauthorized internal and external individuals.
- Associated Individuals involved in research are also subject to the Health System’s Conflict of Interest in Research Policy (#GR065).
- Trustees and certain key employees also are required to complete additional disclosure forms related to the Internal Revenue Service Form 990 and CMS-855a Enrollment Form.
- Employees must comply with Health System’s policy 800.03 that restricts the use of Health System work time and other resources on outside engagements.
- This policy’s FAQ document has additional information regarding commonly asked questions.

Gifts and Interaction with Industry Policy and Business Courtesies to Potential Referral Sources Policy

These policies are related to the Conflicts of Interest and Recusal policy and can be consulted for additional information, particularly in cases involving relationships with drug and medical device companies and social gifts and gratuities.

The complete Policy and related materials are available from the Office of Corporate Compliance or visit our Department page on HealthPort.

SAMPLE	ADMINISTRATIVE POLICY AND PROCEDURE		
POLICY TITLE	POLICY #	DEPARTMENT:	
Prepared by: Physician Contracts Committee	Effective Date:	Last Revised/Reviewed:	Page 1 of 5

Scope

This policy applies to X and all of its members and affiliated entities, and their personnel, including but not limited to, their employees, medical staff, students, physician office staff, and volunteers (collectively, the Health System).

Purpose

To establish parameters for the extension of Business Courtesies to Potential Referral Sources and their Immediate Family Members.

Definitions

Practitioner: means a licensed or registered doctor of allopathic medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, a chiropractor, a nurse, a mid-wife, physician assistant, physical therapist or optometrist.

Immediate Family Member: means spouse; natural or adoptive parent, child or sibling; stepparent, stepchild, or stepsibling; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and the spouse of a grandparent or grandchild.

Potential Referral Source: means any Practitioner who may refer Medicare or Medicaid patients to the Health System regardless of whether or not he or she is an employee of the Health System.

Business Courtesies: means items of value given to another free of cost or at a discount, as well as social events sponsored or hosted by the Health System such as meals, sporting events, theatrical events and receptions. Examples set forth below further elaborate on what is and is not included in this definition.

Annual Limit: means the maximum value of all Business Courtesies that may be extended to a Potential Referral Source in a calendar year as specified by the Stark Law. The Annual Limit is adjusted for inflation each year, and is \$380 in 2013.

Policy

It is the obligation of the Health System to comply with the federal Ethics in Patient Referrals Act and related regulations, also known as the Stark Law. See 42 U.S.C. § 1395nn and 42 C.F.R. §§ 411.350-357. See also N.Y. Pub. Health Law § 238-a. Accordingly, the Health System may

SAMPLE	ADMINISTRATIVE POLICY AND PROCEDURE		
POLICY TITLE	POLICY #	DEPARTMENT: Corporate Compliance	
Prepared by: Physician Contracts Committee	Effective Date:	Last Revised/Reviewed:	Page 2 of 5

extend Business Courtesies to a Potential Referral Source and his or her Immediate Family Members provided that the total value of such Business Courtesies does not in the aggregate exceed the Annual Limit. To assure that the Annual Limit is not exceeded, such Business Courtesies shall be tracked as set forth below.

Business Courtesies extended to a Practitioner who has a bona fide employment arrangement with the Health System are not subject to the Annual Limit and do NOT need to be tracked for purposes of this Policy, provided that the employment arrangement complies with the Health System's Policy X, entitled Compensation Valuation Methodology. See Examples and Exceptions, Section 2.c.

Nothing in this policy permits any Business Courtesy or other benefit that is understood by either party to be offered or provided as an inducement to refer patients or business or as a reward for such referrals, nor may a Business Courtesy be extended to a Potential Referral Source who solicits it.

Any Business Courtesy must be modest in nature and shall not be provided to any spouse of a Potential Referral Source unless the spouse is an applicable business partner.

Please Note: Business Courtesies extended to individuals and entities that are not Potential Referral Sources are governed by the Health System's Code of Ethical Conduct and Health System Policy on Gifts and Interactions with Industry. These documents also address receipt by Health System employees of Business Courtesies from business associates, including Potential Referral Sources.

Procedure

1. Health System individuals may extend a Business Courtesy to a Potential Referral Source and his or her Immediate Family Members if the Business Courtesy meets all of the following conditions:

- a. It is not cash or a cash equivalent, such as gift certificates, checks or stock instruments;
- b. It does not exceed the Annual Limit or cause the total value of Business Courtesies extended to the same Potential Referral Source and that Potential Referral Source's Immediate Family Members to exceed the Annual Limit;
- c. It is not determined in any manner that takes into account the volume or value of referrals or other business generated by the Potential Referral Source; and
- d. It is not offered or provided as an inducement to refer patients or business or as a reward for such referrals, and is not extended to a Potential Referral Source who solicits it.

SAMPLE	ADMINISTRATIVE POLICY AND PROCEDURE		
POLICY TITLE	POLICY #	DEPARTMENT: Corporate Compliance	
Prepared by: Physician Contracts Committee	Effective Date:	Last Revised/Reviewed:	Page 3 of 5

2. The Office of Corporate Compliance shall maintain a Business Courtesy log to track Business Courtesies to Potential Referral Sources and his or her Immediate Family Members.
3. Health System individuals must notify the Office of Corporate Compliance either via email or by telephone before any Business Courtesy can be offered to a Potential Referral Source and/or his or her Immediate Family Members.
4. The Health System requestor shall provide the Office of Corporate Compliance the following information: the Potential Referral Source's name, the applicable Health System facility(s) offering the Business Courtesy, a description of the Business Courtesy, the date of the Business Courtesy, and the monetary value of the Business Courtesy.
5. The Office of Corporate Compliance will send the requesting individual an email approving the proposed Business Courtesy provided that its monetary value does not cause the Annual Limit to be exceeded. If the proposed Business Courtesy would cause the Annual Limit to be exceeded, the Office of Corporate Compliance will deny the request to provide the Business Courtesy.
6. If the Business Courtesy is a meal, the requesting individual shall not go over the monetary amount approved by the Office of Corporate Compliance. The requestor should provide the Office of Corporate Compliance a copy of the receipt of the meal if the meal expense was either lower or higher than the approved amount.
7. If the proposed Business Courtesy's monetary value changes, the requesting individual must notify the Office of Corporate Compliance of the change in monetary value before the Business Courtesy is provided to the Potential Referral Source. The Office of Corporate Compliance will send the requesting individual an additional email approving the revised Business Courtesy proposal, provided that the change in monetary value does not cause the Annual Limit to be exceeded. If the proposed Business Courtesy exceeds the Annual Limit, the Office of Corporate Compliance will deny the request to provide the Business Courtesy.
8. If a Business Courtesy is inadvertently provided to a Potential Referral Source before receiving the Office of Corporate Compliance's approval, the requesting individual shall immediately notify the Office of Corporate Compliance and provide it with the applicable information about the Business Courtesy.

Examples and Exceptions

1. Examples of Business Courtesies that must be tracked under this policy include, but are not limited to, the following:
 - a. sporting events or other similar events such as theater and concerts, including the cost of the tickets;

SAMPLE	ADMINISTRATIVE POLICY AND PROCEDURE		
POLICY TITLE	POLICY #	DEPARTMENT: Corporate Compliance	
Prepared by: Physician Contracts Committee	Effective Date:	Last Revised/Reviewed:	Page 4 of 5

- b. local recreational events, such as golfing, fishing, boating, hunting, including cart fees and meals, but excluding the value of the charitable contribution if the event is a charity event;
 - c. flowers or other gifts provided to Practitioners or their Immediate Family Members when they are hospitalized or to recognize a special event, such as a birthday or other family occasion;
 - d. perishable items (e.g., food, wine) provided to a Practitioner's office; and
 - e. hosting holiday or other parties for Practitioners and their Immediate Family Members other than one appreciation party per year as described below. See Examples and Exceptions, Section 2.f.
2. The following activities are **NOT** considered Business Courtesies, may be provided to Potential Referral Sources without being counted toward the Annual Limit, and do not need to be tracked:
- a. conferring benefits valued at less than \$32 per occurrence to a Potential Referral Source who is a member of the medical staff, provided:
 - i. the benefits are conferred within a hospital, ambulatory surgery center or other Health System facility;
 - ii. the benefits are offered only during periods when the Potential Referral Source is making rounds or engaged in other services or activities that benefit the facility or its patients; iii. all members of the medical staff practicing the same specialty are offered the same benefit;
 - iv. the benefit is reasonably related to the provision of, or designed to facilitate directly or indirectly the delivery of, medical services at the facility; and v. the benefit is not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties.

Examples of this exception include: free parking in the facility's garage and modest meals in the physician's lounge.

- b. providing Business Courtesies in exchange for their fair market value price;
- c. providing Business Courtesies pursuant to a bona fide employment arrangement that complies with the Health System's Policy 800.12, entitled Compensation Valuation Methodology;
- d. providing a business meal where the purpose is to discuss the Potential Referral Source's duties under a personal services agreement with the facility where the agreement specifically contemplates such a Business Courtesy;
- e. providing a business meal to a Potential Referral Source practicing within the geographic area served by the Health System to discuss a potential bona fide employment relationship, provided that appropriate documentation of the business purpose is kept by the applicable business department;
- f. providing **one** local medical staff appreciation event (including a holiday party) per year so long as: (i) the facility has a formal medical staff; and (ii) all members of the

SAMPLE	ADMINISTRATIVE POLICY AND PROCEDURE		
POLICY TITLE	POLICY #	DEPARTMENT:	
Business Courtesies to Potential Referral Sources		Corporate Compliance	
Prepared by: Physician Contracts Committee	Effective Date:	Last Revised/Reviewed:	Page 5 of 5

- medical staff are invited. However, any gifts or gratuities provided in connection with the event are Business Courtesies and must be tracked accordingly;
- g. providing a business courtesy such as a business meal to a Potential Referral Source at a facility's medical related committee pursuant to a written agreement; and
 - h. providing any other Business Courtesy if it meets an applicable exception under the Stark Law, as amended, and is approved in writing in advance by the Office of Legal Affairs.

REFERENCES to REGULATIONS and/or OTHER RELATED POLICIES

42 U.S.C. § 1395nn
 42 C.F.R. §§ 411.350-357
 N.Y. Pub. Health Law § 238-a
 Gifts and Interactions with Industry Policy
 Code of Ethical Conduct



Opening a New Hospital/ Medical Center A Look at the Imperative Role of Compliance

Jane VanNess, JD, CHC - Hospital Compliance Officer
Monica R. Freedle, CHC - Hospital Compliance Program Manager



Agenda

About Kaiser Northwest & Westside Medical Center

Getting Started

Highly Reliable Organization

Key Compliance Activities

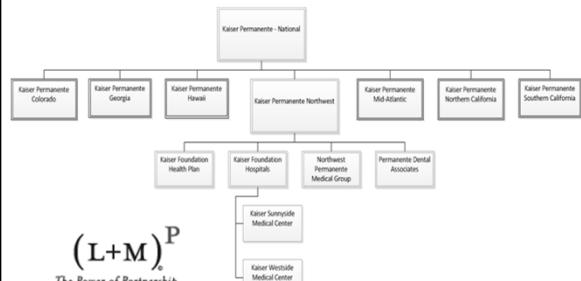
Licensing and Accreditation/Medicare Billing

Lessons Learned

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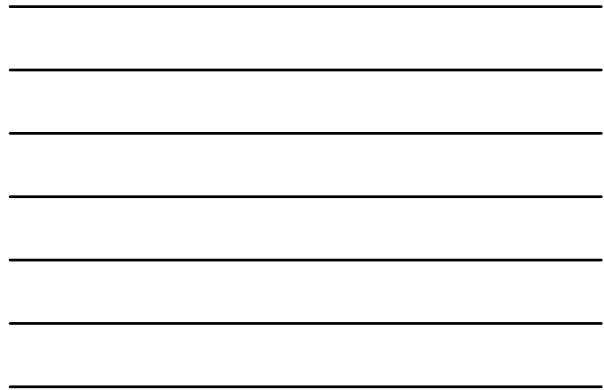
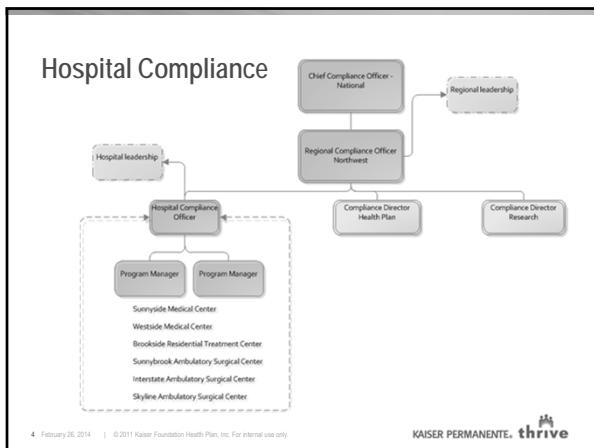


A Look at Kaiser Permanente Northwest



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Hillsboro, Oregon (Portland Metro)



Kaiser Westside Medical Center (KWMC)

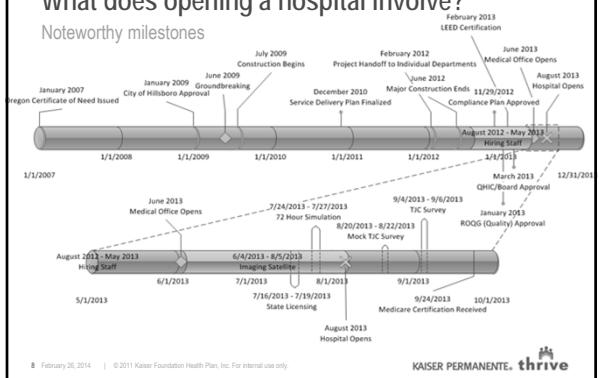


Getting Started



What does opening a hospital involve?

Noteworthy milestones



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When does Compliance get involved?



- Hospital Compliance was part of the AR&L, Compliance and Legal Workgroup which began in June 2010
 - Other areas joined – Quality, Safety, Infection Control, Chief Nursing Officer, Chief Medical Officer, Risk Management, Labor Partners
 - Later known as "Big Q"
- Development of a "Compliance Plan"
- Initial review of building floor plans

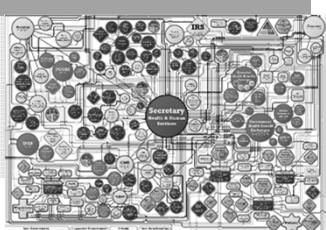
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What is our first task?

Identify all applicable laws and regulations

- Federal
- State
- The Joint Commission
- Licensing Bodies
- Local



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How do we track compliance?

- Categorize legal/regulatory requirements
 - Licensing
 - Building and facilities
 - Provision of care
 - Billing and finance
- Notify key players
- Develop timeline
- Track compliance



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What needs to be tracked?

Some examples

- Required staff
 - What leaders and positions are required to be on-site?
 - What committees are required? Who are the required members?
- Required signage
- Required trainings
- Licensing/certification requirements
- Facility/building requirements
- Obtaining approvals from governing bodies

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Get Involved



Big Q



Leadership Team



Command Center

Tracked hospital preparation and readiness for August opening.

Hospital Compliance Officer

All follow up was tracked in this meeting which transitioned to the daily operations brief after opening.

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Business Partners

- Hospital Leadership
- Engineering
- Facilities
- Safety
- Admissions/ Business Office
- Legal
- Infection Control
- Chief Medical Officer
- Accreditation, Regulatory and Licensing
- Pharmacy
- Quality
- Nursing- leaders and floor staff
- Surgical Services
- Hospital Compliance
- Information Technology
- PT/OT/Speech Therapy
- Lab
- Clinical Informatics
- Imaging
- Labor

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Highly Reliable Organization

"The core passion of everyone who works at KWMC is to provide our patients, their families, and the community with the highest level of care and service."

— KWMC Cultural Norms and Expectations



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Patient-and-Family Centered Care

Cultural Norms and Expectations at Westside Medical Center

- Leadership – “everything in the culture is focused on patient and family centered care”
- Hearts and Minds – “fully committed to the shared of values of patient-and-family centered care”
- Respectful Partnership – “Every care interaction is anchored in a respectful partnership, anticipating and responding to patient and family needs.”
- Reliable Care – “Patients say, ‘Staff was available to give the care I needed.’”
- Evidence-based Care – “there is open communication and apology”

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A Challenge to Overcome

Westside Specialty Medical Office opened three months before the hospital.

- This was not part of the plan. Flexibility was required.
- Imaging Department (a hospital department) scheduled to open with the hospital
- How will clinic patients receive imaging services?
- Application to State allowing us to operate Imaging as a satellite of Kaiser Sunnyside Medical Center
- Satellite had to be fully opened and then closed to re-open as a Westside Hospital department

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Preparing Staff For Opening

Big Top Event

- Westside Orientation two + months prior to opening
- One week of learning, team-building, uniform fittings and more
- 900-1500 attendees each day
- Included transfers

3+ months training

- Leadership beginning training earlier
- All staff taking interpersonal communications classes
- Tracers and test runs
- 72 hour simulation

Continued Learning

- Continued tracers
- Rounding on units
- Staff aware of knowledge gaps
- Survey and License Preparation
- Specialized trainings

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Compliance Participation Right Before Opening

Education	Tracers and Rounding	Survey and License Prep
Big Top Presentation Rounding Compliance Training	Active participation in both walk-through and scenario based tracers	Policy Reviews Progress Tracking Auditing Staff Knowledge

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Licensing and Accreditation



Pre-Opening Activities

Major compliance projects

- HIPAA Readiness Audit
- Regulatory Signage Audit
- Medicare COP Review
- EC in the ED (Emergency Contraception)
- Simulation Documentation Audits
- Employee File Audits
- Shared Service Agreements
- Pharmacy Audit
- EMTALA Response Plan & Training
- Policy Revision & Creation

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Other Compliance Preparation Work

- Compliance rounding and training
 - Focus on Principles of Responsibility
 - "We Are Ready" booklet
 - Patient Rights and Responsibilities
- "Live" auditing of process compliance during simulations
- Continued tracking of compliance readiness (Site of Service)
- National Facilities Compliance visit
- Continued work with AR&L team to submit and track licensing paperwork
 - State licensing
 - Pharmacy
 - OCR Submission
 - Lab / CLIA
 - Imaging
 - Medicare Certification

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The Surveys

State Licensing	Mock TJC Survey	TJC Survey
<ul style="list-style-type: none">■ Approximately 1 month before opening■ No findings■ Positive experience for hospital and state■ Learning opportunity	<ul style="list-style-type: none">■ Full 3 day mock survey■ Actual staff and patients involved■ Findings taken to command center for follow up	<ul style="list-style-type: none">■ Successful survey – accreditation obtained■ 3 indirect findings■ 1 direct finding■ Active leadership engagement during process led to real-time training and improvements

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Compliance's Role in Surveys

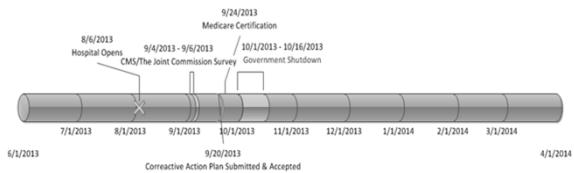
- During the surveys
 - Running
 - Scribing
 - Escorting
 - Proofing policies and materials
 - Researching
- After the surveys
 - Participation in action plan development and resolution
 - Tracking action plans through completion
 - Auditing and monitoring activities to ensure ongoing compliance

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Medicare Billing

A longer process than imagined



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Lessons Learned

Some audits or reviews must be repeated once patients are in the hospital.

Create a clear ownership for HR and Credentialing files and processes.

Survey preparation for staff should include physicians.

Clearly define responsibilities for staff during and after surveys.

Keep track of surveyor and participant locations during surveys.

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Questions?

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Monica R. Freedle, CHC: [\(monica.r.freedle@kp.org\)](mailto:monica.r.freedle@kp.org), (971) 310-4722

Objectives

Learn how to:

- Communicate with operational staff to improve prevention and detection efforts
- Engage operational managers/directors in compliance monitoring
- Capture and document routine monitoring that demonstrates compliance effectiveness

2

Communication

- Research shows that each person hears accurately what is said only 1/3 of the time; the other 2/3 of the time the information is distorted. (U.S. Office of Personnel Management)
- The most effective way to communicate is to recognize other people's styles and talk to them on their own level.

3

Communication and Compliance

- Effective communication is a compliance officer's most important skill.
 - Listen and understand others
 - Allow others to listen and understand you
- Effective communication → Effective compliance strategies

4

Operating an Effective Compliance Program

- Creating a culture of compliance
- Make compliance activities proactive vs. reactive
- Identify and respond in a comprehensive and understandable manner

5

Operating an Effective Compliance Program

- Policies and procedures
- Measuring effectiveness
- Training
- Lines of communication
- Internal auditing
- Enforcement and prompt response to issues

Source
Take the Initiative: Cultivate a Culture of Compliance with Health Care Laws. Health Care Fraud and Prevention and Enforcement Team (HEAT), OIG. Available at: <http://oig.hhs.gov/compliance/provider-compliance-training/index.asp>

6

Rules of Effective Communication

- **Simplicity.** Use small words. The most effective language clarifies rather than obscures.
- **Brevity.** Use short sentences. And, never use a sentence when a phrase will do.
- **Credibility.** Credibility is as important as philosophy. Remember that people have to believe it to buy it. Your words must be sincere.
- **Consistency matters.** Repetition, repetition, repetition. Brand your product and stay in the public eye.

From *Words That Work* by Dr. Frank Luntz

7

Rules of Effective Communication

- **Novelty.** Offer something new. Tell customers something that gives them a brand new take on an old idea. A message that combines surprise and intrigue works best.
- **Sound and texture matter.** The sounds and texture of language should be just as memorable as the words themselves. A string of words that have the same first letter, the same sound, or the same syllabic cadence is more memorable than a random collection of sounds.

From *Words That Work* by Dr. Frank Luntz

8

Rules of Effective Communication

- **Speak personally.** Personalize and humanize the message. If the listener can apply the language to a general situation or human condition, that is humanization. If the listener can relate that language to his or her own life experiences that is personalization.
- **Visualize.** A slogan or message should have a strong visual component, something to see and almost feel. "Imagine" is one of the most powerful words.

From *Words That Work* by Dr. Frank Luntz

9

Rules of Effective Communication

- **Ask a question.** This can be rhetorical or not. Questions are interactive! “Imagine yourself in this situation. What would you do?”
- **Provide context and explain relevance.** You have to give people the “why” of the message before you tell them the “therefore” and the “so that.”

From *Words That Work* by Dr. Frank Luntz

10

Communication & Compliance

- Communication is a compliance key value
- Build communication plans into compliance activity planning (policies, work plans, root causes, risk assessments, audits)
- Review communication successes and areas for improvement regularly
- Gather feedback often (up, down, operations, and delegates)

11

Analyzing Communication Practices and Patterns

- “You don’t know where you are going if you don’t know where you have been...”
- This is particularly important if:
 - You’re faced with recovering from prior bad communication
 - You’re new to your role
 - Your organization has new leadership
- 360° Review – look up, down, in the mirror, around, and out
- Gather input (does not need to be formal)

12

Analyzing Communication Practices and Patterns

- Evaluate the past:
 - How long have you been in your role?
 - What was your predecessor's style?
 - What is the organization's culture?
 - What bridges need strengthening?
 - People-specific?
 - Compliance role/intent?
 - Verbal communication?
 - Written communication (particularly emails)?

13

Analyzing Communication Practices and Patterns

- Evaluate the present:
 - What works?
 - What doesn't work?
 - What limitations exist?
 - Who are your allies?
 - What relationships need could be improved?
 - Review a case study (e.g., audit experience)

14

Analyzing Communication Practices and Patterns

- Where do you want to go in the future?
 - What would people respond well to based on your current understanding?
 - What specific goals do you have for the program?
 - How does communication fit into your auditing and monitoring plan?
- Develop a game plan
 - Write it down
 - Keep it pinned on your wall

15

Individual Communication Styles

- All individuals fall within four communication styles: action, process, people, and idea
 - Effective speakers know their personal communication style as well as their audience's
 - The most effective way to communicate is to recognize other people's styles and talk to them on their own level

Style	Content (they talk about...)	Process (They are...)
Action	Results, objectives, performance	Down to earth, direct, impatient
Process	Facts, procedures, planning	Factual, systemic, logical
People	People, communication, feeling	Spontaneous, warm, empathetic
Idea	Concepts, possibilities, issues	Imaginative, unrealistic, full of ideas

16

Engage Operational Managers in Compliance Monitoring

- Make it about *their* success
 - Learn their business. Meet their employees. Visit their work areas.
 - Compliance does not need to be “something extra.” Compliance is inherently built into managed care operational success.
 - You are a team member who can help them meet their goals.
 - Let them develop auditing and monitoring measures.
 - Beware of email pitfalls
 - Ideas
 - “Members (or Providers) First” moments at meetings
 - Departmental monitoring survey
 - Regulatory communication workgroup
 - Code of conduct
 - Pre-tests/tests

17

Communicating with Operational Areas to Improve Prevention and Detection

- Maintain visibility with frontline staff—talk to everybody
 - Trust building
 - Provide context for what you do
 - Make time for one-to-one communication (listen for clues!)
 - Tailor communication appropriately (length, detail, verbal vs. written, visuals)
 - Be open and accepting of criticism
 - Set expectations and develop joint accountabilities
 - Let people know what to expect from you and help them learn what you expect from them

18

Capture Routine Auditing and Monitoring

- Think of simple ways to document your 'seemingly' miscellaneous compliance activities
 - Condense information into a meaningful tool/format
 - Give the format context—make it part of the big picture
 - Celebrate successes
 - Resources
 - Systems
 - Spreadsheets
 - Calendaring
 - Lists
 - Multi-task (use what is already being prepared for other purposes)
 - Ideas
 - Policy and procedure "tracers" (find out realities—use gaps to develop compliance measures)
 - Make audit/monitoring plan visible
 - Report measure outcomes at operational team meetings

19

“I know that you believe you understand what you think I said, but I’m not sure you realize that what you heard is not what I meant.”

- Robert McCloskey (1914 - 2003); American author and illustrator of children's books. Two-time Caldecott award winner for ***Make Way for Ducklings*** and ***Time of Wonder***.

20

Questions?

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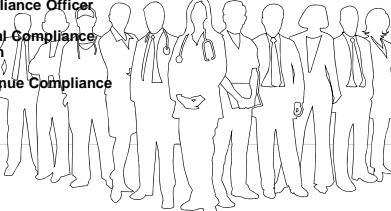


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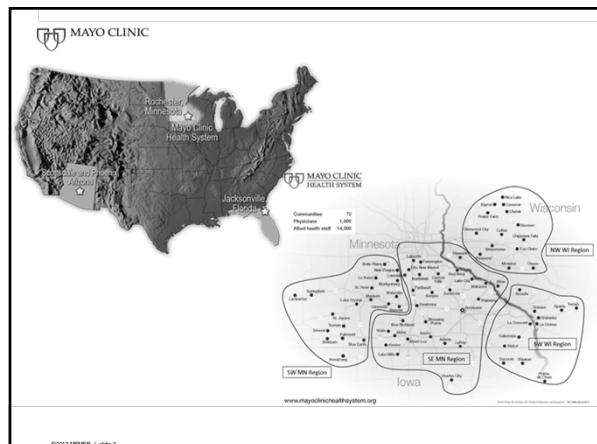

What the Heck is ERM? Is There an “8th” Element of a Good Compliance Program?

Kim Otte, Chief Compliance Officer
Chris Davies, Regional Compliance Officer, NW Wisconsin
Brenda Mickow, Revenue Compliance Officer

Integrity and Compliance TOGETHER



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MAYO CLINIC

What is Enterprise Risk Management (ERM)?

- Historically risk management referred only to insurance and legal liabilities (malpractice)
- ERM is a risk-based approach to managing an enterprise, a framework to identify, assess, mitigate and communicate risk in an integrated approach to help influence decision making and strategic development

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What is ERM? (cont.)

- The key is to develop an approach that fits well within our culture, influences decision-making, is sustainable and demonstrates value through mitigating risks and/or capitalizing/converting risks into opportunities
- Collective genius
- Corporate capability

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Benefits of ERM

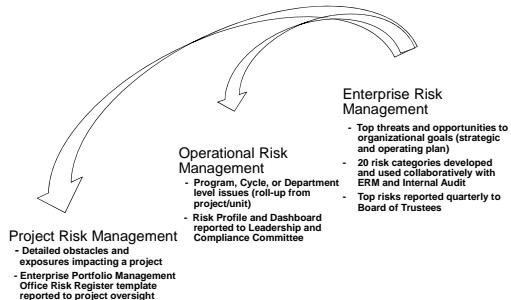
- Create a risk aware culture
- Identify, communicate and manage cross-enterprise risks
- Provide integrated reporting
- Focus on priority risks
- Enhance risk response decisions

2008 Deloitte Survey in Fundamentals of ERM, John Hampton, 2009

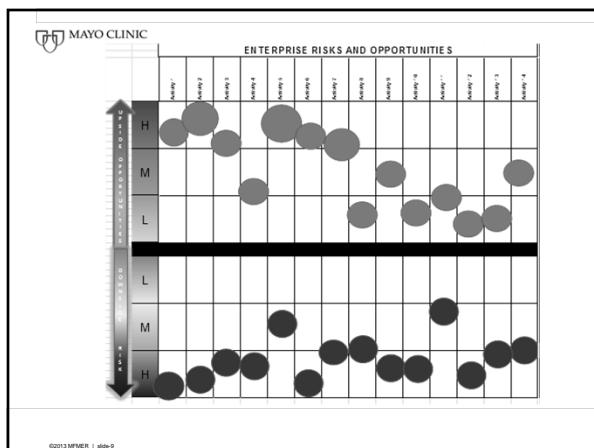
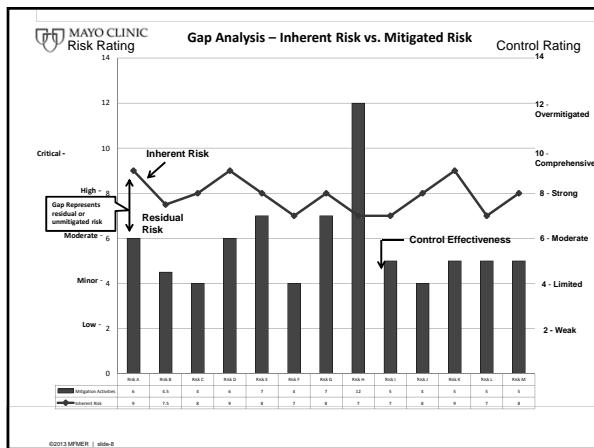
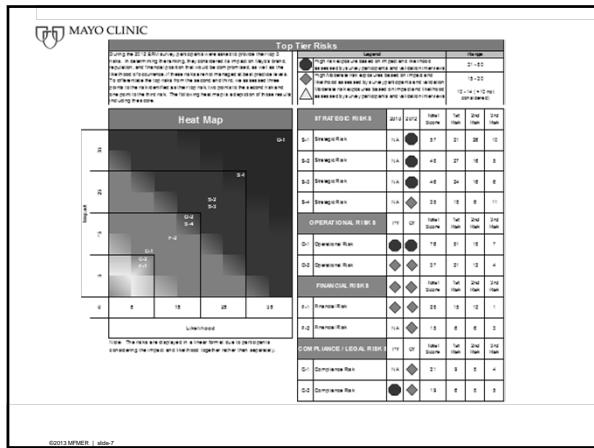
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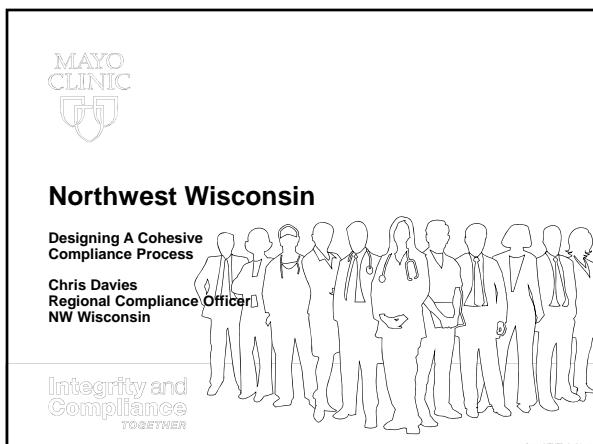
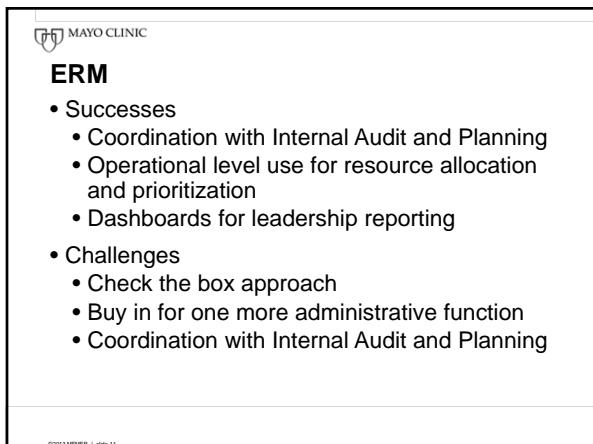
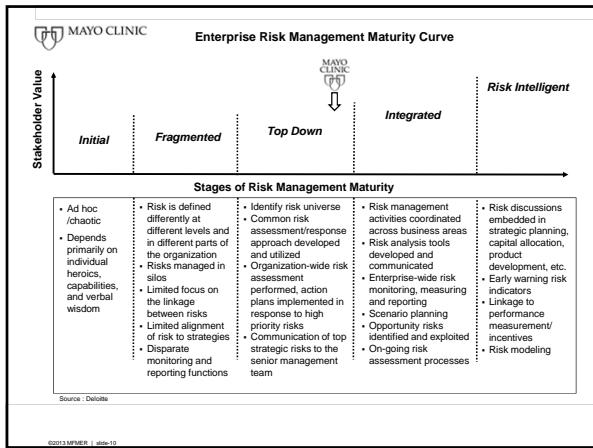


Risk Continuum



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7(8) Elements Established

- 1991 – United States Sentencing Guidelines
- Feb '98 – OIG published “Compliance Program Guidance (CPG) for Hospitals” (1998 - 2003 other health care CPGs)
- 2004 – Amendments to Federal Sentencing Guidelines
- 2005 – OIG published Supplemental Compliance Program Guidance for Hospitals
- 2010 – Federal Sentencing Guidelines Manual and Supplement

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7 (8) Elements

- Designation of a Compliance Officer and Compliance Committee
- Development of compliance policies and procedures, including Code of Conduct
- Developing open lines of communication
- Appropriate training and education
- Internal monitoring and auditing
- Responding to detected deficiencies
- Enforcement of disciplinary standards
- Evaluation of the program effectiveness**

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Our Self Evaluation

- Designation of a Compliance Officer and Compliance Committee
- Development of compliance policies and procedures, including Code of Conduct
- Developing open lines of communication
 - Communication was good when things were bad
 - Communication was bad when things were good

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Our Self Evaluation (cont.)

- Appropriate training and education
 - We provided "Compliance 101" or "issue specific" training
 - We did not provide compliance process training

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Our Self Evaluation (cont.)

- Internal monitoring and auditing
 - We know directors have auditing and monitoring in place
 - We didn't know what they were and if they addressed existing risks
- Responding to detected deficiencies
 - Often, Directors would respond to deficiencies ad hoc
 - There wasn't a plan to address deficiencies as part of the mitigation plan

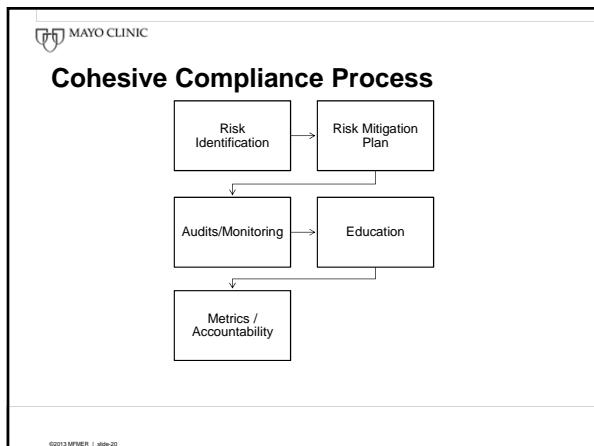
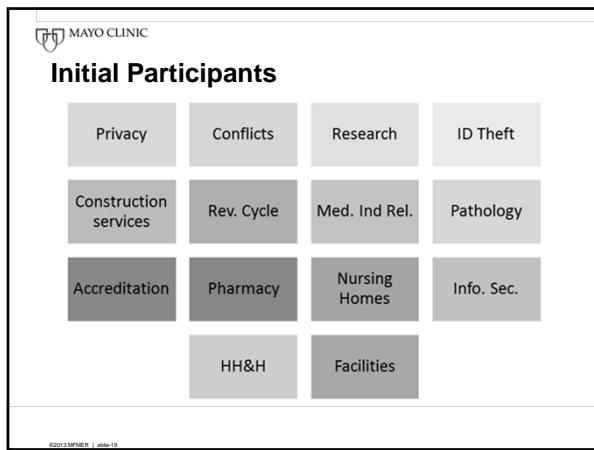
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Our Self Evaluation (cont.)

- Enforcement of disciplinary standards
- Evaluation of our Integrity and Compliance program effectiveness
 - Mayo has strong leadership with a commitment to a culture of compliance
 - The timing was right for our region to implement a pilot to improve effectiveness and efficiency

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MAYO CLINIC

Documenting Risks

Subject Matter	Key Compliance Risk		SME's Assessment of Strength of current Controls	Risk Mitigation Plan Description	Responsible party	Barriers	Additional Needs to address barriers	Departmental Role	Integrity and Compliance Office Role	Monitoring Plan (yes/no)
	Risk Description	Regulation, guidance, policies, etc.								
Accreditation										
Conflicts of Interest										
Construction Services										
Facilities										
Nursing Homes										
Pathology										
Pharmacy										
Privacy										
Revenue Cycle										

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Documenting Audits

Subject Matter	Description	Objective	Frequency	Reported to	Responsible Party
Accreditation					
Conflicts of Interest					
Construction Services					
Facilities					
Nursing Homes					
Pathology					
Pharmacy					
Privacy					
Revenue Cycle					

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Documenting Education

Subject Matter	Topic	Objective	Frequency	Format
Accreditation				
Conflicts of Interest				
Construction Services				
Facilities				
Nursing Homes				
Pathology				
Pharmacy				
Privacy				
Revenue Cycle				

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Assessing and Scoring

1. Benchmarking the individual risk mitigation plan against standards in the community, Mayo Clinic, and nationally
 - Is it a good mitigation plan?
2. Assessing the interrelatedness of the Director's compliance process
 - Is there a cohesive compliance process?
3. Measuring the severity and priority of the risk
 - What does Compliance do with the information?

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Cohesive Compliance Process Scoring (example only)

Lack of Standardization at CAH Pharmacies

Risk Identification Plan

- Do you have a process to identify risks?
- This risk identified through systematic process to identify convergence risks.

Risk Mitigation Plan

- Have you developed a plan to address the risk?
- Pharmacy leadership to take active role in CAH pharmacies to assist with regional policies and best practice habits.

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Cohesive Compliance Process Scoring

Training, Education and Communication

- Have you reached out to learn or teach others who are knowledgeable or affected by this risk?
- Regional and CAH pharmacists, physicians and nursing leadership meet to review and share best practice.

Auditing and Monitoring

- Have you developed an auditing & monitoring plan to keep abreast of this risk?
- No audits or monitoring of this specific risk.

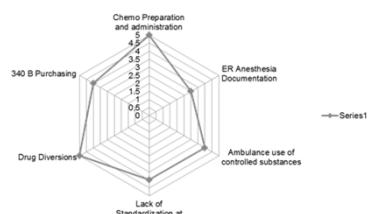
Accountability plan for deficiencies

- If issues are identified by auditing & monitoring, are those issues addressed?
- Clear line of leadership established.

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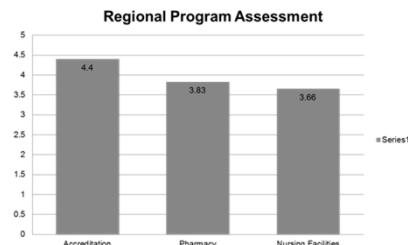
Dept. Compliance Assessment Pharmacy (example only)



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Regional Program Assessment



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Program Assessment Pilot

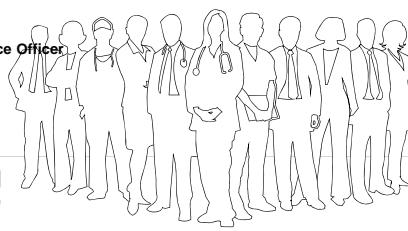
- Successes
 - Greatly improved working relationships
 - The plan made it “much more doable” to work through identified risks
 - Focuses resources on managing risks rather than owning them
- Challenges
 - Obtaining initial buy in
 - Time intensive
 - Resources to follow up on compliance risks

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Revenue Cycle Compliance Risk Assessment

Brenda Mickow
Revenue Compliance Officer



Integrity and
Compliance
TOGETHER

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Revenue Cycle Risk Assessment

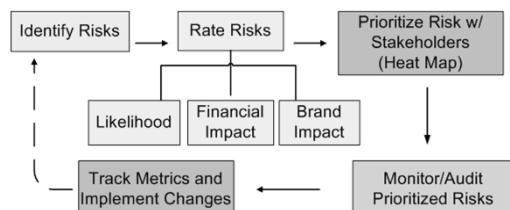
- What is it?
 - A tool to assist in identifying the highest Revenue Cycle risks
- Why have one?
 - Provides objective criteria to determine risks
 - Assists in prioritizing limited auditing and monitoring resources
 - Supports communication to stakeholders

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Revenue Cycle Risk Assessment

Risk Assessment Flow Chart



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Revenue Cycle Risk Assessment

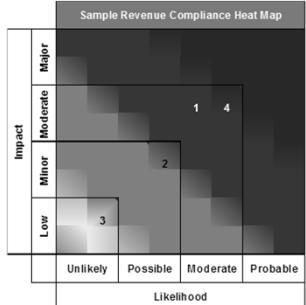
- Example of Compliance Risk Matrix

#	Potential Risk	Likelihood				Impact	Mitigating Factors
		Department of Justice	OIG Report	OIG Work Plan	Recovery Auditors		
1	Hospital Admission Status	x		x		x	L
2	Medical Device Credits	x	x	x		M	L
3	Anesthesia Personally Performed						x
4	Evaluation & Management Services	x	x	x	x	M	L
						L	x
							x

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Revenue Cycle Risk Assessment



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Revenue Cycle Risk Assessment

- Successes
 - Objective way to identify and rate risks
 - Improved customer buy-in of prioritized risks
 - Reduces one-off risks brought forward
 - Leadership allocates resources based on risk
- Challenges
 - It's different
 - Requires data mining
 - Limited tools and resources

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THANK YOU
QUESTIONS?

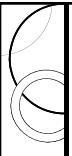
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Be Ready for ICD-10 Best Practices for Educating Coders

Mary Pat Jackey BSN, RN
Clinical Educator
Commonwealth Health
Corporation
Bowling Green, KY

Michelle Leavitt
Director, Learning
Solutions
HealthcareSource
Clifton Park, NY

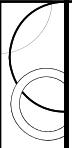


Learning Objectives

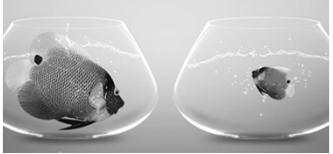
- Learn industry best practices for:
 - Assessing coders
 - Delivering targeted, tailored ICD-10 education
- Hear a specific case example of success stories from Commonwealth Health



INDUSTRY BEST PRACTICES



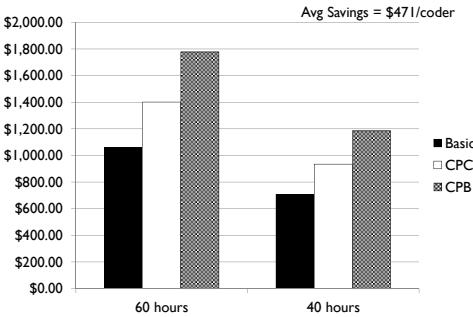
Step 1: Determine current knowledge



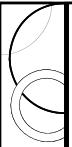


Thought Exercise

Avg Savings = \$471/coder

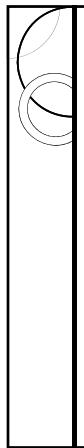


Hours	Basic	CPC	CPB
60 hours	\$1,100	\$1,400	\$1,800
40 hours	\$700	\$900	\$1,200



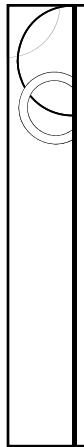
Step 2: Foundational education

- Anatomy & Physiology
- Basics of ICD-9/ICD-10



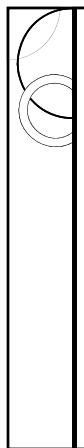
Step 3: In-depth coding instruction





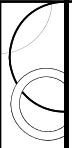
Step 4: Practice, practice, practice

- Case studies
- Practice documentation
- Dual coding



Step 5: Celebrate!



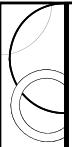


Step 6: Keep it going





COMMONWEALTH HEALTH'S EXPERIENCE



Overview

- Commonwealth Health Corporation(CHC)
4 hospitals – ~ 3100 employee's, numerous healthcare facilities and physician practices.
- 9 physician practice coders
- 13 Inpatient Coding Specialist
- 8 Clinical Documentation Specialist



What we knew in the beginning:

- ICD- 10 training was going to require more than sending medical coders to classes to learn diagnosis codes.
- Would need to identify staff members who will need training.
- **Only Coders have to re-learn how to code!**
- Everyone else just has to understand the change in the process and concentrate on improved, more specific documentation.
- Identify what level of education and awareness are needed for each set of staff members.



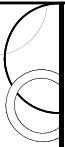
Plan Training

Organization ICD-10

- Basic awareness training to key stakeholders
 - Senior management, IT, clinical department managers, medical staff, etc
- More Intense awareness training guidelines, codes
 - All currently involved with ICD data

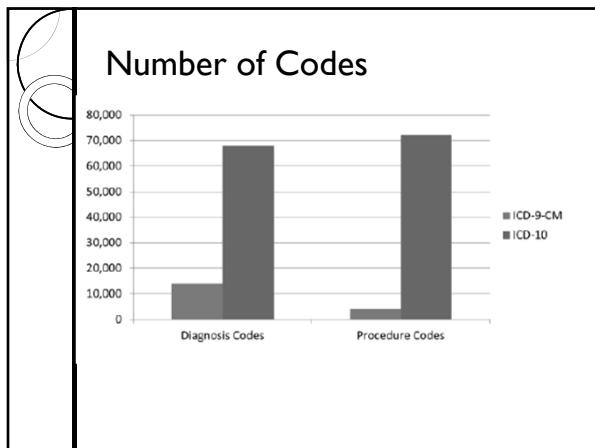
Coding Training

- Role based training
- Provide Training based on knowledge gaps
- Begin with new structure and definitions, guidelines and move to more intense training



Major changes from ICD-9 to ICD-10

- Not just the usual annual update
- ICD-10 markedly different from ICD-9
- Major changes to the coding and billing systems for all healthcare services and payers.
- Requires changes to almost all clinical and administrative systems
- Requires changes to business processes
- Changes to reimbursement and coverage
- **MANDATORY compliance by October 1, 2014**

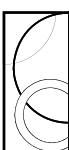


What Did We Do First?

- Steering committee which consists of key stakeholders (2011)
 - Executive Leaders, HIM, IT, Coding , Physician Practice, Financial Resources Department,, Finance, etc
 - **Assess level of education needed for each group (coders , nursing, physicians, ETC)**
 - **Everyone will NOT need same level of Education**
 - **Mandatory**
 - **Will cost – time and money**
 - **Education documentation requirements**
 - **Classroom versus Online Training**

Things to think about??

- Should staff be paid for this training?
 - Should it be done during work hours?
 - How do you handle loss in productivity?
 - Should there be deadlines for assignments?
 - Should all coders work on same lessons every week?
 - Do you need per-diem coders during staff training?
 - How do I document staff training and proficiency tests after training?



What Did We Do? (2012)

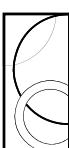
- After careful review we purchased 16 E-Learning courses from a vendor that would integrate with our Learning Management System.
 - Anatomy and Physiology
 - Pathophysiology and Pharmacology
 - ICD-10 PCS and ICD-10 CM components
 - Specific Assessments and Courses
 - CEUs
 - Easy assignment
 - Easily Track completion of courses
 - Self paced
 - Test preparation
 - 1 year to complete (Ongoing Education)



Timeline of Completion

Coders and Clinical Documentation Specialists

- I year to complete (Jan 1, 2012-Jan 1, 2013)
 - Each coder was given designated time during their work schedules to complete the E-Learning modules.
 - Anatomy and Physiology
 - Pathophysiology and Pharmacology
 - Then instructed to complete assessments, courses and exams as assigned.



So where are we now?

- 2012- E-learning modules (coders, CDI)
 - 2013-Coders are receiving Advance Training through outside online vendor.
 - Dual Coding
 - Using Translator Tool
 - Vendor Readiness
 - Payor Readiness



Where are we now?

- Physician ICD-10 Newsletter every month
- ICD-10 icon
- “Doctor Day”
- Office Manager/Billers/Coders Lunch/Breakfast
- Updated all forms - changed to include ICD-10 language
- Revenue Cycle Testing
- Dual coding



Summary

- Every health care professional should have a basic understanding of ICD-10
- One size does **not** fit all when educating staff
- Early planning is key to successful implementation
- Take advantage of every minute left
- Monitor resource sites for information



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Inside Counsel, Outside Counsel, General Counsel: How Should a Compliance Officer Conduct an Investigation?

Donna Thiel, Chief Compliance Officer,
Extendicare Health Services Inc.
Barbara J. Duffy, Shareholder, Lane
Powell PC

1

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What We Will Cover

- Framing the investigation for efficiency yet conducting a thorough review.
- Identifying the right investigator(s); Outside counsel? In-house?
- Guidelines for conducting your investigation interviews and how to conclude the investigation.

2

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Ongoing Example of Investigation

- Hypothetical Scenario for Discussion:
 - Physician Certification and Recertification of Skilled Nursing Services are Required to Verify that a Resident Requires Daily Skilled Nursing Services
 - Received Information that the Responsible Nurse Not Obtaining Physician Signatures
- What to do Next?

3

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Scope of the Investigation: Consider the Source

- Hotline Call
 - Employee H/R Complaint
 - Potential Compliance Event
- Audit Outcomes
 - Self-identified Issues
- Sentinel Event
- Government Investigation
 - Subpoena
 - On-Site

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Scope of the Investigation: Initial Assessment

- Is the Event Clinical, Billing, H/R or other?
- Does immediate action need to be taken?
 - Potential Resident Harm
 - Enforcement Agency On-Site
- Is it an Isolated Event?
- Could this have been occurring for an extended period of time?
- Could this become a repayment issue?

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Assembling the Team

- The Team depends upon the type of event and potential risks
 - Severity of Event
 - Potential Reporting Ramifications
 - Level within the Organization
- Using Lawyers?
 - Privileged?
 - Not Privileged?

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Assembling the Team

Event-Driven

- Tier 1
 - Internal investigation conducted by Area/Regional Staff
 - “Ask and answer”
 - Limited Compliance/Legal Involvement
 - Example: Compliance Hotline Call (H/R type)
- Tier 2
 - Internal investigation conducted by company resources
 - May be directed by General Counsel
 - Neutral staff member may go on-site to conduct investigation
 - Corporate Resources research issue
 - Example: Isolated Billing Issue or Falsification of Records
- Tier 3
 - Investigation conducted by third party or company resources
 - May be directed by Outside Counsel
 - Corporate Research and Counsel interviews are necessary
 - Example: Systemic Billing Issue or Regionally directed Fraud or Ethics violation

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Investigator(s)

- Discretion
 - Judgment on how much to disclose
- Privilege Needed?
- Credibility
 - Outside resources
 - Accountants, lawyers, clinicians...
 - No ax to grind
- Capability

- Protecting the investigation with a privilege
 - Work product or attorney client privilege
- If the investigation is subject to a privilege, if you retain the privilege you preserve your options
 - You can decide to waive the privilege and use the investigation to your advantage
 - If not subject to a privilege, the investigation is generally discoverable

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Attorney or No Attorney

- Privilege
 - Need to make clear that the investigation is being conducted for the benefit of the Company, not any particular individuals
 - If properly conducted on behalf of the company, the company can choose to waive the privilege
 - Make sure no one who is interviewed is under the mistaken belief that the attorney represents them personally

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Attorney or No Attorney

- Privilege
 - Not all communication with an attorney is subject to privilege
 - Communication;
 - Between privileged persons;
 - Intended to be confidential;
 - For the purpose of seeking, obtaining or providing legal advice (not business advice) to the client; and
 - Confidentiality was not waived by disclosure.

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Attorney or No Attorney: Keeping the Privilege with the Company

- *Upjohn Co. v. U.S.* 449 U.S. 383 (1981)
 - The Corporation is the client
 - Privilege extends to employees with responsibility for the subject matter of the communication ("need to know")
 - Those employees who are being interviewed
 - Whether the communications were made by corporate employees to counsel at the direction of superiors for purposes of obtaining legal advice

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Attorney or No Attorney: Keeping the Privilege with the Company

- *Upjohn Co. v. U.S.* 449 U.S. 383 (1981), cont.
 - Whether the information in the communication (interview) is needed by counsel
 - Whether information concerned matters within the scope of the employee's duties
 - Whether employee was aware the purpose of the communication (interview) was for the benefit of the company
 - Whether the communication was to remain confidential

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Attorney or No Attorney

- *Upjohn* Warning
 - Company is the client
 - Counsel is representing the company, not the employee
 - Instruction regarding confidentiality of interview
 - The privilege belongs to the Company
 - The Company may decide to waive that privilege and disclose the results of the privilege
- Risk?
 - If you don't do this the employee could attempt to assert the privilege and prohibit the company from using the investigation to its advantage

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In House Counsel or Outside Counsel

- Advantages To In-House Counsel:
 - Expense
 - Familiarity with systems, relationships, dynamics and sensitivities
 - Credibility within the organization
 - Readily accessible

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In House Counsel or Outside Counsel

- Advantages To Outside Counsel:
 - Preserves the independence of the investigation;
 - In-house often provide business advice;
 - Distance between Outside Counsel and Company can brighten the line;
 - Communications between In-house and outside are presumed to be privileged
 - Familiarity with preserving and protecting an investigation;
 - Breadth of knowledge of related incidents;
 - Relationships with Gov't enforcement office;
 - Unbiased voice to report to Management

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In House Counsel or Outside Counsel

- Not all documents given to or prepared by in-house counsel are privileged
- Not all conversations with in-house counsel are privileged

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Assembling The Documents

- Data integrity
 - Chain of custody
 - Avoid any question regarding authenticity or integrity of documents
- Scope of the investigation
 - How far back to pull information
 - Accessibility of information
- Billing and medical records
- Financial Records
- Contractual Records

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Interviews

- Interviewees
 - Complainant Interview
 - Witness interview
 - Subject Interview
- Who should interview?
- Sequence of interviews
- Consider a witness during interview
- All interviews must be memorialized

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Concluding the Investigation

- Work product?
- Disclosure?
 - Who makes the final disclosure decision?
 - Who to report to?
 - How to report?
- Lessons Learned
 - Can you benefit from your mistakes?

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Powell PC

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2014 COMPLIANCE INSTITUTE

Is Your Privacy Program Reactive or Proactive?

Tips and Tricks

to

Build a Proactive Program



Health Care
Compliance
Association

HCCA



Sutter Health
We Plus You



Intermountain
Healthcare
Health for Life

Speaker Introductions

Jacki Monson

Sutter Health

Chief Privacy Officer

Office of the General Counsel

Jutta Williams

Intermountain Healthcare

Chief Privacy Officer

Business Ethics and Corporate Compliance



Sutter Health

We Plus You



Intermountain
Healthcare

Health for Life

Objectives

- Identify the challenges and pitfalls for reactive privacy programs.
- Apply Compliance theory and the proactive approach to privacy; choosing a model that can anticipate and gracefully adapts to regulatory change.
- Explore practical experiences for building a proactive privacy program including quick wins will help leadership recognize your program's value.



Sutter Health

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Intermountain
Healthcare

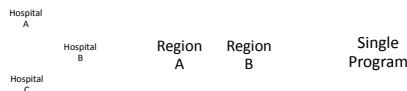
Health for Life

Reactive Privacy Program: Band Aid Approach

- Regulatory Risk
- Lack of Patient Trust
- Reputational Exposure
- Lack of Road Map and Prioritization



How is Privacy Organized?



Decentralized

- Policies are unique at each facility
- Teams develop goals and vision independently.
- Interpretation and application may vary.

Standardized

- Policies may differ but have minimum requirements.
- Education Objectives are coordinated.
- Interpretations are shared between teams.



We Plus You

Introducing the

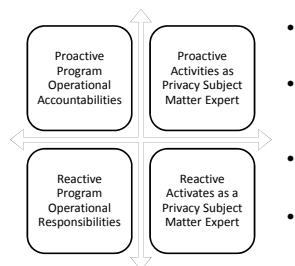
Healthcare

Industry's First

Introducing the

Healthcare

Fire Fighting vs. Fire Prevention



- Program responsibilities that are required to be HIPAA compliant.
 - Opportunities to support other programs as a subject matter expert.
 - HIM, IT, Risk, Clinical Programs
 - Some activities are inherently reactive “fire fights”.
 - i.e. investigation requests
 - Some activities are proactive in nature and when done right act to prevent future fires.
 - i.e. privacy education

**Where are your team's efforts focused?
Is it balanced appropriately?**



Proactive Program Tips and Tricks



Named Privacy Official

- ▶ Each covered entity that exists in your system should have a named privacy official
 - ▶ Create privacy champions across your organization to assist with privacy
 - ▶ Ensure that privacy official develops relationships with all levels of the organization including:
 - ▶ Leadership
 - ▶ Front line staff
 - ▶ Key partners- Legal, HR, Risk Management



High Level Commitment

► Proactive Measures:

- ▶ Establish a regular rather than ad-hoc meeting schedule
- ▶ Deliver education to governance committees on privacy news – Especially recent enforcement activities, fines and penalties!
- ▶ Develop Scorecards and send them as a matter of course
- ▶ Ask leadership for advice; recognize their contribution to setting program strategy
- ▶ Leverage the power of executive endorsement for program initiatives.

► Pitfalls to Avoid

- ✖ Do not let them forget about you.
- ✖ Do not make every meeting with your governance committee a bad news story
- ✖ Typically, privacy programs identify risks and executives make decisions on risk appetite. Know who has decision rights in your organizations and engage them in discussions.



Program Oversight

- ▶ Chief Compliance Officer / Chief Risk Officer
- ▶ Privacy and Security Governance Committee
- ▶ Compliance Committee
- ▶ Audit and Compliance Committee of Board



Policies & Procedures

Proactive Measures

- ▶ Establish clear ownership for privacy policies.
- ▶ Review all policies on a routine basis.
- ▶ Invest in policy management and publication tools.
- ▶ Establish and/or adhere to policies on writing policies.
- ▶ Consistency is key

Pitfalls to Avoid

- ✖ Policies without defined terms. E.g., what is a “treating relationship.”
- ✖ Failing to update secondary materials
- ✖ Writing policies that are too lengthy or too hard to understand
- ✖ Forgetting that audits expect 100% compliance with policies.
- ✖ If exceptions are expected, define a process.

Remember readability matters. Policies are not just regulatory requirements. Workforce wants to do the right thing— we need to make sure they can understand what that is.



Training & Education

–Privacy Education

- Monthly newsletters
 - Annual training
 - Patient impact stories
 - Staff meetings
 - Role based training eg. Physician specific education



–Policy Attestations



–FAQ Database



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Effective Lines of Communication

Proactive Measures

- ▶ Advertise information about privacy rights in public places.
 - Is your NPP listed on your website's privacy page or does it just a message from your webmaster about cookies?
 - ▶ Widely advertise how to contact your office.
 - Email address, phone number, mailing address

When was the last time that you looked at your company's public website? Can a patient or concerned employee find you?



Pitfalls to Avoid

- ✗ Forgetting to advertise your communication channels.
 - ✗ Fail to respond to privacy concerns – even if its just to confirm receipt of the communication.
 - ✗ Requiring specific forms to request amendments, AOD or restrictions, but not making them available for download

When was the last time that you looked at your company's public website? Can a patient or concerned employee find you?



Auditing & Monitoring

► Computerized

- ▶ Implement technology to assist
 - ▶ Focus on a 3-4 rules



► Physical

- ▶ Create audit tool
 - ▶ Incorporate in Joint Commission tracers questions
 - ▶ Require high risk areas to submit self audits bi-monthly



Investigations & Discipline

Proactive Measures

- Work with HR to establish and educate to a formal discipline policy for privacy violations.
- Measure how investigations are going:
 - How long to closure?
 - How often is notice required?
 - Which facilities are doing well?
 - How often is a violation confirmed?
 - What types of incidents are trending?

Pitfalls to Avoid

- Inconsistent application of a discipline policy.
- Incomplete investigation notes. You never know when an OCR inquiry may come.
- Failing to document breach notification decision justifications in investigation notes.

*Don't Forget to celebrate successes!
Write thank you cards to workforce when
investigation reveals they did the right thing.*



Enforcement & Discipline

- Ensure consistent disciplinary process across organization
- Corrective action plans
- Consistent investigations
- Complete documentation



Response and Prevention

Proactive Measures

- Prepare for catastrophic breach before an incident.
 - Build an incident plan
 - Contract with a breach response vendor now.
- Stay involved in the legislative process at both state and federal levels.

Pitfalls to Avoid

- ✖ Figuring out your response plan after a large breach has already occurred.
- ✖ Failing to be involved in the planning phase for key initiatives that involve patient information.
- ✖ Doing nothing when you see proposed law that harms your organization.



Risk Assessment

Proactive Measures

- ▶ Assess the state of your program at least annually.
- ▶ Build a workplan for your team that addresses program gaps.
- ▶ Add time to your calendar to work on these goals.
- ▶ Think like an auditor:

Pitfalls to Avoid

- ✖ Letting acute issues take over. If you knew about an issue and did nothing about it, it could become classified as reckless disregard.
- ✖ Failing to follow HIPAA guidelines for documenting addressable requirements.
- ✖ Forgetting to document why something was considered "reasonable and appropriate" during a risk assessment.



Reporting

- ▶ Scorecard
- ▶ Risk dashboard
- ▶ Metrics that are measurable overtime
- ▶ Identify opportunities through trending privacy incidents
- ▶ Regular reporting to leadership



Response & Prevention

- ▶ Privacy By Design
- ▶ Develop processes to proactively address high risks
- ▶ Conduct annual risk assessment
- ▶ Incident response plan- practice it
- ▶ Root cause analysis
- ▶ Mock audits



Closing Thoughts

- ▶ Reporting metrics crucial to measurable value for resource request
- ▶ Create a program that works for your organization, it's not a one size fits all approach
- ▶ Developing key relationships with your leadership is key to your success



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Who Is a Qualified Health Care Professional (QHP)? A Compliance Update on Using Extenders from CRNAs to PAs

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Agenda

- ▶ Understanding AMA-CPT definition of a qualified health care professional (QHP) vs. clinical staff
- ▶ Examining varying "scope of practice" for QHP
- ▶ Discussing QHPs' credentialing and payer rules
- ▶ Reviewing Medicare "Incident to" billing requirements and reimbursement issues
- ▶ Exploring the impact place-of-services (POS)
- ▶ Investigating why QHPs are under RACs and other auditors scrutiny

3/1/2014

3

Who is a QHP?



- ▶ In 2013, the American Medical Association (AMA) established a definition for a Qualified Health Care Professional (QHP) in terms of which providers may report services:
 - A “physician or other qualified health care professional” is an individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service.”

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4

Who is a QHP?

- ▶ These professionals are distinct from “*clinical staff*”. A clinical staff member is a person who works under the supervision of a physician or other qualified health care professional and who is allowed by law, regulation and facility policy to perform or assist in the performance of a specified professional service; but who does not individually report that professional service.
 - Clinical staff are medical assistants, licensed practical nurse, etc.
 - Other policies may also affect who may report specific services
 - Inclusion or exclusion (in the AMA-CPT codebook) does not imply any health insurance coverage or reimbursement policy.

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5

Who is a QHP?

- ▶ Anesthesiologist Assistant (AA)
- ▶ Certified Nurse Mid-Wife (CNM)
- ▶ Certified Registered Nurse Anesthetist (CRNA)
- ▶ Clinical Nurse Specialist (CNS)
- ▶ Clinical Social Worker (CSW)
- ▶ Nurse Practitioner (NP)
- ▶ Physician Assistant (PA)
- ▶ Physical Therapist (PT)
- ▶ Others potential QHPs, Athletic Trainer, Dietitian

3/1/2014

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Why the Growth in QHPs?

► Health Care Reform

- The implementation of national health insurance coverage will reportedly result in about 32 million new insured.
 - According to a June 2012 article in the Los Angeles Times, the Association of American Medical Colleges has forecasted a shortage of 175,000 doctors by 2025.
 - The American Academy of Family Physicians estimates that 149,000 extra doctors will be needed by the year 2020.
 - US will need to increasingly rely on mid-level provider (QHPs) support to care for the newly insured.

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Why the Growth in QHPs?

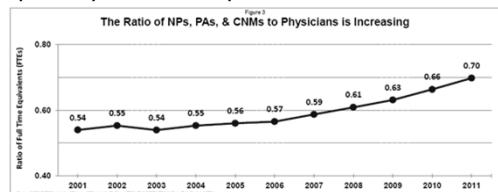
- ▶ Numerous studies have found that when proper mechanisms are in place, QHPs can help to improve patient satisfaction, efficiencies and quality of care.
 - When appropriate supervising and collaborative measures are not in place, or policies and procedures are not followed, patient care can be negatively impacted and physician liability exposure can increase.

3/1/2014

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Ratio of QHPs Increasing

- ▶ NPs, PAs and CNMs are often underutilized in primary care practices at a time when many communities face shortages of primary healthcare providers



3/1/2014

10

The Risk

- Risk for the facility
- Risk for the supervising practitioner (e.g., the physician)
- Vicarious liability/*respondeat superior*
- Expectations of the patient
- Negligent hiring/retention
- Negligent supervision

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10

What is a QHP's "Scope of Practice"?

- Dependent upon state law and regulations
- All 50 states recognize some QHPs
- PAs and NPs are allowed to practice in 50 states and DC
 - NPs may practice independently in 18 states and have limited or restricted practice privileges in Puerto Rico.
 - PAs must practice under physician supervision in 37 states, and have limited or restricted privileges in 13 states.
 - A PT can practice independently in all 50 states including DC, except Alabama may require a professional referral.

3/1/2014

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What is a QHP's "Scope of Practice"?

- State rules can be complex, hard to find at times, change often and conflict with Federal rules and regulations, payer's coverage or hospital guidelines and bylaws
- Prescriptive authority is a prime example of the disparity in practice environments between the states and types of QHPs
 - Nurse Practitioners and Physician Assistants have prescriptive rights in all states, which are also regulated and may differ from state to state

3/1/2014

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CRNAs

- ▶ The laws in most states permit CRNAs to work with physicians (such as surgeons) or other authorized healthcare professionals.
 - ▶ CRNAs are qualified to make independent judgments regarding all aspects of anesthesia care, based on their education, licensure, and certification.
 - ▶ Opt-out states
 - Medicare defers to states (17 states) relying on CRNAs to provide anesthesia care.

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- CRNAs

- ▶ Payment can be made for medical or surgical services furnished by non-medically directed CRNAs if they are allowed to furnish these services under state law (however, payment may be difficult to get!).
 - These services may include the insertion of Swan-Ganz catheters, central venous pressure lines, pain management, emergency intubations, and the pre-anesthetic examination and evaluation of a patient who does not undergo surgery.

3/1/2014

Anesthesiologist Assistants (AAs)

- ▶ The AA develops and implements an anesthesia care plan in an assistant role/capacity.
 - ▶ According to the Commission on Accreditation of Allied Health Education Programs (CAAHEP), the AA must work under the direction of an anesthesiologist.
 - ▶ AA may not work under the direction of other physicians or healthcare professionals.

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Anesthesiologist Assistants (AAs)

- ▶ The anesthesiologist who is responsible for the AA is available to prescribe and direct particular therapeutic interventions in the operating room.
 - ▶ Currently, eighteen (18) states and the District of Columbia authorize the practice of an AA through either a licensure or certification process.

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- ## Other Types of QHPs

- Certified Nurse Mid-Wife (CNM)
 - Scope of practice includes a broad array of woman health services, including physical exams, prescribing medications, and assisting in child birth. The guiding principles of the practice of CPMs are to work with women to promote a healthy pregnancy.
 - CPMs are legally authorized to practice in 28 states
 - CPMs are not legally authorized to practice in 23 states
 - CNMs have achieved equitable reimbursement for their services under Medicare. As of January 1, 2011, the CNM reimbursement rate increased from 65% to 100% of the Medicare Part B fee schedule.

3/1/2014

Other Types of QHPs

- ▶ **Clinical Social Worker (CSW)**
 - A holistic approach, providing counseling and behavioral modification services.
 - Medicare covered services are those that the CSW is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are *performed for the diagnosis and treatment of mental illnesses*. (ICD-9 codes 290.0–319, all-inclusive). Payment is at 75 percent of the physician fee schedule.
 - Medicare coverage in the office setting is billed directly to the Part B carrier.

16

Other Types of QHPs

- ▶ Physical Therapist (PT)
- ▶ Certified Nutrition Specialist (CNS)
- ▶ Others potential QHPs,
 - Athletic Trainer, Dietitian
 - State rules and payer rules govern coverage and reimbursement.

3/1/2014

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Nurse Practitioner (NP) (CNS)

- ▶ Evaluate patients, diagnose, order and interpret diagnostic tests, initiate and manage treatments—including prescribe medications as permitted by law—under the exclusive licensure authority of the state board of nursing.
- ▶ A registered nurse with advanced training at a master's degree level with relevant experience and license to practice.
- License: State regulations, Board of Nursing
- Collaboration: with physicians

3/1/2014

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Physician Assistant (PA)

- ▶ A medical professional who must be nationally certified and state-licensed to practice medicine with the supervision of a physician.
 - Medicare pays for medical and surgical services provided by PAs in all settings at 85 percent of the physician's fee schedule. Physician supervision is not required when the service is being billed to Medicare under the PA's name.
 - Scope of practice is determined by the PA's education and experience. It includes ordering lab tests, evaluating medical history, diagnosing and treating medical conditions, prescribing medication as permitted by the law, assisting in surgery

3/1/2014

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Role of the NPs/PAs

- ▶ Preoperative patient management
- ▶ Assistants at surgery PA and NPs (AS modifier required)
- ▶ ICU, critical care management
 - Start a-lines, chest tubes, read x-rays, lumbar punctures, run codes and help meet current patient outcomes and update the family daily
 - PLUS, have prescriptive authority
 - Most NPs work under collaboration agreement with an MD; may work independent in some states

3/1/2014

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PayScale Website Reports

- ▶ Average pay for a Nurse Practitioner is \$81,085.00. They may earn anywhere between \$63,029.00 – \$107,842.00.
- ▶ Average pay for a Physician Assistant is \$81,682.00. They may earn anywhere between \$66,592.00 – \$113,988.
- ▶ Average pay for a CRNA is \$160,759.00. They may earn anywhere between \$114,325.00 and \$239,689 with 10 or more years experience.

Source: <http://www.payscale.com>

3/1/2014

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Payor Credentialing

- ▶ The services provided by QHPs are typically covered by health care insurance carriers
- ▶ CMS has established Internet-based Provider Enrollment, Chain and Ownership System (PECOS) as an alternative to the paper (CMS-855) enrollment process.
 - Internet-based PECOS will allow physicians and non-physician practitioners to make a change in their Medicare enrollment, view their Medicare enrollment information on file with Medicare, or check on status of a Medicare enrollment application via the Internet.

3/1/2014

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Payor Credentialing

- ▶ The Council for Affordable Quality Healthcare, or CAQH, is a centralized “universal” source of data that commercial payers generally use for credentialing (www.caqh.org).
- ▶ Contact the specific payor you wish to be able to bill, and ask how to set up a contract. The payor will go to CAQH for your credentialing information and make a decision about whether or not they want to contract with you, and if so, the terms.

3/1/2014

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“Incident to” vs. Direct Billing

- ▶ **Direct Billing**
 - Medicare and most other payers now credential NPs/PAs, and some other QHPs may apply for individual provider numbers for direct billing purposes. All covered services rendered may be billed using the NPPs direct provider number.
 - 85% of the MPFSDB amount for NP/PA/CNS.
 - 65% of the MPFSDB amount for CNM.
 - Other payers may pay at 85% or a different amount.

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“Incident to” vs. Direct Billing

- ▶ “Incident to” services are defined as those services that are furnished incident to physician professional services in the physician’s office (whether located in a separate office suite or within an institution) or in a patient’s home.
- ▶ These services are billed as Part B services to your carrier as if the physician personally provided them, and are paid under the physician fee schedule at 100%.

3/1/2014

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"Incident to" vs. Direct Billing

- ▶ "Incident to" services are relevant to services supervised by QHP such as physician assistants, nurse practitioners, clinical nurse specialists, nurse midwives.
- ▶ "Incident services" supervised by QHP are reimbursed at 85 percent of the physician fee schedule.

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"Incident to" vs. Direct Billing

- ▶ To qualify as "incident to" services a physician must personally perform an initial service and remain actively involved in the course of treatment.
 - You do not have to be physically present in the patient's treatment room while these services are provided, but you must provide direct supervision. That is, you must be present in the office suite to render assistance if necessary.
 - The patient record should document the essential requirements for incident to service.

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Place of Service Issues

- ▶ Restrictions by State law and by payer coverage.
 - For example, CSWs only have direct reimbursement by Medicare for services performed in the office setting.
 - There is no "incident to" billing in the facility setting.
- ▶ Medicare physician fee schedule includes two payment amounts depending on whether a service is performed in a facility setting, such as an outpatient hospital department or ambulatory surgical center, or in a non-facility setting, such as a physician's office.
 - The payments to physicians are higher when the services are performed in non-facility settings.

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Reviews/Audits Related to QHPs

- The list of issues in the 2014 OIG Work Plan includes “Physical therapists—High utilization of outpatient physical therapy services Billing and Payments.”
 - Prior OIG work found that claims for therapy services provided by independent physical therapists were not reasonable or medically necessary or were not properly documented.
 - Focused on independent therapists who have a high utilization rate for outpatient physical therapy services. Medicare will not pay for items or services that are not “reasonable and necessary.”

3/1/2014

Reviews/Audits Related to OHPs

- ▶ 2014 OIG Workplan: 5% of QHP or non-physician practitioners attributed to recovered or returned improper payments.
<http://oig.hhs.gov/reports-and-publications/archives/workplan/2014/Work-Plan-2014.pdf>

3/1/2014

Reviews/Audits Related to OHPs

- ▶ The Office of Inspector General (OIG) released a report, *"Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services"* analyzing services that nonphysicians perform for which physicians bill Medicare.
 - The OIG found that, in January to March 2007, Medicare allowed \$12.6 million in unqualified nonphysician-rendered services (that is, roughly 14.5% of the nonphysician rendered services and roughly 7% of total billed services).

2/1/2014

Reviews/Audits Related to QHPs

- ▶ OIG issued in May 2012 a report on “*Coding Trends of Medicare Evaluation and Management Services*”.
- RAC Audits of E/M Services Set to Begin in 15 States to Target CPT Codes 99214, 99215 (9/18/2012)

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Reviews/Audits Related to QHPs

- ▶ 2013 OIG Work Plan
- ▶ “We will review physician billing for “incident to” services to determine whether payment for such services had a higher error rate than that for non-incident-to services. We will also assess Medicare’s ability to monitor services billed as “incident-to.”

<https://oig.hhs.gov/reports-and-publications/archives/workplan/2013/Work-Plan-2013.pdf>

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Thank you!!!!

Questions?????

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Qualified Healthcare Professional (QHP) State Matrix

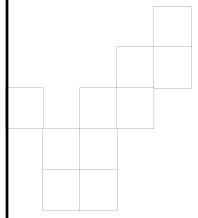
(Click on profession title to see requirement details)

State	Physical Therapist (PT)	Physician Assistant (PA)	Nurse Practitioner (NP)	Anesthesiologist Asst. (AA)	Certified Prof. Midwife (CPM)	Athletic Trainer (AT)	Clinical Social Worker (CSW)	Nurse Anesthetists (CRNA)
Alabama	X (prof. referral req.)	XX	XXX	X		X (License Required)	XXX	XX
Alaska	X	XX	X		X	X (No regulation)	XXX	X
Arizona	X	XX	X		X	X (License Required)	XXX	XX
Arkansas	X	XX	XXX		X	X (License Required)	XXX	XX
California	X	XX	XX		X	X (No regulation)	XXX	X
Colorado	X	XX	X	XX	X	X (Regist. Required)	XXX	X
Connecticut	X	XX	XXX			X (License Required)	XXX	XX
Delaware	X	XX	XXX		X	X (License Required)	XXX	XX
District of Columbia	X	XX	X	XX		X (License Required)	XXX	XX
Florida	X	XX	XX	X	X	X (License Required)	XXX	XX
Georgia	X	XX	XX	X		X (License Required)	XXX	XX
Hawaii	X	XX	X			X (License Required)	XXX	XX
Idaho	X	XXX	X		X	X (License Required)	XXX	X
Illinois	X	XX	XXX			X (License Required)	XXX	XX
Indiana	X	XX	XXX		X	X (License Required)	XXX	XX
Iowa	X	XX	X			X (License Required)	XXX	X
Kansas	X	XX	XXX			X (License Required)	XXX	X
Kentucky	X	XX	XXX	X		X (License Required)	XXX	XX
Louisiana	X	XX	XXX		X	X (Cert. Required)	XXX	XX
Maine	X	XX	X			X (License Required)	XXX	XX
Maryland	X	XXX	XXX			X (License Required)	XXX	XX
Massachusetts	X	XX	XX			X (License Required)	XXX	XX
Michigan	X	XXX	XX	XX		X (License Required)	XXX	XX
Minnesota	X	XX	XXX		X	X (Regist. Required)	XXX	X
Mississippi	X	XXX	XXX			X (License Required)	XXX	XX
Missouri	X	XXX	XX	X	X	X (License Required)	XXX	XX
Montana	X	XX	X			X (License Required)	XXX	X
Nebraska	X	XX	XXX			X (License Required)	XXX	X
Nevada	X	XX	X			X (License Required)	XXX	XX
New Hampshire	X	XX	X	XX	X	X (License Required)	XXX	X
New Jersey	X	XXX	XXX		X	X (License Required)	XXX	XX
New Mexico	X	XX	X		X	X (License Required)	XXX	X
New York	X	XX	XXX		X	X (Cert. Required)	XXX	XX
North Carolina	X	XXX	XX	X		X (License Required)	XXX	XX
North Dakota	X	X	X			X (License Required)	XXX	X
Ohio	X	XX	XXX	X		X (License Required)	XXX	XX
Oklahoma	X	XXX	XX	XX		X (License Required)	XXX	XX
Oregon	X	XX	X		X	X (Regist. Required)	XXX	X
Pennsylvania	X	XXX	XXX			X (License Required)	XXX	XX
Rhode Island	X	XX	X			X (License Required)	XXX	XX
South Carolina	X	XX	XX	X	X	X (Cert. Required)	XXX	XX
South Dakota	X	XX	XXX			X (License Required)	XXX	X
Tennessee	X	XXX	XX		X	X (License Required)	XXX	XX
Texas	X	XX	XX	XX	X	X (License Required)	XXX	XX
Utah	X	XX	XXX		X	X (License Required)	XXX	XX
Vermont	X	XX	X	X	X	X (License Required)	XXX	XX
Virginia	X	XX	XX		X	X (License Required)	XXX	XX
Washington	X	XXX	X		X	X (License Required)	XXX	X
West Virginia	X	XXX	XXX	XX	X	X (Regist. Required)	XXX	XX
Wisconsin	X	XXX	XXX	XX	X	X (License Required)	XXX	X
Wyoming	X	XX	X		X	X (License Required)	XXX	XX
Puerto Rico	X		XXX					XX
Virgin Islands	X		X				XXX	XX

KEY: X = Allowed to Practice in this State with Supervision by a Physician
 XX = Allowed to Practice in this State with Supervision by a Physician
 XXX = LIMITED, RESTRICTED OR SPECIALIZED Practice Rights w/supervision
 Not allowed to practice in this State/Area

QHP PayScale Website Reports

Certified Registered Nurse Anesthetist (CRNA) <ul style="list-style-type: none">• CRNA: Average pay is \$160,759.00. They may earn anywhere between \$114,325.00 and \$239,689 with 10 or more years experience.	Physician Assistant (PA) <ul style="list-style-type: none">• PA: Average pay is \$81,682. They may earn anywhere between \$66,592 to \$113,988	Anesthesia Assistant (AA) <ul style="list-style-type: none">• AA: Average pay is \$100,000. They may earn anywhere between \$95,000 - \$120,000	Certified Nurse Mid-Wife (CNM) <ul style="list-style-type: none">• CNM: Average mid-range pay of a CNM is \$89,916. They may earn anywhere from \$79,093 to \$96,000	Clinical Nurse Specialist (CNS) <ul style="list-style-type: none">• CNS: Average pay of a CNM is \$70,000. They may earn anywhere from \$50,000 to \$100,000	Clinical Social Worker (CSW) <ul style="list-style-type: none">• CSW: Average pay of a CNM is \$49,830. They may earn anywhere from \$31,410 to \$74,030	Nurse Practitioner (NP) <ul style="list-style-type: none">• NP: Average pay of a CNM is \$81,085. They may earn anywhere from \$63,029 to \$107,842	Physical Therapist (PT) <ul style="list-style-type: none">• PT: Average pay of a CNM is \$79,860. They may earn anywhere from \$55,000 to \$112,000
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Voluntary Disclosure: When and Where

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Director, Aegis Compliance & Ethics Center, LLP

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2013 SDP Update Goals

- More transparency on guidelines and expectations
- Simplify process by addressing common issues and questions
- Consolidate previous guidance

2

Why Disclosure is Important

- Legal and ethical duty
- Sign of an effective compliance program
- Risk further liability if don't

3

SDP Benefits

- Lower multiplier
- No CIA
- More timely resolution
- Avoid Government-initiated investigation
- May address 60-day rule liability

4

Who and What is Eligible

- Who = Everyone subject to 42 CFR 1003
- What = potential violations of federal criminal, civil, or administrative law for which CMPs are authorized
 - Not admitting liability
 - Acknowledge potential liability that want to resolve through a settlement and payment of money
 - Arrangement-by-arrangement analysis for AKS/Stark

5

What is Not Eligible

- Errors or overpayments where no potential violation
- Requests for opinion on whether there is a potential violation
- Stark-only conduct

6

Submission Content

- One main submission, with one supplement
- Simplified contents
- Must include the 11 issues plus specific information in excluded person or AKS sections to be accepted

7

Claims Calculation

- All claims or statistically valid random sample
- Use point estimate
- Simplified audit protocol

8

Employing Excluded Persons

- Include Specific Information
- Check everyone when find one
- Damages Proxy

9

AKS and Stark

- Arrangement-by-arrangement analysis
- AKS or AKS and Stark = SDP. Stark only = CMS
- Explain why potential violation
- See common questions list
- Include remuneration and claims amounts

10

Resolutions

- Cooperation essential
- Standard 1.5 multiplier
- Coordination with DOJ
- Inability to pay = raise early

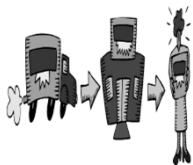
11

Disclosure*Prevention**Prevention**Prevention*

12

Disclosure

- Process
 - Education
 - Auditing & Monitoring



13

Questions to ask in determining whether to self-disclose

- Has there been a violation of law, regulation, rule or guidance?
 - Do you have federal health care funds to which you are not entitled?
 - If so, how much?
 - Was the conduct leading to the violation or receipt of federal money reckless or intentional?
 - Was it merely documentation?
 - Did it involve quality of care?
 - Are you under a CIA?
 - Are you vulnerable to a potential whistleblower?
 - Is this a hot area?
 - On the OIG work plan?
 - Area of great publicity or interest?

Factors to consider when deciding whether to disclose

<u>Pros</u>	<u>Cons</u>
Peace of mind	Point of no return
Good Corporate Citizen	Other issues exposed
Reduced Multiplier	Referral to OIG/DOJ?
No CIA or CCA	State and private entities?
No exclusion	Loss of control

Scenario

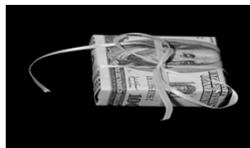
- It is determined that Dr. Howser, a Urologist, has ownership in a laser company that is providing a laser and technician services to the organization. There is no written agreement for the services. This has been in place for the past year. It has been further determined that the organization was reimbursed \$3 million for Medicare referrals made by the Urologist during this time period.



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Scenario

- Dr. Feelgood, the outgoing Chief of Staff, was given a gift of a European vacation valued in excess of \$7,000. She is a high admitting Cardiologist. The issue was not identified until 2 years after the gift was given.



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Scenario

- Because of concerns with your physician transaction process you conduct an audit of payments made to physician over the past 6 months. As a result of this audit you identify multiple concerns with payments made to several physicians without an agreement, payments made above FMV, gifts provided to physicians in excess of the non-monetary compensation limits as well as numerous office leases which are expired.



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Scenario

- Dr. Kildare, a neurologist, has a Medical Director agreement. However, he has not provided the required number of hours but was paid as though he had. An audit indicated this has been occurring for the past two years.



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Deloitte

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THE STATE UNIVERSITY
OF NEW JERSEY

A Unique Approach to Auditing the Primary Care Exception

HCCA 2014 Compliance Institute San Diego March 31, 2014



Agenda

- UMDNJ background
- The Primary Care Exception (PCE)
- Identifying data
- The analysis
- Validation of results and gaps addressed
- Reporting the results



- The nation's largest (\$1.8B) free-standing public health sciences university in the country with more than 6,000 students and 15,000 employees, including nearly 3,000 faculty members, located on five different campuses. It is a statewide network of eight schools, two hospitals and three faculty practice plans with more than 1,300 employed physicians on five campuses

NJ Medical and Health Sciences Restructuring Act eliminated UMDNJ effective July 1, 2013

- University Hospital became a stand alone state entity
- The School of Osteopathic Medicine joined Rowan University
- All other units joined Rutgers, The State University of New Jersey

2

Background information

UMDNJ School of Osteopathic Medicine (SOM)

Organization Information	<ul style="list-style-type: none">· 223 paid faculty at UMDNJ-SOM· 18 full time paid faculty in the Department of Family Medicine· 26 total family medicine residents for the 2011/2012 academic year
---------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

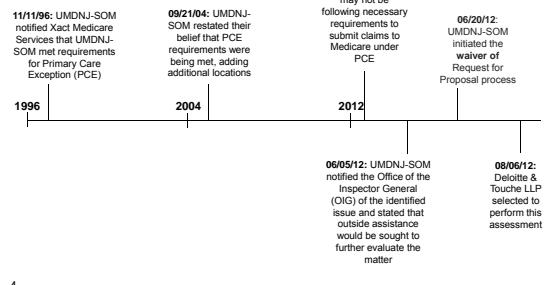
Today, the SOM is a component of Rowan University.

3

Source: http://www.rowan.edu/integration/updates/latest_updates.php

Background information

Chronology of events



4

Background information

Current Environment

- UMDNJ **was operating** under a Corporate Integrity Agreement (CIA) with the Office of Inspector General of the Department of Health and Human Services (OIG), which began on September 25, 2009 and is effective through September 24, 2014.
 - Office of Ethics, Compliance & Corporate Integrity ("OECCI") was responsible for University wide Compliance Program.
 - Under the terms of the CIA, UMDNJ was required to report certain "reportable events" to the OIG.
 - This issue was reported preliminarily by telephone to the OIG and then formally in writing on June 5, 2012. This notification stated that UMDNJ had identified certain overpayments related to compliance with the PCE and that UMDNJ would be seeking outside assistance in further evaluating this matter.

5

Medicare's Primary Care Exception

Primary Care Exception

CMS Pub 100-4 Chapter 12:

Exception for E/M Services Furnished in Certain Primary Care Centers

Teaching physicians providing E/M services with a GME program granted a primary care exception may bill Medicare for lower and mid-level E/M services provided by residents. For the E/M codes listed below, teaching physicians may submit claims for services furnished by residents in the absence of a teaching physician:

New Patient	Established Patient	Preventative Medicine
99201	99211	G0402
99202	99212	G0438
99203	99213	G0439

For this exception to apply, a center must attest in writing that all the following conditions are met for a particular residency program. Prior approval is not necessary, but centers exercising the primary care exception must maintain records demonstrating that they qualify for the exception.

7

Primary Care Exception

CMS Pub 100-4 Chapter 12:

Exception for E/M Services Furnished in Certain Primary Care Centers

- Outpatient department of a hospital or another ambulatory care entity in which the time spent by residents in patient care activities is included in determining direct GME payments.
- Does not include physician's office or home visits.
- Residents must have completed at least six months of a GME approved residency program.
- Teaching physicians may not supervise more than four residents at any given time.
- Must direct the care from such proximity as to constitute immediate availability.
- The teaching physician must be physically present for the critical or key portions of services furnished by the residents with less than six months in a GME approved residency program.

8

Primary Care Exception (continued)

Teaching physicians submitting claims under this exception must:



- Not have other responsibilities (including the supervision of other personnel) at the time the service was provided by the resident
 - Have the primary medical responsibility for patients cared for by the residents
 - Ensure that the care provided was reasonable and necessary
 - Review the care provided by the resident during or immediately after each visit. This must include a review of the patient's medical history, the resident's findings on physical examination, the patient's diagnosis, and treatment plan (i.e., record of tests and therapies)
 - Document the extent of his/her own participation in the review and direction of the services furnished to each patient

Residency programs most likely qualifying for this exception include family practice, general internal medicine, geriatric medicine, pediatrics, and obstetrics/gynecology.

Certain GME programs in psychiatry may qualify in special situations such as when the program furnishes comprehensive care for chronically mentally ill patients. These would be centers in which the range of services the residents are trained to furnish, and actually do furnish, include comprehensive medical care as well as psychiatric care. For example, antibiotics are being prescribed as well as psychotropic drugs.

9

Primary Care Exception (continued)

Patients under this exception should consider the center to be their primary location for health care services. The residents must be expected to generally provide care to the same group of established patients during their residency training. The types of services furnished by residents under this exception include:

- Acute care for undifferentiated problems or chronic care for ongoing conditions including chronic mental illness;
 - Coordination of care furnished by other physicians and providers; and
 - Comprehensive care not limited by organ system or diagnosis

Services performed by residents under the primary care exception should be billed with the GE modifier - *Service has been performed by a resident without the presence of a teaching physician under the primary care exception*

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New Jersey Medicaid requirements

Primary Care Exception – New Jersey Medicaid

New Jersey Administrative Code N.J.A.C. 10:54-2.2 Direction of Physician Services allows for an exception to the participating physician's physical presence requirement for resident services, but it applies to "Services are furnished at the outpatient department of a hospital or another licensed ambulatory care facility, and not at a physician's office or a patient's residence."

The SOM services are provided in the physician office setting and based on information provided in interviews and the data analysis the teaching physician was not present for the services being analyzed. As such, all the New Jersey Medicaid services were categorized as errors.

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Identifying the data and electronic analysis

Data and work plan

A work plan was developed to analyze the claims in question

1. Initial review of two years of claims with the GE modifier by UMDNJ
 - Confirmed that GE not used consistently
 - Confirmed that teaching physicians were not present for all services provided by residents through a manual review of schedules and claims data
2. Deloitte & Touche LLP was hired as an outside consultant to assist with further evaluation and calculation of repayment obligation, if any.
3. Work plan was discussed at meeting attended by UMDNJ OECC, Deloitte Partner and OIG Monitor.

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Data and work plan

A work plan was developed to analyze the claims in question

4. Interviews with practice management and physicians at multiple locations were conducted to clarify and confirm the issue:
 - Resident scheduling
 - Assignment of Teaching Physicians and oversight of Family Medicine Residents Practice management and physician knowledge of the PCE requirements
 - An investigative team conducted additional interviews to assess intent
 - Assessed the availability of data (scheduling and billing) in regards to the PCE

5. Based on the initial records reviewed and interviews, the issue was confirmed to be that teaching physicians were seeing their own patients while supervising residents at most — but not all — locations.

- 6. Options discussed were a sampling approach or electronic analysis:
 - Determine the availability of data in regards to the PCE exemption.
 - GE Modifier not applied so could not be used to identify PCE claims.
 - The IDX scheduling module was implemented in May 2000.
 - The scheduling system has fields for recording the billing doctor, the scheduling doctor and the time the patient is scheduled.
 - Patient was scheduled to the resident, but billed by teaching physician

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Data and work plan

A work plan was developed to analyze the claims in question.

7. Residents and teaching physicians are scheduled together in half day blocks of time.

- B. Data analysis plan was developed to calculate the amount of overpayment.

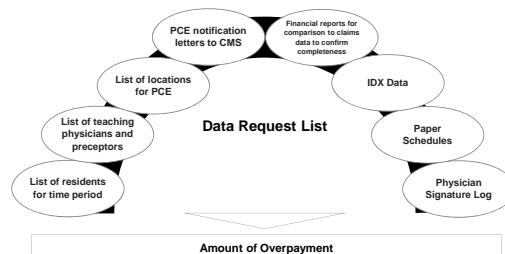
 - Scheduled times for teaching physicians were analyzed for times scheduled within two hours of the times patients were scheduled for each resident service
 - Two hours established as it was determined that residents are scheduled in half day time blocks and a four hour window should be a conservative window for the evaluation
 - This methodology was tested for one month of claims (December 2009), along with a review of 27 medical records to further assess the results of the data analyzed

The draft work plan was then presented to UMDNJ's monitor from the OIG

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Data request

A data analysis plan was developed to calculate the amount of overpayment



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The analysis - source documentation and population of data

IDX paid claims data that contained scheduling information was used for the analysis with dates of service from May 30, 2000 through September 28, 2012

Claims data analyzed was limited to the CPT codes that are included in the primary care exception:

- 99201 – 99203
- 99211 – 99213
- G0402, G0438, G0439
- For Medicaid – the preventive medicine codes were included (99381 – 99387 and 99391 – 99397)

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The analysis - source documentation and population of data (cont.)

Several steps were taken to confirm the results of the automated analysis:



IDX data sets, supporting tables and data availability were confirmed by extracting and validating various samples of data sets.

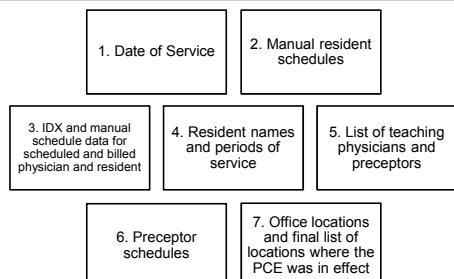
Finance Reports were created to confirm the completeness of data and accuracy of data for each of the years. This data showed a less than <1% variance.

Samples of office medical records were reviewed to confirm the results of the analysis.

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The analysis - source documentation and population of data (cont.)

Key Data Used for the Analysis



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The analysis - results

Example of Results (1)

Medicare - 2 hr Comparison analysis

Resident Schedule			Teaching Physician Schedule							
R INV.	Billing Doctor	Scheduled Doctor	PROC	R SVC DT	R TM	Billing Doctor	Scheduled Doctor	T VIS.	T SVC DT	T TM
1	Teaching Physician	ResidentA	99213	21-Aug-00	03:45PM	Teaching Physician	Teaching Physician	1	21-Aug-00	03:00PM
1	Teaching Physician	ResidentA	99213	21-Aug-00	03:45PM	Teaching Physician	Teaching Physician	2	21-Aug-00	02:30PM
2	Teaching Physician	ResidentB	99203	24-Aug-00	10:30AM	Teaching Physician	Teaching Physician	3	24-Aug-00	11:00AM
2	Teaching Physician	ResidentB	99203	24-Aug-00	10:30AM	Teaching Physician	Teaching Physician	4	24-Aug-00	08:45AM
2	Teaching Physician	ResidentB	99203	24-Aug-00	10:30AM	Teaching Physician	Teaching Physician	5	24-Aug-00	11:00AM
2	Teaching Physician	ResidentB	99203	24-Aug-00	10:30AM	Teaching Physician	Teaching Physician	6	24-Aug-00	09:00AM
2	Teaching Physician	ResidentB	99203	24-Aug-00	10:30AM	Teaching Physician	Teaching Physician	7	24-Aug-00	10:45AM
2	Teaching Physician	ResidentB	99203	24-Aug-00	10:30AM	Teaching Physician	Teaching Physician	8	24-Aug-00	08:45AM
2	Teaching Physician	ResidentB	99203	24-Aug-00	10:30AM	Teaching Physician	Teaching Physician	9	24-Aug-00	10:45AM
2	Teaching Physician	ResidentB	99203	24-Aug-00	10:30AM	Teaching Physician	Teaching Physician	10	24-Aug-00	10:45AM

(1) These do not reflect actual patient data or results.

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Validation of The Analysis

Some discrepancies were identified in the data:

- Some of the IDX data did not have the scheduling physician or time recorded.
- Practices reported in interviews did not always match what the data showed, e.g., one office indicated that the attending only saw one patient at the start of a shift when there were three or four residents in the office and then did not see any other patients during the four-hour shift.
- When assessing physician and resident names, there were discrepancies in spelling and format that required clean up.
- Some residents eventually became attending physicians so dates of residency status were used to confirm whether the physician who saw the patient was a resident.

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Validation of The Analysis

- ACL was the statistical sampling software used in selecting the samples
- Random claims selections were generated from ACL to identify the samples for further testing
- The sample selected was a validation sample to confirm the results of the data analysis rather than a statistically valid sample to be used for extrapolation of errors
- Confirm Billing doctor and scheduled doctor within the IDX system align with the documented notes within the record for the resident and the teaching physician/preceptor
- Confirm office location and time
- Confirm teaching physician/preceptor documented as required for the PCE

Review the care provided by the resident during or immediately after each visit. This must include a review of the patient's medical history, the resident's findings on physical examination, the patient's diagnosis, and treatment plan (i.e., record of tests and therapies)

Document the extent of his/her own participation in the review and direction of the services furnished to each patient

Validation of the results was performed using the office medical records documented by the physicians.

Validation

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Validation of the analysis

Some discrepancies were identified in the validation record review for claims identified as not in error:

- There were instances where the billing doctor name in IDX was not the physician who was scheduled and signed the record. When these cases were rechecked using the correct physician name, it was found that the physician who was supervising was seeing their own patients at the same time that the resident was seeing patients.
 - The physician at times did not document his/her review of the resident service as required by the PCE.
 - The physician at times signed the record at a later date.
 - For some records, the physician handwriting in the paper record was not legible.

The number of instances of the missed variance was identified and added to the confirmed errors for repayment.

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Validation of the analysis

Sample ID	Service Date	Time	Signature Detail	Comment	TP signs on DOS	TP Attests	TP signing matches DR	Recheck of claims data	Allow	New Doctor name to query
1	5/23/2012	06:00AM	Residentsign on 5/23 and 5/29, TP signs on 5/29		N	Y	Y	Y		
2	11/10/2008	02:00PM	Residentsign on 11/10, TP signson 11/12	Signed by diffent physician than billing physician.	N	Y	N	Y	N	
3	2/15/2011	02:00PM		TP signs that he performed the service with the resident.	Y	Y	Y	Y		
4	5/22/2012	06:00AM	Residentsign on 5/22, TP signson 5/29		N	Y	Y	Y		
5	6/8/2012	10:15AM	Residentsign on 6/8, TP signson 6/11		N	Y	Y	Y		

These do not reflect actual patient data or results.

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Closing comments

Closing comments

Data analysis

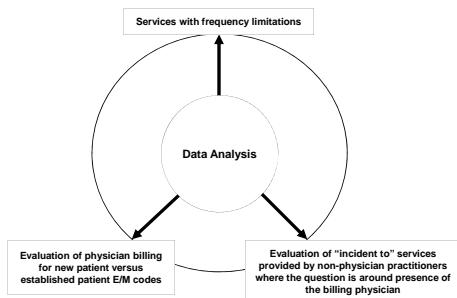
Disadvantages
• Requires ability to use tools such as SAS and Access
• Requires availability of required data points for the time period under review
• Careful review and confirmation of data is needed

Advantages
• Evaluate complete population if available
• Works for a very large population of claims
• Accuracy
• Efficient process – less labor intensive compare to record review
• Recognized cost savings

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Closing comments

Other investigations where data analysis may be used



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Discussion and questions

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TRINITY HEALTH | CATHOLIC HEALTH EAST

It's A New World: Ensuring Orders & Certification in EHRs

Presenters:
Mary Beth Pace, Director, Case Management
Harriet Kinney, Manager, Integrity & Compliance

CHE Trinity Health
Livonia, Michigan

Learning Objectives

- The challenges of ensuring the correct admission order (inpatient, outpatient) in an electronic health record (EHR) system
- Risks and compliance concerns with missing orders and certification with the new Two-Midnight Rule
- Process improvement recommendations to ensure compliance

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Today's Environment

- Many hospitals have EHRs
 - Some are completely electronic
 - Many are hybrids – paper and electronic
- Long-standing regulations for orders and certification documented in Conditions of Participation, CFR, state regulations
 - Audited by The Joint Commission, federal and state regulatory representatives
- CMS promulgated new regulatory guidance for orders and certification, effective for dates of service on and after October 1, 2013

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Our Journey



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- **Geographic Reach:** 21 States
- **Hospitals 86, Continuing Care Facilities and Home Health and Hospice Programs:** 109
- **Revenue:** \$13.3 billion
- **Community Benefit Ministry:** \$938 million
- **Employees:** 87,000
- **Physicians:** 3,200 employed

Continuum of Care Services

- **Senior Care:** 89 total long term care, assisted, independent living and affordable housing communities
- **Home Health/Hospice:** nearly 2.8 million visits

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Background

One integrated EHR and A/D/T system for our 40 hospitals (acute and CAH) in 9 states; 5 Medicare Administrative Contractors

Financial loss and increasing compliance risk over 6 months on medical necessity including issues with Level of Care (inpatient/outpatient) order

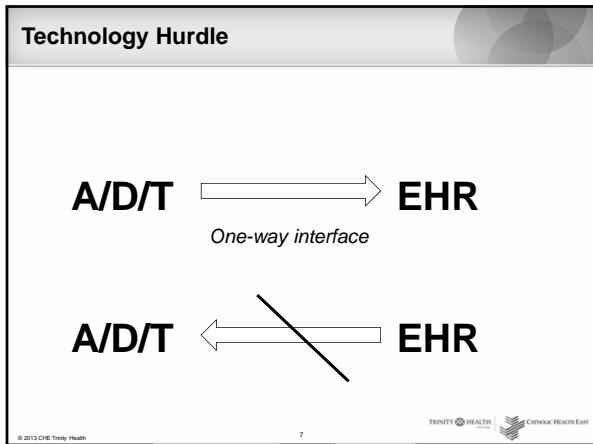
- No order documented
- Missing or conflicting documentation supporting Level of Care order
- Inappropriate changes from one Level of Care to another
- Confusion between Level of Care vs. Bed & Board moves

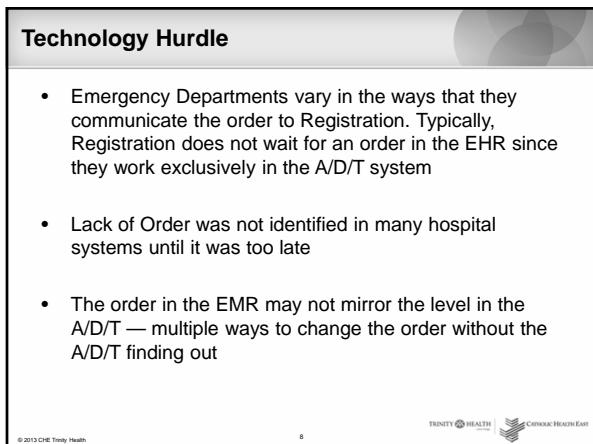
Multiple order types available in the EHR for documenting Level of Care orders

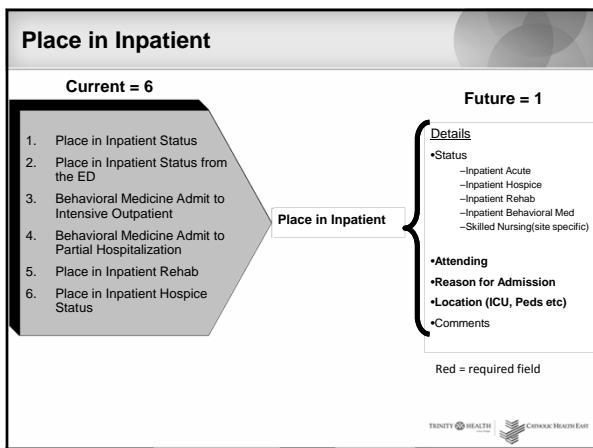
- Lack of standard definitions
- Inconsistent use of order types

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Place in Outpatient

Current = 6	Future = 1
<ol style="list-style-type: none"> 1. Place in Outpatient Status 2. Place in Outpatient Status-Ambulatory 3. Place in Outpatient Status-Ambulatory Surgery Home Today 4. Place in Outpatient Status-Ambulatory Surgery Overnight Stay 5. Place in Outpatient Status - Infusion/Transfusion 6. Place in Outpatient Status-Procedure 	<p>Place in Outpatient</p> <p>Details</p> <ul style="list-style-type: none"> • Status <ul style="list-style-type: none"> -Procedure (Example: dialysis, Radiology procedure, ECT) -Infusion/Transfusion -Surgery-Extended Stay -Observation • Attending • Reason for Admission • Location (ICU, Peds, etc) • Comments <p>Red = required field</p>

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Steps Taken

- CMIO team approval obtained
- CNO and CMO calls performed
- EHR IT system support and liaison calls
- Senior leadership buy-in and approval
- Rollout



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Regulatory & Operations Hurdle

CMS IP Only List

- Operational challenges:
 - Pre-registration / Registration
 - Surgical scheduling
 - IP Only List check (prior to surgery)
 - Physician order
 - Supporting documentation

*Still working on this –
If anyone has solved this, please share!!!*

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The Two-Midnight Rule

October 1, 2013



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Overview

Practitioner should order acute IP admission status if the patient's stay is expected to exceed 1 Medicare utilization day (crosses 2 midnights) or requires a procedure listed on the IP Only List

- No change in the use of OP Observation Services
- No change with patients who have procedures on the CMS IP Only List
- Applies only to Medicare Traditional (Part A), not Medicare Managed Care
- Physician order still required for IP admission
- Physician documentation must support reasonable basis for medical necessity, the order, and expectation to stay over 2 midnights

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Old Way - New Way

CMS states this is no different than what it has always required; however, it 'feels' different for acute care and critical access hospitals, physicians

- Regulations for orders and certification have been in CMS regulations since the start of Medicare
- The Final Rule updated, quantified and formalized longstanding policy so it can be formally measured and assessed (audited)

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Physician Required Documentation - Orders

- Content:** Order must specify admission for IP services
 - Applies to Acute, CAH, IP Psych, IP Rehab (Rehab has additional directions to follow, specified in IRF regulations)
 - Verbal order is ok; however, it must be authenticated (signed, dated, timed) **prior to discharge** (or earlier if the State or hospital requires it)
 - Physician decision of less than / greater than 2 midnights
 - May be a verbal (not standing) order that identifies the qualified admitting practitioner; must be countersigned by the ordering practitioner promptly and prior to discharge
- Timing:** Must be furnished at or before the time of the IP admission. CMS does not allow for retroactive orders or the inference of orders
 - Can be written in advance of the formal admission

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Physician Required Documentation - Orders

- Specificity:** 'Inpatient Status', 'For inpatient services', or similar language. 'Admit to ICU', 'Admit to Step-down', etc. is no longer acceptable
 - 'Admit to ER', 'to Recovery', 'to Short Stay Surgery', 'Admit to Observation' define non-IP services, and does not meet IP admission requirements
- Ordering physician/practitioner:**
 - Authorized by the state to admit patients and has been granted admitting privileges by the hospital's medical staff (e.g., may be the attending or the physician on call for the attending; the hospitalist; the surgeon or surgeon on call)
 - Residents and non-physician practitioners, with countersignature by ordering practitioner prior to discharge
 - ED physicians who does not have admitting privileges but authorized by the hospital to issue temporary or "bridge" IP admission orders, with countersignature by ordering practitioner prior to discharge
 - Knowledge of the patient's hospital course

If the order is not properly documented in the medical record, the hospital should not submit a claim for Part A payment

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Physician Required Documentation - Certification

- Content:**
 - Reason / Diagnosis for inpatient services
 - Estimated length of time the patient needs to be in the hospital
 - Plans for post-hospital care (if appropriate),
 - CAH: Must certify the patient may reasonably be expected to be discharged / transferred within 96 hours after admission to CAH
 - Authentication of the order, certifying that IP services were ordered in accordance with the regulations governing the order
- Timing:**
 - Certification begins with the order for IP admission
 - Certification completed and authenticated (signed, dated, timed) prior to discharge
 - CAH: Certification required no later than 1 day prior to the date on the claim

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Physician Required Documentation - Certification

- **The physician/practitioner signing the certification must be:**
 - The physician responsible for the case; or
 - Another physician who has knowledge and is authorized to do so by the responsible physician or the hospital's medical staff
- **Recertification:**
 - Psychiatric: At 12 days, then recertify per at least every 30 days
 - All other hospitals, see regulations for guidance pertaining to outliers and those not subject to PPS
- **Format**
 - No specific procedures or forms are required for certification or recertification
 - Must be a separate, signed statement for each certification and recertification

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Next Steps



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Next Steps – Part 1

EHR Changes - Orders

- Physician Order and expectation related to length of time in the hospital
- Auto-routing of all admit orders that are signed by PAs, NPs, and residents to the physician's inbox.

And.... Downtime order processes!

DRG _____	Time _____	Patient Stamp
Downtime orders - Inpatient		
Admit patient to IP status		
<input type="checkbox"/> Direct Stay 2 months or greater <input type="checkbox"/> Direct Stay shorter than 2 months <input type="checkbox"/> Procedure on the CMS IP only list		
Have I reviewed the care and treatment for my patient. It is my intention for an update today for the following reasons: Dagnosis Treatment plan Patient risk factors Here are the follow up care plans (if known):		
<small>Print my signature in accordance with my understanding of the requirements for electronic signatures. I acknowledge that I have read and understood CPH-C-2004.</small> Provider Signature _____		

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Admit to Inpatient Status

Print View | Back | Place in Inpatient Status Order 0/20/2013 9:21 EDT 0/20/2013 9:21 EDT

Details for Place in Inpatient Status

()

*Required Start Date/Time: Admitting Physician:

*Reason for Admission:

Additional Instructions/Comments:

*Attending Physician:
Location:

Place in Inpatient Status Options:

- Inpatient Behavioral Health Voluntary
- Inpatient Behavioral Health Non-Voluntary
- Skilled Nursing (site specific)
- Doctor's Office (site specific)
- Obstetrics
- Pediatric

“Change” to Admit to Inpatient Status Order

1 Admit / Discharge / Transfer

3012013 14:30 EDT 3012013 14:30 EDT
 Change Patient To Out... Order 3012013 14:30 EDT 3012013 14:30 EDT

Details for Change Patient to Inpatient Status

Order Details | Order Comments | Diagnose |

*Requested Start Date/Time: 03/02/2013 [142] [EDT]
 *Attending Physician: Additional Institutional Comments:
 *Reason for Admission: *Status:
 Admitting Physician: Location:
 *Discharge Facility:

Admitting Physician: Location:
 Discharge Facility:

View Request Details | By Date | Filter by Name/Status

“Change” to Admit to Outpatient Status Order

1 Admit / Discharge / Transfer
Change Patient to Out... Order 30310013 14:32 EDT 30310013 14:32 EDT
Change Patient to Out... Order 30310013 14:32 EDT 30310013 14:32 EDT

Data for Change Patient to Outpatient Status

Details [Order Comments] [Diagnosis]

***Required Start Date/Time:** 03/21/2013 1433 EDT ***Outpatient Status:** Observation

***Reason for Outpatient Visit:**

Additional Instructions/Comments:

***Attending Physician:** Caring#:

***Observation:**

- Observation
- Diagnostic Evaluation
- Diagnostic Partial Hospitalization
- Psychiatric Intensive Observation
- Diagnostic Intensive Outpatient Observation

ADD: 2 options for “Observation” status:

Observation - Expect stay one midnight or less

Observation - Expect stay more than one midnight

ADD: 2 options for "Observation" status:
Observation - Expect stay one midnight or less
Observation - Expect stay more than one midnight

Next Steps – Part 2	<p>EHR Changes - Certification</p> <ul style="list-style-type: none"> Auto pop-up of the Certification form the second time the physician signs into a patient's chart HARD stop so nothing can be done until the Certification is completed <p>PATIENT INPATIENT CERTIFICATION - MEDICAL</p> <p>CERTIFICATION: I certify that inpatient hospitalization is medically necessary for the medical treatment of the patient and that services will be provided in accordance with 42 CFR 411.3 and that the services that will be provided may be a single admission or two midnights and the medical record will contain clinical documentation supporting that rationale.</p> <p>INITIAL DIAGNOSIS: As documented within the History & Physical.</p> <p>REASON FOR INPATIENT MEDICAL TREATMENT OR INPATIENT DIAGNOSTIC STUDY:</p> <p>[Reason here=>]</p> <p>EXPECTED LENGTH OF STAY: _____ days</p> <p>(Documentation further supporting reason for inpatient services will be documented within but not limited to the History & Physical, Physician Progress Records, Consultation Reports, Operative Reports, Nursing documentation, and ancillary support documentation.)</p> <p>PLAN FOR POST HOSPITAL CARE:</p> <p>Name: _____ Facility: _____ Other: _____</p>
----------------------------	------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Next Steps – Part 3

- **Toolkit**
 - Decision tree: Inpatient vs Outpatient
 - FAQs for physicians and key stakeholders
 - Education for physicians
 - **Evaluating Pre-bill audits for cases less than 2 midnights**
 - Electronic "self-audit" options
 - Implications for days in A/R and DNFB
 - Daily monitoring reports
 - **Communications**
 - Everyone involved – monthly Open Door Forum WebEx/conference calls
 - Patient communication

Concerns

- Tremendous change for physicians
- Confusion regarding time in hospital as the *only* requirement to be addressed
 - CMS confirmed that Medical Necessity is still a component of the process to determine if a patient should be IP or OP
 - The Order and Certification are to be considered along with medical record documentation to support Medical Necessity
- Challenges in communicating changes and impact to Medicare patients

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Concerns

- IP Only List processes
- Internal post discharge audits
 - Resources and capabilities
 - Impact on days in A/R and DNFB
- CMS contractors
 - "Probe and Educate" audits period – extended through September 30, 2014
 - Small samples (10-25 claims per hospitals) less than 2 midnights
 - MACs citing education and further review as necessary
 - Transmittal 505 rescinded
- Lost revenue and increased compliance risk if we don't get it right

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Process Improvement Recommendations

- Work with all teams and EHRs to improve operational processes
 - Automate
 - Standardize
- Gather data and reporting volume to Finance leadership
- Create reports that each team needs
 - Distribute daily/weekly
- Use an hour every month to hold your own Open Door Forum call
 - Distribute FAQs after each call

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Appendix Regulatory References

- CMS 1599-F, effective for dates of service on and after October 1, 2013 (August 2, 2013)
- Hospital Inpatient Admission Order and Certification (updated January 30, 2014)
- MLN Matters SE1333, "Temporary Instructions of Final Rule 1599-F for Part A to Part B Billing of Denied Hospital Claims" (September 26, 2013)
- CMS FAQs, "2 Midnight IP Admission Guidance & Patient Status Reviews for Admissions on or after October 1, 2013" (updated February 24, 2014)
- Temporary Instructions for Implementation of Final Rule 1599-F for Part A to Part B Billing of Denied Hospital Inpatient Claims, SE1333 Revised (October 23, 2013)
- Reviewing Hospital Claims for Patient Status: Admissions On or After October 1, 2013 (updated February 24, 2014)
- Selecting Hospital Claims for Patient Status Reviews: Admissions On or After October 1, 2013 (updated February 24, 2014)
- Medicare Inpatient Hospital Probe & Educate Statute Update (February 24, 2014)

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AR Systems, Inc
Training Library Presents

Mastering the Chaos: Attacking the 2 Midnight Rule - An Operational Focus

Instructor:



Day Egusquiza, Pres
AR Systems, Inc

RAC 2014

1

Medicare Fee for Service RAC Program , FY 2010 – July 2013 (per CMS)

	FY 2010 Oct '09-Sept '10	FY 2011 Oct '10-Sept '11	FY 12, 1st Q Oct '11-Sept '12	FY 2013 Oct '12-March 2013	TOTAL AS OF 3rd Q 2012	TOTALS as of April 2013 July, 2013
Overpayments Collected	\$75.4M	\$797M	\$2,291.3	\$1,371.3	\$2.5B	\$4.5B \$5.4B
Underpaymt Returned	\$16.9M	\$141.9M	\$109.4M	\$65.4M	\$289.3M	\$333.6M \$370M
Total Corrections	\$92.3M	\$939.3M	\$2,400.7	\$1,436.7	\$2.8B	\$4.8B \$5.7B
Overpayment issues	Region A/ Proformat/ DCS	Region B/CGI	Region C/ Connelly	Region D/HDI	PENDING APPEALS? May significantly change figures.	Note: Region C and A added Minor Surgery done as Inpt , 8- 13
	Cardiovas Procedures/ Inpt	Cardiovas Procedures/ Inpt	Cardiovas Procedures/ Inpt	Minor surgery and other treatment billed as inpt		

BAC 2014

6

AHA/RAC Denials by Reason: 3rd Q 2013

96% of denied \$ were complex
56% w/o findings

RAC Denials by Reason, 3rd Q of 2013/ 4 th Q 2012 by \$\$ impacted					
Region	A	B	C	D	All
Medically Unnecessary Admission/incorrect setting	50/55/ 66%	72/75/ 78%	70/77/ 73%	55/55/ 58%	50/67/ 72%
Incorrect DRG or other coding error	13/12/ 4%	1/6/6% 4/2/5%		2/12/ 2%	5/5% 5/5%
Other	35/20/ 17%	24/15/ 10%	17/9/ 10%	33/24/ 18%	25/16/ 15%
No or insufficient documentation	0/4/1%	1/1/1%	4/5/1%	1/4/2%	2/3/1%
Med unnecessary beyond 3 midnights/SNF	2/2%/1	1/1%/0	3/2%/1	20/20%/0	2% /0

Complex Denials/Setting By Dollar	
64% of denials =wrong setting	
% of Complex Denials for Lack of Medical Necessity for Admission – thru 3rd Q 2013/4th Q 2011- by \$\$ Impacted	
Syncope and collapse (MS-DRG 312) 15/14/18/14/17/ 25/21%	
Percutaneous Cardiovascular Procedure (PCI) w drug-eluting stent w/o MCC (MS-DRG 247) 19/17%/19/21/23 /24/14%	
T.I.A. (MS-DRG 69) 4/0/0/0/0/6/8%	
Chest pain (MS-DRG 313) 10/10/10/13/10/9 /8%	
Esophagitis, gastrotro & misc digest disorders w/o MSS (392) 11/13/16/13/10/3 /0%	
Back & Neck Proc exc spinal fusion w/o CC/MCC (DRG 491) 0/5/5/5/%//	

AHA RACTrac

RAC 2014

4

Appeals		
3rd Q/2nd Q/1st Q 2013/4th Q/ 3rd Q/ 1st Q 2012		
Value of appealed claims: \$1.5B reported thru 3rd		
Ave 247 appeals per hospital up to 309 per		
hospital/3rd Q		
Major backlog /3rd Q, 70% of all appeals still pending		
	% of denials appealed	% of denials overturned on appeal ¾ still pending...
Region A	41/31/51/ 50/51/41	67/71/79/81/82 /70
Region B	48/43/45/ 38/39/40	63/77/79/74/82 /84
Region C	45/39/39/ 39/37/27	67/74/76/75/77 /79
Region D	47/48/48/ 48/48/43	42/61/60/62/61 /55
National	47/40/44/ 42/42/34%	63/70/72/72/74 /75%

AHA RACTrac

RAC 2014

5

What's New In the World of Audit?	
Pre-payment MAC – all J's impacted	
Post payment RAC new focus	
Medicaid audits rolling out nation wide	
Physician practice audits	
And the definition of an Inpt.Oct 1, 2013	

RAC 2014

6

Hot updates – March 2014

- ▶ Effective 3-6, Medicare contractors may automatically deny claims that are 'related' to other claims that have been denied as a results of a pre or post payment review.
 - ▶ Contractors need not issue ADRS for the 'related' claims prior to issuing the denial.
 - ▶ MAC, RAC, ZPIC have the discretion to deny - 'related' if documentation associated with one claim can be used to validate another
 - ▶ An inpt claim denied - the physician claim can be determined not to be reasonable and necessary.
 - ▶ A dx test denied - the professional component denied.
 - ▶ The change could impact coverage of payment for numerous services and products including, for instance episodic care, (eg SNF, home health and hospice) and rented DME.

**WOW - all are officially
In this together!**

Update Sub regulatory
Guidance/FAQ 3-12-14

BAG 2014

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More hot updates 3-14

www.cms.gov/research-statistics-data-and-systems/Monitoring-programs/Medicare-FFS-Compliance-programs/recovery-audit-program/recent_updates.html

- ▶ PRG Schultz – out as a RAC subcontractor. Not enough money!!
YEAHOO
 - ▶ CMS announces RAC “pause” (2-19-14)
 - ▶ Feb 21 – last day may issue an ADR
 - ▶ Feb 28th – last day MAC may issue a prepayment ADR for the RAC demo project
 - ▶ June 1st – the last day a RAC may send denied claims to the MAC to recoup payment.
 - ▶ 5 changes to the RAC program announced:
 - ▶ No longer discuss or appeal/30 days wait to allow time to discuss
 - ▶ RAC confirm receipt of discussion
 - ▶ RAC not paid until 2nd level appeal is upheld.
 - ▶ CMS will revise ADR limits that will take into account different claim types
 - ▶ CMS will review adjust ADR limits in accordance with the hospital’s

And more updates

- "Medicare calls for review of two midnight denials" Modern Healthcare, 2-26-14
 - CMS told contractors to re-review all Medicare inpt denial payments since Oct 1, 2013.
 - One of the reasons to extend the Probe and Ed: get the initial MAC audits consistent with the regs.
 - CMS said its contractors had requested 29,000 MR as of Feb 7, and 6,000 of those were complete. No news on % denied.
 - Transfer update: During MedLearn call (2-26-14) CMS updated: receiving hospital CAN count time at a sending hospital toward their own 2 MN benchmark.
 - Sending hospital - if there is knowledge that the pt is being transferred/next day, the pt is obs as only 1 MN is appropriate in the sending hospital.

1-8-14 : Procurement process (call with AHA)

- ▶ CMS announced that the agency has extended thru June 1 the current RAC contracts. The contracts were set to expire in Feb and the extension will provide a transition period to implement the new contacts. Importantly, for hospitals, CMS staff said that the contract extensions allow the current RACs to send additional documentation requests to hospitals thru Feb 21, 2014.
- ▶ Any ADRs sent after that date must come from the RACs that have been awarded new contacts, according to CMS, and will be governed by the terms of the new contracts.
- ▶ CMS staff said it is in the process of soliciting quotes.

RAC 2014

10

Expanded education on 2 MN & Probe update

- ▶ Jan 30, 2014
- ▶ CMS updates: "Hospital inpatient Admission Order and Certification"
- ▶ Lots of clarity on signatures, verbal, etc.
- ▶ www.cms.gov/Medicare/Medicare-fee-for-service-payment/acuteinpatientPPS/do wnloads/IP-Certification-and-order-01-30-14.pdf

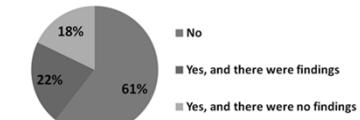
- Jan 31, 2014
- ▶ "Extension of the probe and educate period."
 - ▶ All elements of no RAC auditing remains/MAC only
 - ▶ MACS will continue to select claims for review with admission dates between March 31 and Sept 30, 2014 (so 10-13 – 10-14)
 - ▶ They will continue to deny if found not in compliance.
 - ▶ Hold educational sessions thru Sept 30, 2014 w/hospitals

RAC 2014

11

Feedback from attendees – Compliance 360 webinar (2-14)

Have you had activity from the probe and educate 10-25?



RAC 2014

12

More Updates – OIG work plan 2014

- ▶ OIG 2014 work plan
- ▶ “New inpt admission criteria”
- ▶ “We will determine the impact of new inpt admission criteria on hospital billing, Medicare payments, and beneficiary payments.
- ...determine how varied among hospitals in FY 2014.
- ▶ “Context: Previous OIG work found overpayments for short inpt stays, inconsistent billing practices among hospitals and financial incentives for billing Medicare inappropriately. ...expected 2 MN = inpt, less than 2 MN= outpt, The criteria represent a substantial change in the way hospitals bill for inpt and outpt stays.”

RAC 2014

13

Congress passes FY14 spending bill with important healthcare provisions

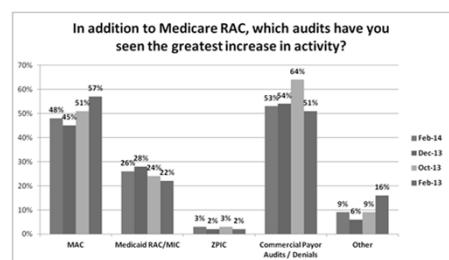
1-16-14 HR 3547

- ▶ Directs CMS to develop a plan with a timeline, goals, and measurable objectives to improve the RAC process.
- ▶ Congress notes that roughly ½ of the 43,000 provider appeals of RAC determinations were overturned at the Office of Medicare Hearings and Appeals (OMHA), prompting congress to express concern that the CMS RAC program has created incentives for RACs to take overly aggressive actions that result in RACs ‘chasing dollars after the fact.’
- ▶ ..to establish a systematic feedback process with the OMHA, CMS programs and the RACs to prevent the appearance that RACs are selecting determinations to increase their fees.
- ▶ ...the explosion in appeals in RAC determinations and other provider/supplier claims has led to a significant backlog at OMHA.

RAC 2014

14

Results from Feb 14 Compliance 360 Free Webinar – Attacking the 2 MN rule



RAC 2014

15

HOT AS A PISTOL – New Inpt ruling PLUS Billing for denied hospital inpt claims

MLN Matters SE1333, effective 10-13

"Temporary instructions for implementing of Final Rule 1599-F for Part A to Part B billing of denied hospital inpt claims." (www.cms.gov/outreach-and-education/Medicare-learning-network-MLN/MLNMattersarticles/downloads/SE1333.pdf)

FEAR OF AUDIT IS NOT JUSTIFICATION TO VIOLATE BENEFICIARIES RIGHTS OR DEPRIVE THE HOSPITAL OF COMPLIANTLY EARNED REIMBURSEMENT.
(Physician advisors on RAC RELIEF 11-13)

RAC 2014

16

The new Medicare Inpt = Implementation period of Oct 1, 2013 thru Dec 31, 2013 (update 9-26-13)
MM 8421 FY IPPS regs, Transmittal R2778CP and now thru 9-30-14

Good references:

- ▶ **OIG report:** Medicare recovery audit contractors ad CMS's Action to Address Improper Payments, Referrals of potential fraud and performance (OEI-04-11-00680) <http://go.usa.gov/D48j> (Looked at what CMS is doing about preventing the improper payments identified by RAC 10/11)
- ▶ **CMS's FINAL inpt rule:** published 8-19-2013; effective 10-1-13. Most of the language from the proposed rules remained unchanged. <http://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientPPS/fy2014-ipps-final-rule-home-page.html>
- ▶ **Hospital inpt admission order and certification, CMS, dated 9-5-13.** www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientPPS/downloads/IP-certification-and-order-09-05-13.pdf
- ▶ **Remember – inpt only list is the exception to 2 midnight rule.**

RAC 2014

17

It never changed... Documentation to support the level of care...

- ▶ "No Medicare payment shall be made for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Title XVIII of the Social Security Act, Section 1862 (a) (1) (A)
- ▶ "Observation services must also be reasonable and necessary to be covered by Medicare." (Medicare claims processing manual, Chapter 4, 290.1) Obs did not change.
- ▶ "The factors that lead a physician to admit a particular patient based on the physician's clinical expectation are significant clinical considerations and must be clearly and completely documented in the medical record." (IPPS CMS 1559-F, p 50944)
- ▶ Only a physician can direct care ...and...Patient Status....

RAC 2014

18

FAQ CMS update 9-26-13 and now probe and educate thru March 2014. Implementation period guidance

<http://cms.gov/research-statistics-data-and-systems/monitoring-programs/medical-review/inpatienthospitalreviews.html> (has update with FAQ 11-1-13)

- ▶ During the 3 /now 12 months, (Oct -Oct 1, 2014) implementation, CMS will instruct MACs not to review claims spanning more than 2 midnights after admission for a determination of whether an inpt admission and pt status were appropriate.
- ▶ In addition, for a period of 90/180 days, CMS **will not** permit the RAC to review inpt admissions of 1 midnight or less beginning Oct 1, 2013.
- ▶ **The MAC will do a prepayment probe & educate-DOS of Oct 1 March 1, 2014 (now thru Oct 1)**
- ▶ **WPS reports: 58500 as a reason code on RAs/probe & Ed.**

RAC 2014

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MAC Actions Following Patient Status Probe Reviews

Number of Claims in Sample That Did NOT comply with Policy (Date of Admission October – March 2014)			
	No or Minor Concerns	Moderate to Significant Concerns	Major Concerns
10 claim sample	0-1*	2-4*	7 or more*
25 claim sample	0-2*	3-13*	14 or more*
Action	For each provider with no or minor concerns, CMS will direct the MAC to: <ol style="list-style-type: none"> 1. Deny non-compliant claims 2. Send summary letter to providers indicating: <ul style="list-style-type: none"> • What claims were denied and the reason for denial • That no more reviews will be conducted under the Probe & Educate process • That the provider will be subjected to the normal data analysis and review process 3. Await further instruction from CMS 	For each provider with moderate to significant concerns, CMS will direct the MAC to: <ol style="list-style-type: none"> 1. Deny non-compliant claims 2. Send detailed review results letters explaining each denial 3. Send summary letter that: <ul style="list-style-type: none"> • Offers the provider a 1:1 phone call to discuss • Indicates the review contractor will REPEAT Probe & Educate process with 10 or 25 claims 4. Repeat Probe & Educate of 10 or 25 claims with dates of admission January – March 2014 5. If problem continues, Repeat Probe & Educate with increased claim volume of 100 - 250 claims 	For each provider with major concerns, CMS will direct the MAC to: <ol style="list-style-type: none"> 1. Deny non-compliant claims 2. Send detailed review results letters explaining each denial 3. Send summary letter that: <ul style="list-style-type: none"> • Offers the provider a 1:1 phone call to discuss • Indicates the review contractor will REPEAT Probe & Educate process with 10 or 25 claims 4. Repeat Probe & Educate of 10 or 25 claims with dates of admission January – March 2014 5. If problem continues, Repeat Probe & Educate with increased claim volume of 100 - 250 claims

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More regulatory updates..

- ▶ CMS's Frequently Asked Questions/Nov 2014
 - ▶ www.cms.gov/research-statistics-data-and-systems/monmitoring-programs/medical-review/downloads/reviewinghospitalsclaimsfinal.asp
- ▶ CMS's Instructions for Probe and Educate

Each MAC is doing their own education on how it will roll out. CMS will do an update in Jan/posted Nov. One good example: Noridian www.noridianmedicare.com/cgi-bin/coranto/viewnews.cgi?id=EflykyEAyyOGlomhgg&tmpl=part-a-viewnews&style (how receive request/30 days to reply)

RAC 2014

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More audit guidance – RAC

- ▶ "CMS will not permit RAC to conduct pt status reviews on inpt claims with dates of admission between Oct 1, 2013–March 31, 2014.(Now Oct1) These reviews will be disallowed PERMANENTLY, that is, the RAC will never be allowed to conduct pt status reviews for claims with DOS during that time period. "
- ▶ "In addition, CMS will not permit RAC to review inpt admissions of LESS than 2 MNs after formal inpt admission that occur between Oct 1–March 31, 2014. (now Sept)"
- ▶ www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medical-review/inpatienthospitalreviews.html

RAC 2014

22

Effective 12-1-13: new use of occurrence span code 72

- ▶ National UB committee – Occurrence code 72 First /last visit dates
- ▶ *The from/through dates of outpt services. For use on outpt bills where the entire billing record is not represented by the actual from/through services dates of Form Locator 06 (statement covers period) AND*
- ▶ *On inpt bills to denote contiguous outpt hospital services that preceded the inpatient admission. (See NUBC minutes 11-20-13)*
- ▶ *Per George Argus, AHA, a redefining of the existing code will allow it to be used Dec 1, 2013. CMS info should be forthcoming.*
- ▶ *MM8586 ML Matters, Jan 24, 2014 CR 8586*
- ▶ *UPDATE: UG Some MACs are stating 'ignoring' the code!!!*

RAC 2014

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Understanding 2 MN Benchmark – 72 Occurrence Span MM8586 1-24-14

- ▶ EX) Pt is an outpt and is receiving observation services at 10pm on 12-1-13 and is still receiving obs services at 1 min past midnight on 12-2-13 and continues as an outpt until admission. Pt is admitted as an inpt on 12-2-13 at 3 am under the expectation the pt will require medically necessary hospital services for an additional midnight. Pt is discharged on 12-3 at 8am. Total time in the hospital meets the 2 MN benchmark..regardless of Interqual or Milliman criteria.
- ▶ Ex) Pt is an outpt surgical encounter at 6 pm on 12-21-13 is still in the outpt encounter at 1 min past midnight on 12-22-13 and continues as a outpt until admission. Pt is admitted as an inpt on 12-22 at 1 am under the expectation that the pt will required medically necessary hospital services for an additional midnight. Pt is discharged on 12-23-13 at 8am. Total time in the hospital meets the 2 MN benchmark..regardless of Interqual or Milliman criteria.

RAC 2014

24

Where do the patients come from? Two hot spots for referrals into “a bed”

- › ER & Inpt surgery
- › Attack these two places with a pro-pt status focus, not placing and chasing.
- › Develop internal flows to attack:
 - ER – how much UR coverage ? 24/7? or utilize ER lead RNs or house supervisors. No pt is given a bed without pt status ‘blessed.’ Integrated CDI program will help with cross training.
 - Inpt surgery – all daily inpt surgery schedules are reviewed by UR to review output being scheduled as output.
 - Involve the internal UR leaders and PA for patterns.
 - Sr leadership will have to be prepared to push thru the regulation with any problematic providers.

RAC 2014

25

Let's get started– Certification process

- › Lots of ‘chatter’ but evaluate this process flow.
- › 1st question: Can the pt go home safely from the ER? Assess the reasons the provider (ER doc consults with the provider directing care) and document same. (Risk factors, history of like condition with outcome, presenting factors, plan)
- › 2nd question: Can the ER physician (after consulting with the admitting) attest/certify that the pt needs to ‘be in the hospital’ for an estimated 2 midnights to resolve the condition?
- › 3rd question: If no, move to OBS and evaluate closely. If yes, move to inpt with other elements of the inpt certification.

RAC 2014

26

Other hot spots within the new reg

- › Effective DOS 10-13
- › Physician certification is required with every inpt order.
- › Challenges – doctor directing/knowledge of pt’s care must sign/“ordering” status privileges.
- › At beginning of inpt and when converting from obs and prior to discharge.. with the record still supporting inpt LOC
- › Discuss ordering privileges, TO/VO with authentication

- › Key elements of the certification:
- › Must order ‘inpt’ w/
- › Authentication of Inpt order.
- › Anticipated LOS -(2 MN or 1 MN with 1 output MN)
- › Reason for admission=HUGE
- › Anticipated D/C destination and needs (D/C note ok)
- › +CAH – may be reasonably d/c or transferred in 96 hrs.
- › Separate form? Not required
- › Incorporated into existing documentation ‘somewhere?’
- › Consistency always = form
- › (Hospital certification/CMS)

RAC 2014

27

Using the 5 W's documentation for pt status

5 W's - Recovery Analytics

- ▶ What are we treating? Diagnosis
 - ▶ Where is the treatment needed? Inpt or obs?
 - ▶ Why is treatment needed?
Acute/chronic/risk
 - ▶ How are we treating it? What & why
active tx
 - ▶ When do you think they'll get better?
Estimated LOS

BAG-2014

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Name/Title		Position Name	DEPARTMENT/SECTION OR DIVISION
<input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		Position Name	DEPARTMENT/SECTION OR DIVISION
<p>Check appropriate box for presentation:</p> <input type="checkbox"/> <input checked="" type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>			
<p>Please list Dispositive Observations:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>			
<p>What is Required: Services:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>			
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<p>How is the Disposition Being Handled:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>			
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<p>Initials:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>			
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<p>Printed Signature:</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>		<p>Comments: Please type or print in the space below.</p> <p><input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/></p>	

Key elements of new inpt regulations – 2 methods

› 2midnight presumption

- “Under the 2 midnight presumption, inpt hospital claims with lengths of stay greater than 2 midnights after formal admission following the order will be presumed generally appropriate for Part A payment and will not be the focus of medical review efforts absent evidence of systematic gaming, abuse or delays in the provision of care.

Pg 50959

- **Benchmark of 2 midnights**
- "the decision to admit the beneficiary should be based on the cumulative time spent at the hospital beginning with the initial outpatient service. In other words, if the physician makes the decision to admit after the pt arrived at the hospital and began receiving services, he or she should consider the time already spent receiving those services in estimating the pt's total expected LOS."

Pg 50956

"Meeting Criteria" – means?

- ▶ It never has and never will mean – "meeting clinical guidelines" (Interqual or Milliman)
- ▶ It has always meant – the physician's documentation to support inpt level of care in the admit order or admit note.
- ▶ SO –if UR says: Pt does not meet Criteria – this means: Doctor cannot certify/attest to a medically appropriate 2 midnight stay – right?
- ▶ **11/1/2013 Section 3, E. Note:** "It is not necessary for a beneficiary to meet an inpatient "level of care" by screening tool, in order for Part A payment to be appropriate"
- ▶ Hint: 1st test: Can attest/certify estimated LOS of 2 midnights? THEN check clinical guidelines to help clarify any medical qualifiers... but the physician's order with ROA – trumps criteria.

RAC 2014

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More on decision making-Inpt

- ▶ If the beneficiary has already passed the 1 midnight as an outpt, the physician should consider the 2nd midnight benchmark met if he or she expects the beneficiary to require an additional midnight in the hospital. (MN must be documented and done)
- ▶ Note: presumption = 2 midnights AFTER obs. 1 midnight after 1 midnight OBS = at risk for inpt audit
- ▶ Pg 50946

..the judgment of the physician and the physician's order for inpt admission should be based on the expectation of care surpassing the 2 midnights with BOTH the expectation of time and the underlying need for medical care supported by complex medical factors such as history and comorbidities, the severity of signs and symptoms, current medical needs and the risk of an adverse event. Pg 50944

RAC 2014

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And the 'what if's'

- ▶ 412.3 (e) (2) (see p. 50965 of Final Rule) – "If an unforeseen circumstance, such as a beneficiary's death or transfer, results in a shorter beneficiary stay than the physician's expectation of at least 2 midnights, the patient may be considered to be appropriately treated on an inpatient basis, and hospital inpatient payment may be made under Medicare Part A." (Thx, Accretive)
- ▶ Can 1 day stay inpts still occur?
 - ▶ YES –but as the regs clearly state, anticipate an audit as it should be a highly uncommon occurrence.
 - ▶ 1 MN as outpt or OBS and 1 MN as inpt = inpt
 - ▶ Just because a patient dies, is transferred for tertiary care, or leaves AMA, (paraphrased from LCD L27548) it does not change the presentation of clinical factors/criteria that went into the physician's complex medical decision to admit to an inpatient status. (Thx, Appeals Masters)

RAC 2014

33

With unusual cases... Rare and unusual = ordered as a 1 day stay

- ▶ Lots of discussion on : "My patient is very sick, at risk but I don't think they will need 2 midnights. I checked with Interqual/UR and it meets their definition of an inpt. I am admitting and highly anticipate they will only need 1 midnight." (note, not an inpt/obs and monitor closely)
- ▶ **CMS has stated:** Rare and unusual. 2 outlined definitions at this time: inpt only surgeries and initiation of mechanical ventilator with 1 midnight. They are still working on how to address transfers out & hospice referral. NOTE: transferring in hospital must still meet their own 2 MN threshold. The transferring out hospital's LOS does not count. (RAC Summit/12-13)

RAC 2014

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More examples of coverage

CAH: must use the 2 MN presumption/benchmark PLUS certification to **reasonably expect** the pt to transfer or discharge within 96 hrs. If longer, re-do but should be unusual cases. (Watch HR 3991 /eliminate)

Delays: Weekends

If delayed due to convenience/systemic delays/weekends/late tests, do not count toward 2 MN threshold. If need to stay and not safe to discharge, AND need test that is being held until Monday, midnight counts.

BUT TELL THE STORY WELL.

Long obs: Pt in Obs for 2 midnights. 1st Q: did the pt have 48+ hrs of billable obs or just hrs in a bed?

2nd Q: Was the regulation for OBS met? (OBS is: Active physician involvement/ongoing assessment.)

If MET- then the pt was eligible to convert to INP after the first midnight with the physician 'attesting' of the need for medically appropriate care -2nd MN

<http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/IP-Certification-and-Order-09-05-13.pdf>
(WPS Excellent Audio 11-11-13)

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HFMA's HFM article 2-14 issue- 8 Critical Steps for 2 MN Compliance"

- 1) Embed questions from the optional certification form within the electronic orders or use the manual form.
- 2) Empower UR staff to assist with compliance
- 3) Know which procedures are riskiest, such as cath lab procedures and output surgeries that 'stay the night'.
- 4) Target physicians in the ED.
- 5) Hire internal physician advisors to assist with education.
- 6) Understand the implications for transfers
- 7) Use internal audits to identify problem areas
- 8) Learn from the probes and hammer the message home

RAC 2014

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Bad habits – Attack them

- ▶ After an uneventful, but late output invasive procedure, physician orders to **'stay the night'**. This is a FREE service as the pt has no medical reason to be in a bed. Time to discharge .
 - ▶ Liability risk for having a non billable pt in the hospital.
 - ▶ **Have the pt stay the night** and do the test in the am or Mon/wkd.
 - ▶ What is the clinical reason to 'stay the night?' If not an unplanned event leading to OBS, a FREE service.
 - ▶ Is there another clinical reason to be in a bed? Document it well with

At risk examples - output procedures

- Outpt surgery.
 - After routine recovery (up to 4-6 hrs), doctor orders the pt to 'stay the night.'
 - What did the doctor really want? Who is reviewing every 'pt in a bed' after the 4-6 hrs of RR? Why still in house?
 - Cath Lab
 - Doctor has routinely had the patient the pt stay overnight. Historically billed a 1 day inpt stay.
 - Explore options – inpt, outpt or obs.

BAG 2014

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More clarification information

Send questions directly to :
ippsadmissions@cms.hhs.gov.

- ▶ AHA's to CMS:
Sept 26th: "Statement on
Two Midnight Rule"
 - ▶ Included are Sept 18th
situations with
'assumptions.' Pending
 - ▶ **"CMS's long standing
guidance has been that
reviewers should evaluate
the physician's
expectations based on the
information available to the
admitting practitioner at the
time of admission."**
 - ▶ Fed Reg, 8-19-13 R&R
*"Impacts of change in
Admissions and Medical
Review Criteria"* (Chpt
100-04 pg 50592)
 - ▶ Due to estimated increase
of \$220M , reduced
payment of .02%. (CFOs
are very nervous they are
going to loose many inpts
rather than have the gain as
outlined by CMS in final
regs.)
 - ▶ PS OBS still does not count
toward 2 midnights/SNF

RAC 2014

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And more updates – Pt too

- ▶ Transmittal 1315, CR8508, Nov 15, 2013
- ▶ "Immediate suspension of Post Payment Pt Status reviews of inpt hospital admissions 10-1-13 thru 12-31-13."
- ▶ **RAC And SMRC -Can audit:**
 - ▶ Evidence of gaming
 - ▶ Other non pt status – coding, medical necessity of surgical cases, mandated therapy reviews)

- ▶ **EOB remarks/Patient**
- ▶ Denying Part A for an inpt admission subject to CMS ruling 1455-R:MSN 36.8

"Your inpt admission stay is denied. Since you didn't know Medicare would deny these services, you aren't responsible. Your provider may resubmit this claim under Part B. You may be responsible for coinsurance and deductible for covered services."
- ▶ Denying Part B claim subject to CMS ruling 1455-R. 36.9

"This claim for inpt services was originally denied by Medicare and resubmitted by your provider under Part B. You are responsible for any coinsurance and deductible for covered services."

RAC 2014

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'What Ifs' Not Addressed



- | | |
|------------------------|-------------------------|
| ▶ Services unavailable | Consultants unavailable |
| ▶ Weekends & Holidays | Equipment down |
| ▶ Patient safety | Patient & family issue |

(Thanks, Dr Salvador, DE hospital & PA/UR bootcamp faculty)

RAC 2014

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WINS with the 2 midnight rule– Don't be afraid of your inpt...

- ▶ Certification form – always. Consistently start and clarify the pt story.
- ▶ UR in the ER – always involved prior to placement.
- ▶ Hospitalist – always see the pt rapidly/less than 2 hrs from referral to inpt.
- ▶ Integrated CDI program – one ongoing audit, one voice for ed
- ▶ Dedicated beds for OBS.

OBS hasn't changed at all. UR assigned to closely monitor every OBS that exceeds the first midnight.
- ▶ Grow an internal physician advisor—NOW! Ongoing education, UR support/intervention = effective change
- ▶ Actively involve nursing as the eyes of the pt story 24/7.
- ▶ Actively involve surgery scheduling to 'spot' any common outpt surgeries being scheduled as inpt.
- ▶ Beef up the UR committee
- ▶ Beef up the UR's role, separate from case mgt. Front end...

RAC 2014

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And the final 'wow' message– AUDIT OVERLOAD

- Palmetto /MAC just denied heart failure/shock and spinal fusion. (DRG 391/Esophagitis, DRG 191 – COPD with CC.)
- 4th RAC Medicaid ADR cycle – 25 records
- MAC – probe for DRG 290, 640, 641, 690, 688 –stroke case mix group.
- MD RAC denials for automated 'hits'
- PERM request
- Increase with RAC automated and semi-automated denials – first activity in over a yr- over 200+ accts denied
- RAC Prepayment – OT, PT, ST , Therapy cap thresholds
- First RAC post payment ADR in over a year – 272 records
 - Drugs and biological – billed in multiple of dosages specified
 - J9171-billing 1 unit for every 1 mg/pt
 - Elective surgery
 - Minor surgery procedures and other treatment. (HUGE) (Thx, Jordan, NC 8-13)

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AR Systems' Contact Info

Day Egusquiza, President
AR Systems, Inc
Box 2521
Twin Falls, Id 83303
208 423 9036
daylee1@mindspring.com



Thanks for joining us!
Free info line available.
Plus our training website COMING SOON!

JOIN US FOR UR/PA Bootcamp in Chicago
July 14-16 2014

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Value Added

More implementation ideas
Plus MAC audit hot topics

RAC 2014

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More MAC audits

- ▶ Noridian/J3 has announced Probe audits for AZ, MT, ND, SD, UT, WY
 - ▶ Probe for 1 day stays, 2 day stays, 3 day stays and high dollar (w/o definition of \$) CAH=3 day SNF /2013
 - ▶ Prepayment auditing/2012: DRG 389, 313, 512, 191, 545, 517, 243, 244, 227, 607, 445, 242, 921, 310, 23, 670 /?%
 - ▶ A/B auditing: doctor and hospital claims audited (Kyroplasty)—Cert audits
 - ▶ WPS released a CERT review of Epidural Steroid Injections w/large error rate. (1 /31) (LCD30481). Prepayment 310, 313, 192, 690

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And more MAC auditing

- ▶ **Highmark (Now Novitas Solutions)**
 - Probe for DRG 470/Major Joint Replacement or reattachment of lower extremity w/MCC. Need to document end stage joint disease & failed conservative therapy. (EX: Trailblazer Transmittal ID 14362/LCD)
 - Probe for DRG 244 Permanent Cardiac Pacemaker implant w/o CC or MCC.
 - NEW: 313, 392, 292 (2012)
 - **Msg from provider:** Have been having 100% prepayment audit payment for DRG 313/chest pain for almost 2 years now. The site indicates they are being successful around 90% of time at the 3rd level appeal/AJ but it is taking about 18 months. There does not appear to be a change with the pre-payment review even with the overturn rate. (per PA facility history 9-11)

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MACs are beefing up prepayment auditing -with physician impact

- **Trailblazer/Novitas**: to increase consistency in Medicare reimbursement, effective 11-11, Trailblazer will begin cross-claim review of these services. The related Part B service (E&M, procedures) reported to Medicare will be evaluated for reimbursement on a post payment basis. Overpayments will be requested for services related to the inpt stay that are found to be in error.
 - **First Coast & HighMark/Novitas**– similar 3-12 TX hospital lost 470; provider recouped

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Keys to avoid the DRG 470 Pre-Payment Anguish

NJ Hospital: We have had prepayment denials from Novitas (Highmark) in addition to our RAC denials. For the Prepayment Denials, we send appeal with additional information from the doctor's office notes. They are looking for 4 key elements:

- Level of Pain and Effect on ADLs
- Response to Treatment with Medications: NSAIDS and Injections
- Response to Treatment with other modalities: Assist Devices, Braces and PT
- X Ray Findings

In the past, it was ok to just say "did not respond to conservative treatment".

Now they want details documented.

NOTE: Med Learn SE1236 Documenting to support medically necessity of DRG 470

American Association of Hip & Knee Surgeons/AAHKS, June 2012 publication. Created a check list to assist surgeons with the required documentation elements.

Suggestions: Surgery scheduling joins the UR prevention team. Education on new checklist requirement in the medical record /Surgical H&P. Validate it is present prior to procedure. UR works with the Surgeon; surgery works with the surgeon. Alternative idea: Include the physician's notes with the Hospitals. Alert: Many HIM depts would not submit these as they may not be identified as part of the legal medical record. Also some state limitations. Explore HIPAA privacy issues for non-hospital records for treatment, payment or operations.

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More MAC auditing

► **Palmetto, Pre Payment Auditing**

► **Began early 2012** (Site: CA site. Prior to Feb, 2012 – never had a pre-payment audit request. Had 12 in 1st request.)

► DRGs focus:

- 871 Septicemia/Sepsis
- 641 Misc disorders of nutrition
- 690 Kidney / UTI
- 470 Joint replacement
- Probe 227/inpt implant with defib w/o cath or CC or MCC. Aver \$ 42,298. Rebill – ancillary only (11-12)

J15/CGS: DRG 308-310, post payment Cardiac Arrhythmia audit (KY and Ohio). 123 claims, 55 denied. Due to 'moderate error rate of 36.4%, continued complex auditing will occur.

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And more MAC – AL hospital

Cahaba – Pre-Auditing of the below DRGs. (2-12)

- 069 (Transient Ischemia)
- 191 (Chronic Obstructive Pulmonary Disease w CC)
- 195 (Simple Pneumonia & Pleurisy w/o CC/MCC)
- 247 (Percutaneous Cardiovascular Procedure w Drug-Eluting Stent w/o MCC)
- 287 (Circulatory Disorders Except AMI, w Cardiac Cath w/o MCC)
- 313 (Chest Pain)
- 392 (Esophagitis, Gastroenteritis & Misc Digestive Disorders /o MCC)
- 552 (Medical Back Problems w/o MCC)
- 641 (Nutritional & Misc Metabolic Disorders w/o MCC)
- 945 (Rehabilitation w CC/MCC)
- 470 (Joint replacement)

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Sample letter communication

- ▶ Dear pt
 - ▶ As part of ABC hospital's commitment to compliance, we are continuously auditing to ensure accuracy and adherence to the Medicare regulations.
 - ▶ On (date), Medicare and ABC hospital had a dispute regarding your (type of service). Medicare has determined to take back the payment and therefore, we will be refunding your payment of \$ (or indicate if the supplemental insurance will be refunded.)
 - ▶ If you have any questions, please call our Medicare specialist, Susan Jones, at 1 -800-happy hospital. We apologize for any confusion this may have caused.
 - ▶ Thank you for allowing ABC hospital to serve your health care needs.

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Additional Documentation Request “Sample”

- HDI and CGI have started sending their 'New Issue Validation' sample letters.
 - Statement of Work allows sampling of up to 10 claims (in addition the 45 day limit) to prove a vulnerability with a new issue. Results will be issued on the findings with data submitted to the New Issue Board/CMS.
 - HOT: Share what was requested so potential new items are known; preventive work.
 - EX) Readmission within 30 days for AMS.

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CMS series w/ MedLearn

www.cms.gov/RAC

- ▶ SE1024 “RAC: High Risk Vulnerabilities – No documentation or insufficient documentation submitted” (July 2010)
 - ▶ Two areas of high risk were identified from the demonstration project:
 - No reply to request/timely submission (1 additional attempt must be made prior to denial)
 - Incomplete or insufficient documentation to support billable services

B10-0014

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Additional CMS/MedLearn Training

- ▶ SE1024/July submitted No documentation or insufficient documentation
- ▶ SE1027/Sept Medical necessity vulnerabilities for inpt hospitals
- ▶ SE1028/Sept DRG coding vulnerabilities for inpt hospitals
- ▶ SE1036/Dec Physician RAC vulnerabilities
- ▶ SE1037 /Jan 11 Guidance on Hospital Inpt Admission (referencing CMS guidelines, does not mandate Interqual/Milliman, RAC judgment allowed)
- ▶ SE1104/Mar 11 Correct Coding POS/Physicians
- ▶ Special Edition #SE1121/June 11 RAC DRG Vulnerabilities -coding w/o D/C summary
- ▶ SE1210/Mar 12 RAC with MN of Renal & Urinary Tract Disorders
- ▶ SE1236/Sept 12 Documenting Medical Necessity of Major Joint Replacement (hip and knee) DRG 470

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Powerful transmittal

- ▶ Transmittal 47, Interpretive Guidelines for Hospitals June 5, 2009
www.cms.hhs.gov/transmittals/downloads/R47SOMA.pdf
- ▶ "All entries in the medical record must be complete. Defined by: sufficient info to identify the pt; support the dx/condition; justify the care, treatment, and services; document the course and results of care, treatment and services and promote continuity of care among providers.
- ▶ "All entries must be dated, timed and authenticated, in written or electronic format, by the person responsible for providing or evaluating the service provided."
- ▶ "All entries must be legible. Orders, progress notes, nursing notes, or other entries (Also CMS covers in SE1024 MedLearn release)

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Outline of Internal Challenges

- ▶ **Common issues:**
 - Dept leadership not understanding the ownership of accuracy of orders to charges to billed.
 - Fix: Daily charge reconciliation- scheduled against completed.
 - MEU: 2 initial first hrs of hydration. Could happen, but rare. FIX: ER to OBS. ER is completing their drug adm charge ticket and OBS does theirs. They do not 'see' the others so duplication or errors in hierarchy occur.
 - Identify a charge capture analyst for all drug adm. At the conclusion of OBS, 1 ticket, 1 touch, 1 correct charge. Documentation variances identified.

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More common internal challenges

- #### ► DRG validation

- Budget cuts resulted in less coder validation audits. Education thru audit was lost or greatly reduced.
 - Physician querying for clarity delays submission of claims and cash flow
 - MedLearn/RAC findings indicated that DRG changes (up and downward) were the result of records final coded without discharge summaries. Challenging as to wait for the d/c summary = significant cash delays. Common practice - code with queries for clarity. (Special Edition #SE1121/June 11 RAC DRG Vulnerabilities -coding w/o D/C summary)
 - Safety net - audits to review DRG changes from D/C summary. Track by provider with a hx of 'surprises'.

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Concurrent auditing of 2nd opinions for pt status

- ▶ Ensure the attending/provider directing care receiving the 2nd opinion carries the recommendation into the record and directs care from the recommendation
 - ▶ Auditing of the primary provider's documentation should include: Clearly outlining the severity of illness in the admit note/order PLUS nursing documenting to the Intensity of services that must be done as an inpt.
 - ▶ Nursing is usually unaware of the status they are documenting.

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Change the Inpt surgery process

- Surgery director and surgery scheduler join the preventive team.
 - UR reviews all inpt surgeries prior to surgery. Reviews the H&P, discusses how well the surgeon has tied in the risk to the reason for a normal outpt to be done as an inpt.
 - Works with provider and Surgery to potentially revise to an outpt, wait for the adverse/unexpected event and move to obs or inpt or improve the inpt documentation.
 - Involved nursing in the education as they will be the bedside eyes of the pt status.

status
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Payment recoupment impact

June 26, 2009/CMS Website

- CMS reversed earlier decision to AUTO recoupment SNF payment if the hospital is denied/recouped its 3 day qualifying stay.
- If the hospital is recouped for any activity, Part B/physician will be evaluated, but not auto recouped.
- Will look but not auto recoup in both.

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Working together to reduce risk and improve the pt's story

- Joint audits. Physicians and providers audit the inpt, OBS and 3 day SNF qualifying stay to learn together.
- Education on Pt Status. Focus on the ER to address the majority of the after hours 'problem' admits.
- Identify physician champions. Patterns can be identified with education to help prevent repeat problems.
- Create CPOE to assist with completeness of order – Inpt, OBS, with protocol – with reason for decision.

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SAMPLE FOR CERTIFICATION FORM – use obs and inpt to fix both

Affix Chart Sticker

USE FOR ALL PAYERS – EVERY TIME, EVERY TIME

USE THIS SIDE FOR MEDICARE ONLY

Date/ Time	Patient Status	INPATIENT ADMISSION CERTIFICATION/MEDICARE ONLY
Date of Service:		<u>Must be completed by provider for Inpatient Admissions</u>
Check appropriate box for patient status:		<p>This patient is admitted for inpatient services. The patient is medically appropriate and meets medical necessity for inpatient admission in accordance with CMS section 42 C.F.R §412.3. I reasonably expect the patient will require inpatient services that span a period of time over two midnights. My rationale for determining that inpatient admission is necessary is noted in the section below. Additional documentation will be found in progress notes and admission history and physical.</p>
<input type="checkbox"/> Place in Outpatient Observation Diagnosis: _____ Reason for Placement: _____		Primary Diagnosis: _____ Expected Length of Stay: (MEDICARE ONLY) Select One: <input type="checkbox"/> 2 Midnights (MN) Inpatient <input type="checkbox"/> 1 MN Outpatient (ER , recovery or Obs) and 1MN Inpatient
<input type="checkbox"/> Admit to Inpatient Services (Medical) <i>PROVIDER MUST COMPLETE CERTIFICATION</i> Diagnosis: _____ Reason for Admission: _____		For Initial Certification (CAH only) <input type="checkbox"/> I Expect the Length of Stay to Not Exceed 96 hrs For Re-Certification <input type="checkbox"/> The Length of Stay is Exceeding 96 hrs Plans for Post-Hospital Care: See Discharge plan/signed prior to discharge
Attending Provider (Print Name) (Note: if the ER provider does not have ‘admitting privileges, only transitional privileges”, important that this include a statement: Spoke with the admitting/attending_____, and we concur with the admission status.” ER provider signs.		Supportive Findings to Primary Diagnosis: [examples: co-morbidities, abnormal findings, diagnostic abnormalities, exacerbations, new onset of disease with_____ (co-morbidities)] _____ _____ _____ _____ _____ _____
PCP (Print Name) PCP (Print Name) Provider Signature		
Provider Signature Date/Time		Certifying Provider Signature (this 2nd signature required for inpatient admissions as the provider who is directing care.) Date/Time

**SAMPLE FOR
CERTIFICATION FORM – use
obs and inpt to fix both**

Affix Chart Sticker

USE FOR ALL PAYERS – EVERY TIME, EVERY TIME

USE THIS SIDE FOR MEDICARE ONLY

2014 HCCA Compliance Institute
San Diego California
Monday, March 31, 2014 1:30 – 2:30

Session 210
Stark, Anti-Kickback and
Information Technology:
Considerations for the Compliance
Professional

Jim Donaldson

2014 COMPLIANCE INSTITUTE

BAPTIST HEALTH CARE

Jim Donaldson, M.S., MPA, CHC, CIPP/US, CISSP

Director of Compliance, Chief Privacy and
Information Security Officer
Baptist Health Care Corporation
Pensacola, Florida

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BAPTIST HEALTH CARE

Baptist Health Care Corporation

Not-For-Profit Integrated Delivery System
Headquartered in Pensacola, Florida

6671 Employees

Four Hospitals

150+ Employed Providers

Lakeview Center Inc.
Large Behavioral Health Network

Presence in 12 States

Multiple State and Federal Contracts

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Session Goals

- Gain an appreciation and awareness for the growing complexity of Information Technology
- Consider situations involving potential hospital/provider technology related compliance issues.

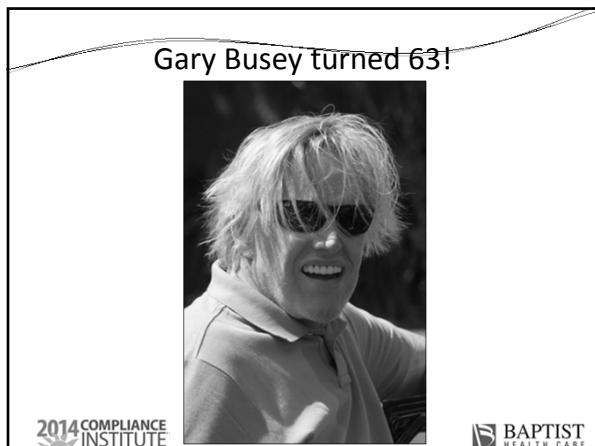
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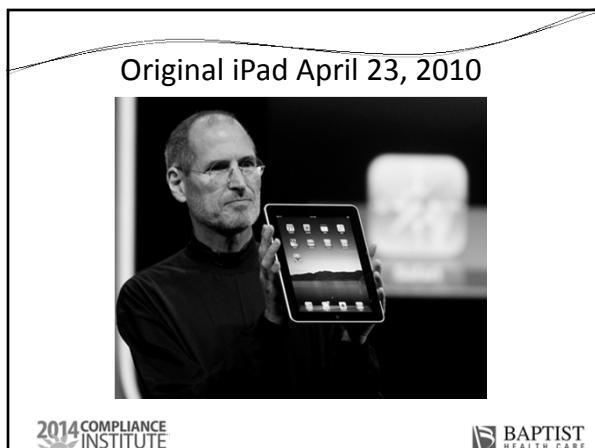
What World Changing Event Occurred on June 29, 2007?

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Remuneration

"Any payment or other benefit made directly or indirectly, overtly or covertly in cash or in kind"



HIPAA Anti-Kickback Statute False Claims Act Stark



HIPAA

Health Insurance Portability and Accountability Act

- Privacy Rule
- Security Rule
- Breach Notification Rule
- Omnibus HIPAA Rule



HIPAA

Business Associate (BA)

- Person who ..on behalf of a covered entity...creates, receives, maintains, or transmits Protected Health Information (PHI)
- A subcontractor that creates, receives, maintains or transmits PHI on behalf of a BA
- Covered Entity may be a BA of another CE
- The Affordable Care Act made BA's subject to parts of HIPAA

HIPAA

Conduit Exception/Requires Access
See: FR Vol. 78 No. 17, January 25, 2013 page 5571

- BA includes Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to PHI to a CE and that "requires access on a routine basis" to such PHI

HIPAA

Conduit Exception

- "Access on a routine basis" is fact specific and based on the nature of the services provided and extent to which the entity needs access to the PHI
- Conduit exception is narrow and intended to exclude only those entities providing mere courier services such as the USPS, FedEx, UPS, and their electronic equivalents

HIPAA

Conduit Exception

- A conduit transports information but does not access it other than on a random or infrequent basis to perform the transmission service or as required by law
- Internet Service Provider – would not routinely access the data for which it facilitates the transfer

HIPAA

Conduit Exception

- Examples of possible BA situations involving data:
 - Cloud based services, Gmail, Box, Skype
 - EHR vendors, and support
- A hospital could easily become a BA of another CE if it provided any services that “creates, receives, maintains, or transmits PHI on behalf of the CE”

Anti-Kickback Statute

AKS

- Criminal Statute – prohibits offering, paying, soliciting or receiving anything of value to induce or reward referrals or generate Federal health care business
- Referrals for any services from anyone
- Requires intent – must be knowing and wilful
- Penalties -\$25,000/5 years per violation
- Program exclusion

False Claims Act (FCA)

"Lincoln Law"

- Imposes civil liability on persons and companies who defraud government programs
- Primary tool in combating fraud against USA
- \$35B Recovered as of 2012
- Allows persons not affiliated with the government to sue on behalf of the people (Qui tam)
- Whistleblower may receive up to 25% of settlement
- Among other elements, prohibits "knowingly making a false record or statement material to a false claim"
- \$15K/service + 3 times assessment of amount claimed

Anti-Kickback and False Claims

The Affordable Care Act (ACA) changed the language of the AKS to provide that claims submitted in violation of the AKS are by default False Claims under the FCA.

ACA further modified AKS in such a way that criminal liability is present if the defendant intended to violate the law regardless of specific knowledge of AKS.

Stark Law

Physician Self-Referral Law

- 1989 to 1992 – Stark I – Financial and referral relationships between clinical labs and physicians
- 1993 to 2008 – Stark II – referral restrictions expanded to several types of 'Designated Health Services (DHS)'

Stark Law

Physician Self-Referral Law

- Under Stark, a physician may not make a Medicare/Caid-covered referral for a DHS to an entity with which the physician or immediate family member has a financial relationship.
- Financial Relationship:
 - Direct or indirect ownership or investment
 - Direct or indirect compensation arrangement
- Prohibits DHS from submitting Medicare claims for those services resulting from a tainted referral.



Stark Law

Physician Self-Referral Law

- No intent standard for overpayment – overpayment/refund obligation (strict liability)
- Intent required for Civil Monetary Penalties (CMP)
- Civil Penalties:
 - Overpayment/refund
 - Knowing violations
 - Program Exclusion
 - Up to \$15,000 CMP for each tainted service
 - Civil assessment up to 3x the amount claimed



Stark Exceptions

Non-monetary compensation limit

§411.357(k)

- No cash, or cash equivalent items or services that don't aggregate to more than \$385 (2014)
- Doesn't take into account Volume or Value of Referrals or Other Business (VOVO-ROB)
- Not solicited by physician or staff
- Doesn't violate AKS or other laws
- Excludes one local appreciation event per year for medical staff



Stark Exceptions

Medical staff incidental benefit

(§411.357(m))

- Available to all members of medical staff in the same specialty without regard to (VOVO-ROB)
- Provided only while physician is making rounds or engaged in activities that benefit hospital or patients
- Used only on hospital campus except Internet, pagers, radios, etc. used OFF campus to access information or contact patients/staff who are on campus
- Presence in hospital website or hospital advertising meets on-site requirement
- Limited to \$32 per occurrence as of 2014 (meal)



Stark Exceptions

Fair Market Compensation

(§411.357(l))

- Agreement between entity and physician meeting:
 - In writing, signed by parties, identifies all items and services
 - Meets timeframe requirements
 - Sets compensation in advance at FMV without regard to value of referrals or other business generated and revenue/per unit test
 - Commercially reasonable
 - Doesn't violate AKS or other laws



Stark Exceptions

Compliance Training

(§411.357(o))

- Practices in local community or service area
- Conducted in local community or service area
- Related to compliance programs, federal and state regulations covering conduct of party, billing, program requirements, etc.
- Basic HIPAA training would fit this exception – HOWEVER there is a fine line between compliance training and consulting



Technology Related Guidance and Advisory Opinions

- OIG AO 12-20 Electronic Interfaces
- OIG AO 11-12 Neuro Telemedicine Technology
- OIG July 1, 1997 Advice Letter
- OIG July 1991 Discount Safe Harbor Preamble

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July 29, 1991 Preamble to the Discount Safe Harbor

A related issue is the practice of giving away free computers. In some cases the computer can only be used as part of a particular service that is being provided, for example, printing out the results of laboratory tests. In this situation, it appears that the computer has no independent value apart from the service that is being provided and that the purpose of the free computer is not to induce an act prohibited by the statute. Rather, the computer is part of a package of services provided at a price that can be accurately reported to the programs. In contrast, sometimes the computer that is given away is a regular personal computer, which the physician is free to use for a variety of purposes in addition to receiving test results. In that situation the computer has a definite value to the physician, and, depending on the circumstances, may well constitute an illegal inducement.

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Electronic Health Record (EHR) Safe Harbor and Exception October 2006 – December 2013

EHR Anti-Kickback Safe Harbor (OIG)
EHR Stark Exception (CMS)

- Protect non-monetary donations of items and services in the form of software or information technology related to EHRs
- Sunsets December 31, 2021

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**Electronic Health Record (EHR)
Safe Harbor and Exception**

- Donors are allowed to provide EHR technology and supporting services to recipients (new rule eliminates laboratories from approved donor list and removes e-prescribing as a required functionality of the donated EHR)
- Does not include hardware but maintenance, support, training, etc. can extend through the life of the exceptions
- Recipient must pay 15% of donor's actual cost PRIOR to the donation. Donor can't loan or finance the %15
- All the standard Stark contract stuff still applies, in writing, signed by both parties, etc.
- Can't condition donations on referrals - criteria a donor can use to determine which recipients they extend the offer to - medical staff, amount of uncompensated care for example.

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**Electronic Health Record (EHR)
Safe Harbor and Exception**

- Can't electronically lock-in referrals, labs, etc. - recipient is free to use the EHR as they see fit
- Doesn't require the donor to offer any EHR the recipient may want - "Sorry doc, you only get one model."
- Doesn't apply if recipient already has been provided similar services/EHR
- Interfaces in/out of donors other systems are covered
- Donated EHR must be "interoperable" / ONC EHR "Certified Technology" approval within 12 months of donation meets the interoperable requirement.
- Non-physician behavioral health practitioners may qualify as recipients

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**Electronic Health Record (EHR)
Safe Harbor and Exception**

EHR software must be 'interoperable'

- **interoperable** means ``able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.''

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 BAPTIST
HEALTH CARE

Electronic Health Record (EHR)
Safe Harbor and Exception
EHR software must be 'interoperable'

- 2013 modification aligned safe harbor/exception with EHR Incentive Program
- Software certified through ONC programs is considered 'interoperable'



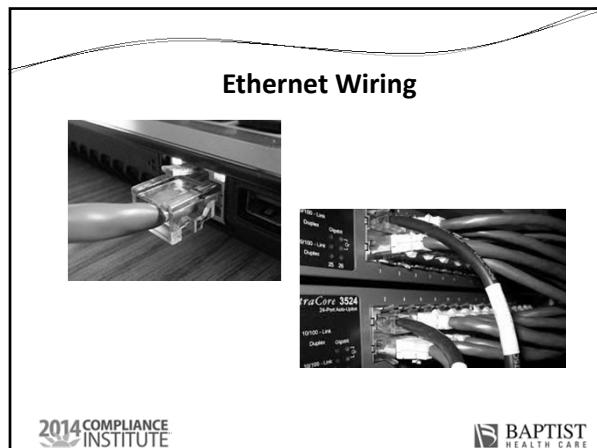
CMS and OIG
Cautioned

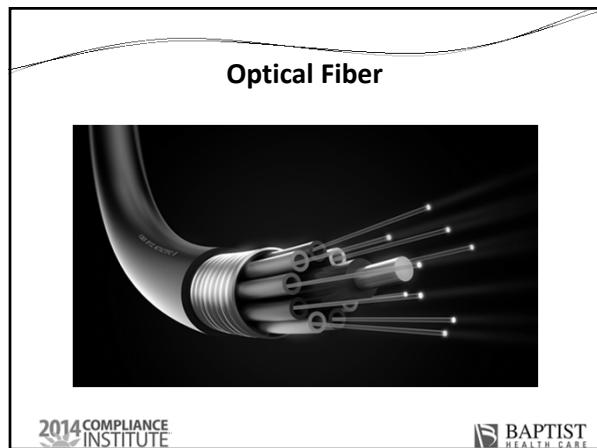
We caution, however, that outside of the context of electronic health records, as specifically addressed in this final rule, both direct and indirect correlations between the provision of free or deeply discounted goods or services and the volume or value of referrals or other business generated between the parties are highly suspect under the AKS (and may evidence outright violations) and do not meet the requirements of other safe harbors under the statute.

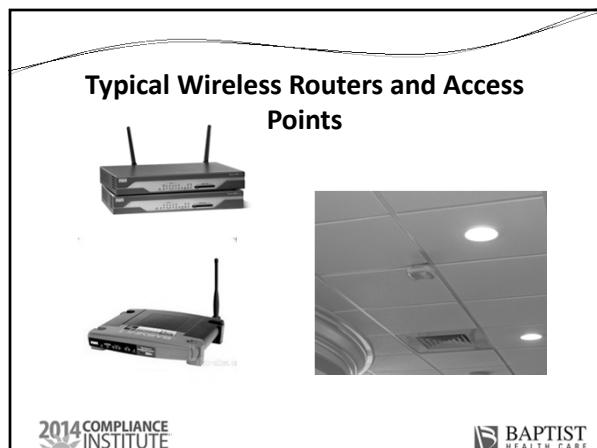


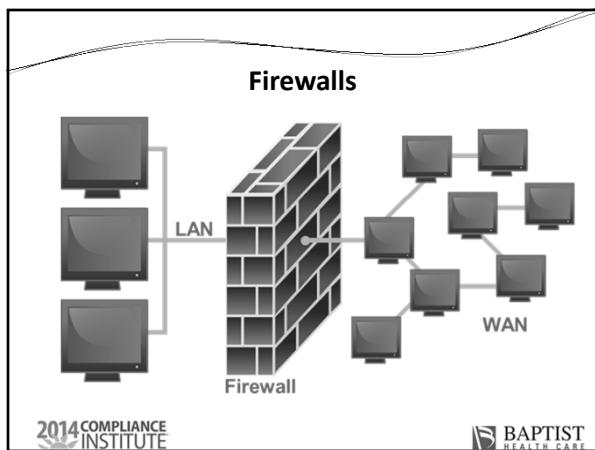
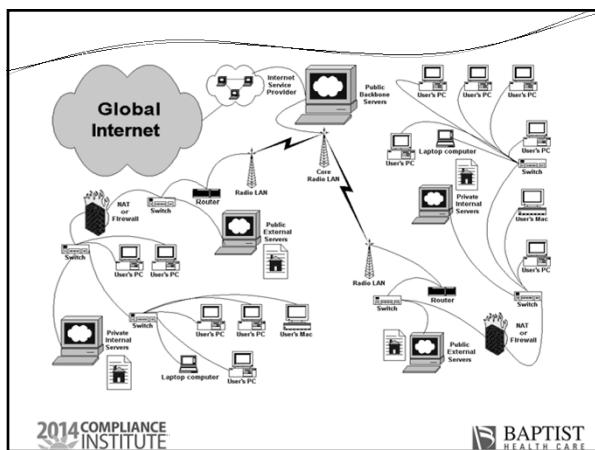
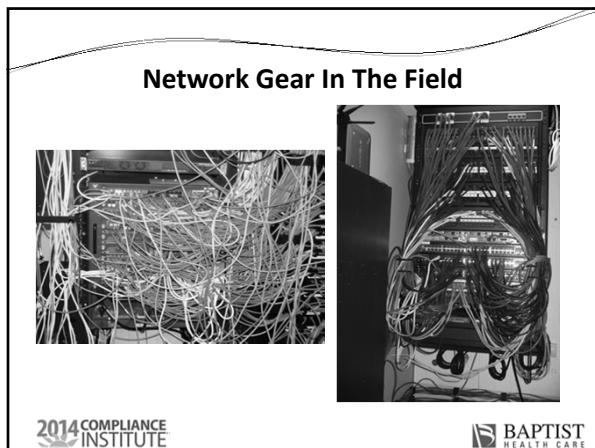
**Examples of
Technology
to
Consider**

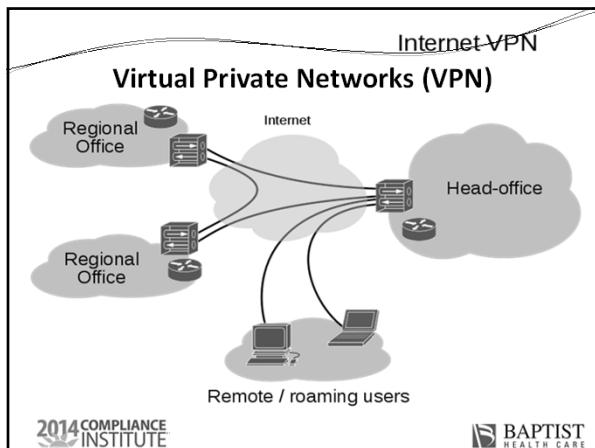


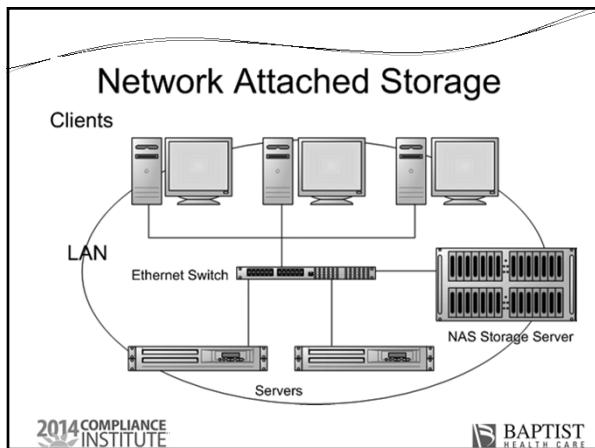


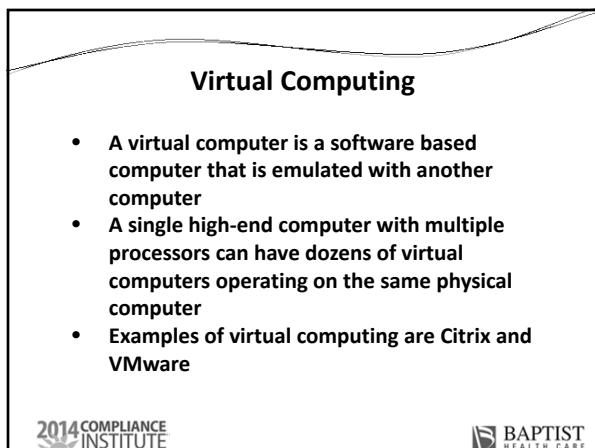












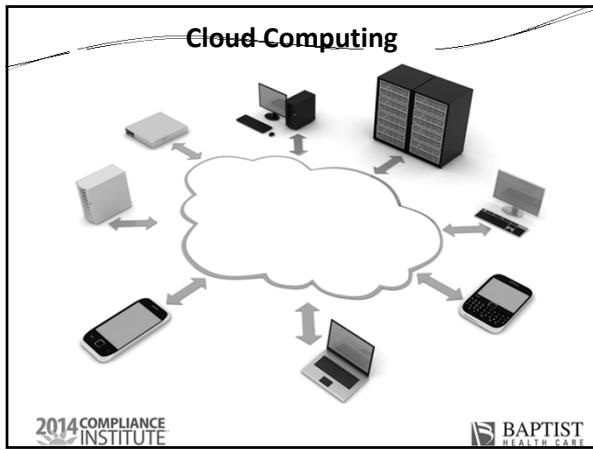
A screenshot of a virtual desktop environment. On the left, a window titled "Virtual Computing" shows the Windows 7 desktop. On the right, another window titled "Windows 7" also shows the Windows 7 desktop. Both windows have standard taskbar icons at the bottom.

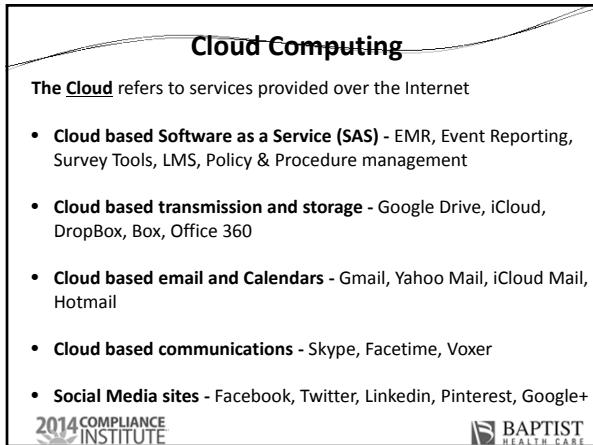
Encryption

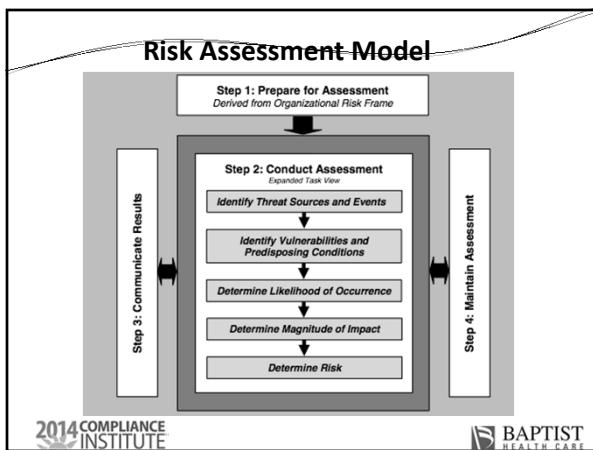
- Process of encoding information in a way that makes it usable only by authorized parties or systems.
- HIPAA requires transmission and data at rest encryption when appropriate.
- Password protecting a file or having a password on your computer is not encryption.

HIPAA and Encryption

- Protected Health Information is unusable, unreadable or indecipherable to unauthorized individuals when it destroyed or encrypted in accordance with NIST standards.
- See NIST Special Pub 800-111 Guide to Storage Encryption Technologies for End User Devices
- Encryption must meet Federal Information Processing Standard (FIPS) 140-2 requirements







Scenario 1

Independent physician asks hospital administrator to have software installed on facility computer to allow for remote access to her office based EMR.



Scenario 2

Independent physician group leasing office space in hospital owned MOB asks to connect the practice computer network to hospital's network to facilitate redundant Internet connection.



Scenario 3

Office administrator at independent physician group utilizing hospital portal asks hospital technician to look at a printing problem his staff are having while printing from the practice's EMR.



Scenario 4

Contracted medical director of service line asks to have hospital's corporate email application installed on his personal smartphone to facilitate communication with facility leadership and staff on matters pertaining to service line management.



Scenario 5

To improve physician satisfaction, a hospital administrator directs his CIO to purchase iPads for members of an independent surgery practice to use while documenting in the hospitals EMR.

What recommendations should the compliance officer make to ensure the plan stays legal?



Scenario 6

A small physician practice needs help with properly implementing a new EHR that was purchased to meet meaningful use requirements and asks the hospital's compliance officer to help validate data that will be used for attestation.

How much assistance can the hospital provide the practice?



OIG 2014 Work Plan

Questions?

2014 HCCA Compliance Institute

San Diego California
Monday, March 31, 2014 1:30 – 2:30

Session 210

Stark, Anti-Kickback and Information Technology: Considerations for the Compliance Professional

Is Your Compliance Program Effective or Merely Window Dressing?

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Setting precedent.

- Window Dressing – A showy misrepresentation intended to conceal something unpleasant, synonymous with façade.
- Does the above definition describe your organization's compliance efforts?
- Could you testify under oath regarding your organization's efforts and compliance program?
- Leading practices to avoid or mitigate enforcement actions
- Competing perspectives of compliance
- The practical realities of an enforcement action

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ACA Compliance Mandate

- ACA requires, as a condition of participation, providers and suppliers to establish and maintain satisfactory compliance programs
- Secretary of HHS to determine timeline and required compliance program elements for specific types of providers and suppliers
- Implementation date still to be determined

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CIAS AND SETTLEMENTS

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Example of No CIA

- Diagnostic Labs offered referral sources low rates for Part A/HMO federal business in exchange for exclusive deals for all Part B business
 - Discounts alleged to be over 70%
- Complaint alleged lab wrote off in kick-backs to skilled nursing facilities
 - Over \$10,000,000 each year
- \$17.5 million settlement
 - No CIA

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Example of CIA

- Ambulance granted discounts as inducement for a facility's referral
 - Lucrative Medicare discharge transports
- Ambulance did "favors" for potential referring facilities and nurses
 - Wine, CPR classes, transports, VCRs, gift certificates, movie tickets
- Compliance officer advised president on illegality of policy
 - Rejected and become whistleblower
- \$3 million settlement
 - CIA

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Factors Resulting in CIAs

- Scope of allegations
 - Amount of damages
- Nature of allegations
 - Failure of care vs. billing
- Provider type
 - Large providers/companies may already have compliance function
- Repeat offenders
- Poor tone at the top/lack of compliance programs
- Reputation of provider

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CIA Trends

- Executive leadership, management, and board attestations/certifications
- Disgorgement of compensation for bad actors
- Supplemental documentation requests
- Multi-issue CIAs
- Quality of care CIAs
- Arrangement reviews

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WHAT DOES COMPLIANCE WINDOW DRESSING LOOK LIKE?

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Hallmarks of Window Dressing

- Insulated from executive management
- Ineffective reporting structures
- Understaffed and underfunded
- Vetting or “cleansing” compliance reports to leadership and to board
- Structured so everyone else is a VP
- Disconnect between leadership and compliance regarding the organization's risks

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Window Dressing, cont.

- Lack of monitoring activities
- Do not repay overpayments
- Limited use of data analytics
- Focus almost entirely on code of conduct, HIPAA, and hotline
- Lack of risk assessments
- Limited risk specific training in operational areas

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Window Dressing, cont.

- This leads to compliance programs that:
 - Are led by marginalized compliance officers
 - Spend more time with politics than compliance issues
 - Insulated from important risk areas
 - Not involved in revenue improvement activities
 - Not aware of consulting and outside counsel activities
 - Have little understanding of systematic compliance risks across the organization

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Window Dressing, cont.

- Most importantly such programs:
 - Cannot deter, detect, prevent meaningful fraud, waste, and abuse
 - Do not obtain benefits if subject to enforcement action

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Window Dressing, cont.

- Other characteristics:
 - Lack of common understanding regarding compliance risks and their potential impact
 - Lack of common terminology
 - Lack of education regarding the impact of potential fines (Stark, Anti-kickback, False Claims Act, HIPAA), including reputational risk and impact to the organization's fund raising efforts
 - Misunderstanding of operational risk, compliance risk, enterprise risk, etc.
 - Competing priorities result in a limited focus on compliance risks

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COMPLIANCE PROGRAM EFFECTIVENESS

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Compliance Effectiveness

- Can personnel describe compliance program?
 - How about key executives?
- Are historical audits and assessments available for inspection or comparison?
 - Are reviews done at regular intervals or only complaint-driven?
- Do you trend high-risk areas and/or require corrective action?
 - Or does corrective action = evidence of wrongdoing?
- Is the hotline used for more than HR issues?
 - Is there a log of all calls and inquiries of compliance office with documented responses?

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Effectiveness, cont.

- Has the program evolved with the organization?
 - Or is there dust on the compliance binder?
- Is there a culture of responsibility and accountability?
 - Or are “some more equal than others?”
- Is the compliance team free to raise concerns?
 - Or has the board asked who is the compliance officer?
- Is there a commitment to compliance?
 - Or is the budget less than optimal and the team housed in a offsite basement?
- Can you convince the government of any of above?
 - Could be difference between repayment v. civil penalties v. criminal charges?

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Effectiveness, cont.

- Follow attainable policies/protocols
- Create well-documented, standardized program
- Require physician disclosures
- Ensure course of dealing does not alter contract purpose/provisions
- Update policies and codes of conduct
- Prioritize compliance functions based on risk

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Effectiveness, cont.

- Consider also:
 - Using data analytics to identify organizational profile
 - Analyzing why and when reopening v. repayment v. disclosure
 - Reviewing Part C and D compliance assessment tool
 - Adopting New York's compliance assessment tool
 - Implementing three lines of defense

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Effectiveness, cont.

"The Third Line"
Independent Compliance Oversight
and Internal Audit will provide
independent oversight and monitoring.



"The Second Line"
Compliance will provide compliance
management, framework and policies.



"The First Line"
Management is accountable for identification
of risks, internal controls, and compliance
activities and monitoring in order to be
compliant with laws and regulations.



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Effectiveness, cont.

- Read AND understand:
 - Advisory opinions
 - Compliance program guidance
 - Work plans/audits
 - Settlement/integrity agreements
 - Press releases
 - GAO reports
 - Comments/preambles to safe harbors/exceptions
 - Blogs/alerts

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PRACTICAL REALITIES OF ENFORCEMENT

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attorneys

Practical Realities of Enforcement

- Indictment/information and conviction
 - Public allegations and trial
 - All questionable past statements/actions raised
 - Billed, not paid, amount drives loss
 - Special enhancements for fraud
 - “Relevant conduct” increases sentence/fine
 - Automatic exclusion/debarment
 - Collateral estoppel under FCA
 - State and private liability

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Realities, cont.

- Civil action and fraud judgment
 - Mandatory trebling/penalties
 - Most evidence admissible
 - To avoid self-incrimination = increase risk/liability
 - State and private liability
 - Agencies usually seek permissive exclusion/debarment
 - Administrative proceedings and adverse finding
 - Multiple programs/agencies
 - Rules of evidence not applicable
 - Negative impact on civil/criminal case

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Questions

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ken.zeko@navigant.com

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Selling prudent.



Updates on the Latest Program Integrity Auditor Targets and Activity

Ralph Wuebker, MD, MBA
Chief Medical Officer
Executive Health Resources

Steven A. Greenspan, JD, LLM
Vice President of Regulatory Affairs
Executive Health Resources

Hospital Accreditation

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"PEER REVIEWED by NIA HCAHPS"

"NIA staff and volunteers determined that this product had met specific criteria for quality and value. This seal is a mark of quality and is not an endorsement of the product or service. It does not guarantee the use of the product."

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- Medicare Overview
- Program Integrity Efforts
- Government Auditors
- Auditor Target Areas
- Best Practices for Success



BAD IPPS Ideas Heard on the Floors

- “We will follow the attending physician order, no need for UR reviews”
- “Nothing has changed. If screen says IP, we will bill IP. Even if it is 1 midnight.”
- “All audits are on hold until Oct 1, 2014. We have no worries! Yeal!”
- “Concurrent review is no longer important. We will just rebill after discharge.”

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Improper Payment Report

* Estimated \$31.2 billion in improper payments in 2013

"The primary causes of improper payments, as identified in the Medicare FFS Improper Payments reports, are insufficient documentation errors, medically unnecessary services, and to a lesser extent, incorrect coding."

Actual and Target Error Rates (%)

A bar chart titled "Actual and Target Error Rates (%)" showing data from 2010 to 2015. The y-axis represents the error rate percentage, ranging from 0.0% to 10.0% in increments of 2.0%. The x-axis lists the years 2010, 2011, 2012, 2013, 2014, and 2015. Each year has a single grey bar representing the actual error rate. The rates are: 2010 (9.1%), 2011 (8.6%), 2012 (8.5%), 2013 (8.3%), 2014 (8.0%), and 2015 (7.5%).

Year	Actual Error Rate (%)
2010	9.1%
2011	8.6%
2012	8.5%
2013	8.3%
2014	8.0%
2015	7.5%

*From the FY 2012 HHS Agency Financial Report (AFR)



Today's Audit Environment

- The regulations have changed, but no clear guidance
- The procedures haven't changed
- How can providers be wrong 90% of the time?
- It is about how the contractors interpret the regulations and they don't even understand them
- If providers don't challenge them, the new interpretations become the new rules

Governmental Audit and Fraud Fighting Entities	
Who	What
OIG	Office of the Inspector General
DOJ	Department of Justice
MCR RAs	Medicare Recovery Auditors
SMRC	Supplemental Medical Review Contractor
MACs	Medicare Administrative Contractors
HEAT	Health Care Fraud Prevention and Enforcement Action Team
CERT	Comprehensive Error Rate Testing
MIP	Medicaid Integrity Plan
MIG	Medicaid Integrity Group
MICs	Medicaid Integrity Contractors
MIG	Medicaid Inspector General
MCD RAC	Medicaid Recovery Audit Contractors
PERM	Payment Error Rate Measurement
ZPICs	Zone Program Integrity Contractors

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Department of Justice (DOJ) Focus Areas

American Hospital Association
American Health Care Association
Peer Reviewed by HCFA
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Current DOJ Activities

- Defibrillators (ICDs)
- NCDs
- Kyphoplasty
- Referrals from other government contractors
- Qui Tam cases

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Areas of Compliance Risk Broadened

Example:

Hospital on the East Coast

- Agreed to pay \$2.8 million to settle Federal claims that it failed to prevent a cardiologist from placing medically unnecessary stents in dozens of patients from 2003 through 2006
- Hospital admitted no liability and had already repaid nearly \$1 million prior to the settlement
- Cardiologist was convicted of healthcare fraud and related charges for falsifying patient records. He made it appear that patients needed coronary stents, and then billed private and public insurers hundreds of thousands of dollars for the unwarranted procedures
- Cardiologist was sentenced to 8 years in prison

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- It is a real problem when Finance starts dictating level of care
 - "we need more IP and less OBS"
- Compliance being left out of meetings
 - if compliance officers do nothing about a violation, but remain at the organization, they may become the 'sacrificial lamb'

Report on Medicare Compliance, March 4, 2013



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Office of Inspector General (OIG) Focus Areas

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Current OIG Audit Activity

- Coding/complications
- Short-stay procedures
- Canceled surgery
- Readmissions
- High-cost cases
- Technical issues

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2014 OIG Work Plan Targets

Targets Impacting Hospitals:

- New inpatient admission criteria
- Critical access hospitals – Payment policy for swing-bed services
- Critical access hospitals – Beneficiary costs for outpatient services
- LTCHs – Billing patterns associated with interrupted stays
- Inpatient claims for mechanical ventilation
- Selected inpatient and outpatient billing requirements
- Nationwide review of cardiac catheterization and heart biopsies
- Payments for patients diagnosed with kwashiorkor
- Bone marrow or stem cell transplants



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Recovery Auditors: Focus Areas

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by HFSMA

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CMS Recovery Amounts (Through FY2013)		
		Total Corrections
October 2009 – September 2010	FY2010	\$92.3
October 2010 – September 2011	FY2011	\$939.3
October 2011 – September 2012	FY2012	\$2,400.7
October 2012 – September 2013	FY2013	\$3,834.8
Total National Program		\$7,267.1

**Total corrections through FY 2013 equal \$7.3 billion
\$6.8 billion in overpayments**

Source: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Medicare-FFS-Recovery-Audit-Program-1st-Qtr-2014.pdf>

Source: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Medicare-FFS-Recovery-Audit-Program-4th-Qtr-2013.pdf>

**CMS Recovery Amounts
(Q1 FY2014 Only)**

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare Fee for Service
National Recovery Audit Program
Figures provided in millions
(October 1, 2013 – December 31, 2013)
Quarterly Newsletter

	Overpayments Collected	Underpayments Returned	Total Quarter Corrections	FY To Date Corrections
Region A: DCS	\$107.2	\$5.8	\$113.0	\$113.0
Region B: CGI	\$106.4	\$3.8	\$110.2	\$110.2
Region C: Connolly	\$382.7	\$66.4	\$449.1	\$449.1
Region D: HDI	\$219.7	\$12.1	\$231.8	\$231.8
Nationwide Totals	\$816.0	\$88.1	\$904.1	\$904.1

Source: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Medicare-FFS-Recovery-Audit-Program-1st-qtr-2014.pdf>

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Top Issues By Recovery Auditor

Region	Overpayment Issues	Areas of Focus
Region A: Performant Recovery, Inc.	Cardiovascular Procedures: (Medical Necessity) Medicare pays for inpatient hospital services medically necessary for the setting billed. Medical documentation for patients undergoing cardiovascular procedures also needs to be complete and support all services provided in the setting billed	NY, PA
Region B: CGI, Inc.	Cardiovascular Procedures: (Medical Necessity) Medicare pays for inpatient hospital services medically necessary for the setting billed. Medical documentation for patients undergoing cardiovascular procedures also needs to be complete and support all services provided in the setting billed	IL, MI, OH
Region C: Connolly, Inc.	Cardiovascular Procedures: (Medical Necessity) Medicare pays for inpatient hospital services medically necessary for the setting billed. Medical documentation for patients undergoing cardiovascular procedures also needs to be complete and support all services provided in the setting billed	FL, LA, TX, NC
Region D: HealthData Insights	Minor Surgery and other treatment billed as Inpatient: (Medically Necessity) When beneficiaries with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for less than 24 hrs, the hospital outpatient for coverage regardless of the hour they presented to the hospital, whether a bed was used, and whether they remained in the hospital after midnight.	CA, MO

Source: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Recovery-Audit-Program/Downloads/Medicare-FFS-Recovery-Audit-Program-1st-qtr-2014.pdf>

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The Next Round of RA's

- CMS is currently in the procurement process for new Recovery Auditor contracts. Due to an earlier delay in that process, extending the current contracts became necessary.
- The existing four Medicare fee for service Recovery Audit Program contracts have been extended to June 1, 2014.
- The Final day to send an ADR letter is February 21, 2014...
 - The "Final ADR" date does not apply to ADRs sent for reviews performed under the Recovery Audit Program's Prepayment Review Demonstration, or the Mandated Medical Review of Outpatient Therapy claims over the \$3700 Threshold.
- Bid Protests have been filed by HealthDataInsights (HDI) and CGI Federal

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- This will occur with the next round of 5-year contracts to be awarded soon?
 - There will be five – four regions as before and a national fifth one
- CMS cut in half — from 60 days to 30 days — the time a RAC has to complete a review after receiving the provider's medical records
 - If deadline missed, RA loses contingency fee
- RACs will be required to help CMS defend overpayment determinations
 - Even up to a federal court
 - Participate in at least 25% of ALJ hearings

Source:: Report on Medicare Compliance, May 6, 2013



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Medicare Administrative Contractors (MACs) Focus Areas



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- Primary responsibility is processing claims
- Now auditing hospitals and physicians
 - Mobile audits
 - Prepayment reviews
 - Focusing on medical necessity
 - ‘Probe and Educate’ program: Oct. 1, 2013 – Sept. 30, 2014
 - Focus on Inpatient claims less than 2-midnights
 - MACs will select a sample of 10 claims for prepayment review for most hospitals (25 claims for large hospitals)
 - Link for more information: www.cms.gov/medical-review
- Increased denial activity, especially during contract renewal periods
- Frequently, guidance provided appears to be inconsistent with statutes, regulations, and manuals

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Probe & Educate

Number of Claims in Sample That Did NOT Comply with Policy (Dates of Admission October – March 2014)			
	No or Minor Concern	Moderate to Significant Concerns	Major Concerns
10 Claim Sample	0-1	2-6	7 or more
25 Claim Sample	0-2	3-13	14 or more
Action	<ul style="list-style-type: none"> • Deny non-compliant claims • Send results letters explaining each denial • No more reviews will be conducted under Probe and Educate Process 	<ul style="list-style-type: none"> • Deny non-compliant claims • Send results letters explaining each denial • Offer 1:1 Phone Call • REPEAT Probe & Educate process with 10 or 25 claims 	<ul style="list-style-type: none"> • Deny non-compliant claims • Send results letters explaining each denial • Offer 1:1 Phone Call • Repeat Probe & Educate • If problems continue, repeat P&E with increased claim volume of 100-250.

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Specific MAC Activity

MAC	Jurisdiction	Activity/Focus
Cahaba Government Benefit Administrators	J10	Current Prepayment Medical Review Log for Part A (not an all inclusive list): DRGs 009, 189, 190, 191, 192, 229-227, 235, 242, 243, 244, 245, 247, 249, 251, 287, 312, 313, 391, 392, 460, 470, 490, 552, 640, 641, 714, 981, 982, 983. Inpatient Rehabilitation Facility A0801-A0803 and A2001-A2004, and CMG's A0701, A0702, A0703. Full list: www.cahabagba.com/part-a/medical-review/10-ab-mac-prepayment-medical-review-log-part-a/ (updated Sept. 10, 2013)
First Coast Service Options	J9	As of October 1, 2013, FCSO has removed every DRG from prepayment review.
Novitas Solutions, Inc.	JH & JL	Novitas has temporarily suspended all of its targeted prepayment reviews.
National Government Services	J6 & JK	Mobile Audit

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Specific MAC Activity (cont)

MAC	Jurisdiction	Activity/Focus
Noridian Healthcare Solutions	JF	Prepayment Review for DRGS 287, 470 and one-day stays (state-specific prepayment reviews. List of affected states can be found at: www.noridianmedicare.com/parta/coverage/service_specific_review_html.aspx)
Palmetto Government Benefits Administrator	J11	No new contractor specific audit activity information at this time.
Wisconsin Physicians Service	J5 & J8	Current prepay edits include 48 hr observation, high dollar claims, inpatient rehab facility, long-term acute care hospital, and short-term acute care hospital
CGS	J1	No new contractor specific audit activity information at this time.

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**Zone Program Integrity
Contractors (ZPICs)
Audit Areas**



NIA Goldmark, Inc., is a member of the American Hospital Association and is a leading authority in the field of medical integrity. It is recognized as a leader in maintaining enhanced products and services. By participating in the ZPICs audit process, you can be assured that your organization is being evaluated by the providers of the highest quality.

*NIA staff and volunteers determined that this product had met specific criteria for quality and value. This seal is not a guarantee of the product's performance or value.

PEER REVIEWED
by NIA

BEST
PROVIDER
2013

2006 • 2007 • 2010 • 2011 • 2012 • 2013

- Formerly Program Safeguard Contractors (PSCs)
- Perform the following functions:
 - Investigate potential fraud
 - Perform medical reviews
 - Perform data analysis
 - Refer cases to law enforcement
 - Conduct interviews and/or onsite visits
 - Identify the need for a prepayment or auto-denial edit and refer these edits to the MAC

- ZPICs do NOT perform the following functions:
 - Claims processing, including paying providers/suppliers
 - Provider outreach and education
 - Recouping monies lost to the Trust Fund
 - Medicare review not for benefit integrity purposes
 - Complaint screening
 - Claims appeals of ZPIC decisions
 - Claim payment determination
 - Claims pricing
 - Auditing provider cost reports

- ZPICs may only use extrapolation as a means to determine overpayment amounts to be recouped if the Secretary determines that one of the following apply:
 - documented educational intervention failed to correct the payment error
 - there is a sustained or high level of payment error

** The determination of a sustained or high degree of payment error is not appealable

ZPIC	Zone	States in Zone
Safeguard Services (SGS)	1	California, Hawaii, Nevada, American Samoa, Guam, the Northern Mariana Islands, Palau, Marshall Islands, and the Federated States of Micronesia
NCI (previously AdvanceMed)	2	Washington, Oregon, Idaho, Utah, Arizona, Wyoming, Montana, North Dakota, South Dakota, Nebraska, Kansas, Iowa, Missouri, and Alaska
Cahaba Safeguard Administrators	3	Minnesota, Wisconsin, Illinois, Indiana, Michigan, Ohio, and Kentucky
Health Integrity	4	Colorado, New Mexico, Texas, and Oklahoma
NCI (previously AdvanceMed)	5	Arkansas, Louisiana, Mississippi, Tennessee, Alabama, Georgia, North Carolina, South Carolina, Virginia, and West Virginia
Under Protest	6	Pennsylvania, New York, Delaware, Maryland, D.C., New Jersey, Massachusetts, New Hampshire, Vermont, Maine, Rhode Island, and Connecticut
Safeguard Services (SGS)	7	Florida, Puerto Rico, U.S. Virgin Islands



Best Practices: Responding to Individual Audits



AHA Solutions, Inc., a division of the American Hospital Association, is a leading provider of hospital management resources to assist in marketing enhanced products and services. By agreement with the American Hospital Association, the AHA Solutions logo is used by the providers to reflect their past to the AHA.



"Other software may be identified and this product has met specific criteria determined by the Health Information Management Process. HFMA does not endorse or guarantee the use of this product."



2008 • 2009 • 2010 • 2011 • 2012 • 2013

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- If you are treating patients and submitting claims, you will likely be audited
- It is about how the contractors interpret the regulations:
 - The regulations have changed and no clarification
 - The procedures haven't changed
- Providers must appeal or the contractors' interpretations become the new standard
 - Determinations based solely reasonableness of 2 MN expectation
 - Timing as sole determining factor (e.g., 2-midnights)
- The solution is NOT to make all prepayment reviewed cases observation
- Appeal cases that are inappropriately denied



Internal Audit Preparation

- **Communicate to all relevant parties quickly and engage them:**
 - Finance
 - Compliance
 - Legal
 - Medical Records
 - Clinical Leadership
 - Physician Advisor
- **Ask key questions internally:**
 - Who does this audit involve?
 - Do we want to review the charts?
 - Do we need legal representation?

The slide features the EHR logo at the top left, which includes the text "EHR Executive Health Resources" and "The Physician Advisor Company". The main title "Communicate with the Auditor" is centered above a bulleted list of items.



What Not to Do

- DO NOT wait until a few days before the auditors arrive to take action
- DO NOT refrain from asking for more information about the audit and audit selection process
- DO NOT simply accept the audit findings as accurate
- DO NOT cease filing appeals
- DO NOT begin self-denying or overusing observation in an attempt to avoid a future audit

- Demonstrate a consistently followed Utilization Review process for every patient
- Educate medical staff on documentation practices to avoid future technical issues
- Prove that the error rate within your hospital is not accurate by focusing on successfully appealing denials
- Hospitals need to be prepared to defend their decisions and advocate for their rights

- Medical Necessity is a complicated issue – but it is possible to achieve success
- Admission decisions must be based on clinical and regulatory evidence and best practices
- Consistent process must be paired with diligent oversight and data review
 - Identify procedural failures
 - Recognize that your hospital will receive inappropriate denials and be prepared to appeal
 - Be prepared to advocate for your hospital

- For Medicare reviews, you should focus on the front end process. If you are focusing on appeals, you've already lost
- Not all auditors are created equal; understand the differences and their potential impacts
- The best appeals address the clinical argument; reinforce your consistent process and follow the regulations



Finally...

- It is no longer a matter of “IF” you are going to get audited, but “WHEN”
- You can win. You have to pay attention on the front end to properly status the patient and fully document your basis for the care provided

EHR
EXECUTIVE HEALTH RESOURCES
The Physician Advisor Company

Questions

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Get the Latest Industry News & Updates



The screenshot shows the homepage of the EHR website. At the top, there's a search bar with placeholder text "Search EHR.com". Below the search bar is a navigation menu with links like "Home", "About", "Contact", "Log In", and "Sign Up". The main content area features a large image of a doctor's office with a computer monitor displaying medical data. Text overlay on the image reads: "Trusted by more than 12,000 health care professionals across the country. Executive Health Resources is the Medical News You Can Use." A large red arrow points from the bottom left towards the "Sign Up" button.

EHR's Compliance Library
 Register today at
www.ehrdocs.com

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 @EHRdocs
<http://www.twitter.com/EHRdocs>

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About Executive Health Resources

EHR has been awarded the exclusive endorsement of the American Hospital Association for its leading suite of Clinical Denials Management and Medical Necessity Compliance Solutions Services.

EHR received the elite Peer Reviewed designation from the Healthcare Financial Management Association (HFMA) for its suite of medical necessity compliance solutions, including: Medicare and Medicaid Medical Necessity Compliance Management; Medicare and Medicaid DRG Coding and Medical Necessity Denials and Appeals Management; Managed Care/Commercial Payor Admission Review and Denials Management; and Expert Advisory Services.

EHR was recognized as one of the "Best Places to Work" in the Philadelphia region by Philadelphia Business Journal for the past five consecutive years. The award recognizes EHR's achievements in creating a positive work environment that attracts and retains employees through a combination of benefits, working conditions, and company culture.

The logo for Executive Health Resources (EHR) is located in the top left corner. It features the acronym "EHR" in large, bold, black letters. Below it, the full name "EXECUTIVE HEALTH RESOURCES" is written in a smaller, all-caps, black font. Underneath that, the tagline "The Physician Related Company" is displayed in a very small, faint, gray font.

LEARNING FROM CORPORATE INTEGRITY AGREEMENTS

What You Need to Know Even if
You're Not Under One

HCCA Compliance Institute - March 31, 2014

Today's Panel



Patrick Braley
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Blair Todd
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Development Officer
WellCare Health Plans,
Inc.

Topics for Discussion

- Latest trends, developments, and challenges presented in Corporate Integrity Agreements (CIA)
- How trends and requirements should inform the structure of your compliance program
- Practical tips for implementing CIA concepts into your compliance program
- Perspective from an Independent Review Organization (IRO)

Why is This Important to Me?

- “CIAs are imposed on companies to help reorient a corporate culture that may have previously been prone to fraud and abuse. In this way, the OIG attempts to directly affect change in third-party billing entities. Such CIAs may also serve as admonitory examples for others within the industry.”

- “CIAs set forth specific requirements that a provider must meet in establishing a compliance program or in maintaining an existing compliance program.”

[Testimony of Lew Morris, Assistant Inspector General for Legal Affairs, before the House Committee on Commerce, Subcommittee on Oversight and Investigations, April 6, 2000]

Why is This Important to Me?

- “CIAs are designed to put the entity at the frontline of promoting compliance.” [Gregory E. Demske, Chief Counsel to the IG, OIG Outlook 2013 audio podcast]

- An appropriately designed and effectively operating compliance program may prevent issues from occurring and/or keep you from having to enter a CIA if one ever does

New/Emerging Trends in CIAs

- Sampling Approaches
 - Emphasis of higher risk areas/facilities

- Increased Sample Sizes & Frequencies

- Extrapolation Requirements
 - Requiring repayment

New/Emerging Trends in CIAs (cont.)

- ❑ Increased Focus on Risk Assessment Process
 - IRO review of how conducted
- ❑ Corrective Actions re: Internal Audit Findings
- ❑ Use of IROs in Different Contexts
 - CMS's bundled payments initiative
 - Clinical Quality Systems Reviews

New/Emerging Trends in CIAs (cont.)

- ❑ Expanded Board of Director Requirements
 - Quarterly review and oversight of compliance program
 - Annual resolution regarding the effectiveness of the compliance program
- ❑ Management Accountability and Certifications
 - Review, oversight, and annual certification at business unit level regarding compliance with Federal healthcare programs and CIA obligations

Implementation Challenges

- ❑ Compliance Department Structure and Governance
- ❑ Retention of Third Party Consultants
- ❑ Infrastructure
 - OIG Reporting
 - Disclosure Log
 - Employee Screening
- ❑ Training
- ❑ Hiring

Trends in OIG's Issuance of CIAs

- Historically, when determining whether a CIA is necessary, OIG considers, among other things:
 - "whether the provider has an effective compliance program and would agree to limited compliance or integrity measures and would annually certify such compliance to the OIG." Open Letter to Providers, Janet Rehnquist, (Nov. 2001).
- OIG's Approach is changing.

Trends in OIG's Issuance of CIAs (cont.)

- Changes
 - Fewer CIAs
 - Focus on organizations that would benefit the most from CIA structure
 - Settlement amounts remain a factor
 - Increased oversight by OIG monitors

Advantage of Voluntary/ Proactive Compliance

- If party to a future OIG investigation or False Claims Act case, it can be helpful to demonstrate:
 - Alleged issue was already on company's risk assessment "radar"
 - Compliance program is already in place to monitor, prevent, and detect such issues

Perspective from an IRO

- IRO's role involves:
 - Assessment of the design and effectiveness of compliance policies, procedures, systems, and controls after they are implemented and put into operation
 - Annual review to report factual findings and provide recommendations for process improvements where applicable

Perspective from an IRO (cont.)

- Expect to see:
 - Written policies and procedures disseminated to applicable departments
 - Familiarity with CIA obligations by compliance department personnel and other applicable departments
 - Senior management support and promotion of the Compliance Officer and CIA obligations
 - Improved statistical compliance with the program from year to year

Perspective from an IRO (cont.)

- Challenges and opportunities:
 - Training statistics
 - Prominence of Compliance Officer
 - Passive Compliance Department involvement
 - Support of Senior Management
 - Documentation of procedures
 - Retention of supporting data / records
 - Communication between departments
 - Focus on the error versus the cause and solution

THANK YOU!

Questions???

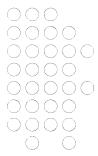
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Home Care and Hospice: Compliance Update: 2014

Health Care Compliance Association

William A. Dombi
Vice President for Law
National Association for Home
Care & Hospice
March 31, 2014



COMPLIANCE: FOCUS ON HOME CARE & HOSPICE

- All enforcement entities looking at home care
 - Billing for services actually rendered
 - Medical necessity
 - Technical compliance/documentation
- High level fraud/False Claims Act investigations
- OIG continues home care efforts
 - Medicaid home care new on the agenda
 - Staff credentials including health screening a target
- Hospice honeymoon is over
- Unique business compliance issues
 - ACA Employer Mandate
 - Fair Labor Standards ACT

Affordable Care Act: What is in store for home care?

- Employer mandate
 - New issues?
 - Redefine "full-time"
 - Ongoing litigation?

ACA Employer Mandate: Home Care Impact

- Many, but not all HHAs have comprehensive health insurance
 - \$3000 per non-insured penalty a risk
- Most Medicaid home care providers do not have health insurance for employees
 - \$2000 per FTE penalty a risk
- Private pay home care companies rarely have employee health insurance
 - \$2000 per FTE penalty a virtual certainty

Employer Mandate: Options

- **CHANGE THE LAW!!!!**
 - Redefine full time to 40 hours per week (30 is current standard)
- Stay below 50 FTEs and/or 30 full time employees
 - Corporate re-organization to break up large companies into multiple small ones not an option
- Limit the number of employees at 30 hours or more per week
- Offer bare bones, qualified health plan
- Seek higher Medicaid rates (good luck!)
- Raise charges to clients (tough sell)

Private Pay Home Care: Companionship Services FLSA Exemption

- DoL rule effectively eliminates minimum wage and overtime exemption
 - Eliminates exemption for 3rd party employment
 - Changes definition of companionship services
 - Excludes 3rd party employers from live-in exemption
 - Medicaid and disability rights advocates opposition
- Increased litigation on W&H issues
 - Validity of claimed FLSA exemption status
 - "hours worked"
 - Break time rights

Medicaid Home Care Compliance Risk Areas

- New compliance efforts in Medicaid home care nationwide likely related to growth in spending
- Dual-eligibles (Medicare maximization)
 - Pre-payment conditions such as a full Medicare denial
 - Post-payment claim by claim review with Medicare claim submissions required
- Private duty nursing: pediatric and adults
 - Frequency and duration
- Personal care services
- Hospice



OIG Oversight Activity

- OIG Workplan (Medicaid Home Care)
 - Medicaid home care worker screenings
 - Medicaid home health claims and CoP compliance
 - CMS policies on Medicaid homebound requirements
 - HCBS: oversight of care quality
 - HCBS: vulnerabilities in providing services
 - HCBS: State administrative costs
 - Medicaid Personal Care Services
 - Home Health Services—Duplicate Payments by Medicare and Medicaid)
 - Hospice Services—Compliance With Reimbursement Requirements
 - State Procedures for Identifying and Collecting Third-Party Liability Payments
 - State Compliance With the Money Follows the Person Demonstration Program



Medicaid Home Care Target Areas

- CLAIMS
- SERVICES RENDERED
- FALSE BILLINGS
- STAFF CREDENTIALS
- REFERRAL KICKBACKS



TARGET: CLAIMS

- UTILIZATION
- AUTHORIZATION OF CARE
- COMPLIANCE/CONSISTENCY WITH APPROVED PLAN OF TREATMENT
- DOCUMENTATION
- TECHNICAL REQUIREMENTS



TARGET: UTILIZATION

- Data analysis to target provider utilization
 - Aberrant patterns outside the norm
 - Statistical deviation
 - Percent increase billing, payment, number visits/services
 - High utilization services/items
 - High cost services/items



F2F Oversight

- ACA requires F2F on Medicaid home health
- CMS yet to promulgate F2F Medicaid rule
- States may implement F2F on their own



Medicaid Personal Care

- OIG audit focus
 - North Carolina,
<http://oig.hhs.gov/oas/reports/region4/41004003.pdf> (\$41.71M) Audit (A-04-10-04003, June 2011)
 - Missing documentation
 - Services not in accordance with plan of care
 - No supervisory nursing visits
 - No verification caregiver qualifications
 - No physician order

1

Medicaid Personal Care

- Washington State,
http://oig.hhs.gov/oas/reports/region9/9090003_0.pdf Audit (A-09-09-00030, June 2011)
 - No timesheets supporting daily service
 - Billed more hours than on timesheets
 - Training deficiencies

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Medicaid Personal Care

- Attendants whose qualifications were not documented, <http://oig.hhs.gov/oei/reports/oei-07-08-00430.pdf> - 10 State review: CA, FL, GA, IL, IA, NE, NY, OH, TN, WV
 - NYC, <http://oig.hhs.gov/oas/reports/region2/20701054.pdf> Audit (A-02-07-01054, June 2009)
 - No medical professional exam of beneficiary before service
 - No nursing assessment
 - No nursing supervision
 - No physician's order
 - N.Y. State, <http://oig.hhs.gov/oas/reports/region2/20801005.pdf> Audit (A-02-08-01005, Oct. 2010)
 - Same as above for NYC and
 - No in-service training for aide
 - Time with patient not documented

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Medicaid Hospice Risk Areas

- Billing for Medicaid personal care to a Medicare hospice patient
 - Medicaid billing for services and items covered under Medicaid hospice benefit
 - Pharmaceuticals
 - Ambulance
 - State Medicaid payment reductions that reflect beneficiary contribution obligation
 - <http://www.oig.hhs.gov/oas/reports/region1/1100004.asp>
 - OIG found that Massachusetts Medicaid did not reduce hospice payments to reflect “spend down” patients’ contribution obligation

ENFORCEMENT ACTIVITY

- Pure fraud
 - Fraud, kickbacks, false records, and more
 - Non-compliance
 - Documentation weakness

PURE FRAUD

- SERVICES NOT RENDERED
 - Agency model
 - Owner
 - Employee
 - Owner + employee
 - Agency + client
 - Individual Provider (IP) model
 - Worker
 - Personal care attendant
 - Nurse
 - Worker + client
 - Client
 - Family

Fraud, kickbacks, false records, and more

- Falsified credentials
- False care records
- Kickbacks for referrals/enrollment
- Bribes
- Client endangerment



NON-COMPLIANCE

- Provider qualifications
 - Unqualified caregivers
 - Excluded caregivers
- Ineligible clients
- Utilization
- Conformance with care plan



DOCUMENTATION

- Provider qualifications
- Service provision
- Claims accuracy



PROGRAM INTEGRITY: OPERATIONAL IMPROVEMENTS

- What is working, what is not
- Time and attendance
- Staff credentialing
- Care plan compliance
- Service documentation
- Policies and procedures
- Staff training and oversight
- Internal auditing



MEDICARE COMPLIANCE: FOCUS ON HOME CARE

- ZPICs and RACS looking at home care
 - Homebound status
 - Medical necessity
 - Technical compliance incl. F2F
- High level fraud/False Claims Act investigations
 - E.g., \$375M physician-directed fraud allegation
- OIG continues home care efforts
 - New report alleges widespread fraud and abuse
 - Report is weak on facts and methodology, strong on hyperbole
- Medicare hospice is new on the agenda



MEDICARE HOSPICE

- FY2014 rates (October 1, 2013)
 - 1.7% MBI update
 - 0.3% MBI reduction under ACA
 - 0.5% Productivity adjustment reduction
 - Continued phase-out of the BNAF (approx impact of .7)
- New Payment Model is still in development (no earlier than October 2014)
 - U-shaped payment distribution
 - Site of service adjustment
 - Routing home care rebased rates
- Claims oversight increasing



Medicare Hospice

- Hospice face-to-face rule
- Terminal illness documentation
- New Cost report
- Hospice and the nursing facility resident



Medicare Hospice: OIG Focus

- Hospice to residents of ALFs
- Hospice General Inpatient Days
- Hospice Marketing Practices and Financial Relationships with Nursing Facilities



Home Health Regulatory Compliance Issues

- HHPPS 2014 rule
- Face to Face rule
- Therapy Assessment rule
- PECOS
- Medicare “improvement” standard lawsuit
- New Medicare CoP sanctions
- New ABN
- Moratorium on new HHAs



2014 Medicare Home Health Rate Final Rule

- CMS Proposed Rule (July 3, 2013) <http://www.gpo.gov/fdsys/pkg/FR-2013-07-03/pdf/2013-15766.pdf>
- CMS Final Rule (December 2, 2013) <http://www.gpo.gov/fdsys/pkg/FR-2013-12-02/pdf/2013-28457.pdf>
- Rebased payment rates
 - Full cut (3.5%) allowed under law (14 points total)
 - Recalibrated case mix weights
 - Limits increases in LUPA visit rates
 - "average cost" calculation
- Outlier eligibility remains same despite low spending
- Remember 2% payment sequestration (February 1 and later payments)
- Remember wage index changes (net reduction of \$30M in expenditures)

2014 Medicare Home Health Rate Final Rule: Assessment

- CMS chose unfavorable calculation method
 - Used proxies for episode revenue and costs
- Better alternatives available
- Ignored cost increases and costs not on cost report
 - Telehealth
 - F2F; therapy assessment
- Silo-ed rebasing rather than aggregation
- Failed to include capital needs

Face to Face Physician Encounters

- Revisions 2013
 - Allow facility-based NPP to perform encounter
 - Require communication with the physician with whom collaborating (i.e. inpatient or community)
 - Allow the facility-based physician to complete the F2F and either certify or communicate findings to the certifying physician in the community
 - Documentation title and date
 - Allow any party to title and date F2F documentation

Who Are F2F Inpatient Physicians

- Physicians caring for patient during:
 - Acute care stay
 - Post acute inpatient stay
 - ED visit
 - Observation stay at an acute care facility
- Includes**
- Residents (however documentation and communication via supervising physician)



F2F Documentation

- Face-to-face description should be a brief narrative describing the patient's clinical condition and how the patient's condition supports homebound status and the need for skilled services.
 - Standardized language prohibited (e.g. considerable and taxing effort)
 - Diagnosis alone is not sufficient to support skilled services
- CMS example
 - "The patient is temporarily homebound secondary to status post total knee replacement and currently walker dependent with painful ambulation. PT is needed to restore the ability to walk without support. Short-term skilled nursing is needed to monitor for signs of decomposition or adverse events from the new COPD medical regimen."



Inpatient F2F Encounter No Certification

- Communication of clinical information from medical record to community physician (i.e. verbal, clinical notes, discharge summary, referral, etc.)
 - Information compilation may be by inpatient support staff
 - Community physician may obtain supplementary information via phone, email, if needed
- Community physician may "adopt" the document as his /her own encounter document but must sign and date the documents(s)
 - CMS will allow the certifying physicians to "adopt" an allowed NPPs clinical notes
- Community physician creates the F2F encounter document based on the facility physician's encounter findings
 - Note: Inpatient physician or NPP signature not required



Inpatient F2F Encounter with certification

- Facility-based physician
 - Completes the F2F encounter document based on his/her findings or the findings of an NPP
 - Information compilation may be by inpatient support staff
 - Signs and dates the document ; "hands off" to community physician
 - Signature not required by the physician who signs the POC

Requirements for Home Health Services Certification

- Certification
 - Physician certifies eligibility for home health services
 - The home health services are or were needed because the patient is or was confined to the home
 - The patient needs or needed skilled services ;
 - A plan of care has been established and is periodically reviewed by a physician; and
 - The services are or were furnished while the patient is or was under the care of a physician.
 - Includes F2F attestation

F2F Certification Statement(s)

- 42 CFR 424.11 General procedures.
 - (a) *Responsibility of the provider.* The provider must—
 - (1) Obtain the required certification and recertification statements;
 - (2) Keep them on file for verification by the intermediary, if necessary; and
 - (3) Certify, on the appropriate billing form, that the statements have been obtained and are on file.
 - (b) *Obtaining the certification and recertification statements.* No specific procedures or forms are required for certification and recertification statements. The provider may adopt a method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form...
 - (c) *Required information.* The succeeding sections of this subpart set forth specific information required for different types of services. If that information is contained in other provider records, such as physicians' progress notes, it need not be repeated. It will suffice for the statement to indicate where the information is to be found.

Other important considerations

- Checkboxes created by the physician are acceptable
- Home health agencies may not create, transcribe, add to, or alter F2F documentation
- F2F samples may not be patient specific
- Start of Care may be revised if late encounters
 - Count back 30 days
 - Realignment of SOC: may use original OASIS, updated
 - Delete original OASIS
 - Realignment of SOC due to late F2F requires realignment of therapy 13 and 19

F2F

- MLN Clarification on documentation:
<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1405.pdf>
- Not very helpful
- Lawsuit???
- Excess documentation in relation to ACA requirements
- Failure to provide adequate and clear guidance on acceptable documentation

Therapy Reassessment

- For late assessments, the visit on which the reassessment is conducted will be covered
- The visit prior to the late reassessment will not be covered
 - Reassessment conducted on visit 14
 - Visit 14 will be covered but not visit 13
- In single therapy cases reassessment must be conducted on the 13th /19th therapy visit
- In multi-discipline cases:
 - Each discipline must conduct a reassessment on therapy visit 11, 12,or 13
 - Each discipline must conduct the reassessment on therapy visit 17,18,or 19 for each discipline
 - Non-coverage will apply only to the discipline that fails to conduct the reassessment on time
 - Reassessments may be conducted on the visit closes to, but no later than the 13/19th therapy visit, if there is no scheduled visit for that discipline within the required time frame.

MEDICARE HOME HEALTH: Alternative Sanctions

- Applies to condition level deficiencies
- Sanctions include:
 - Directed corrective action
 - Temporary management
 - Payment suspension
 - Civil monetary penalties
 - \$500-\$10,000
 - Per diem/per instance
 - Termination
- Informal dispute resolution possible
- CMPs and payment suspension no earlier than 7/1/14,
- Appeal rights w/o penalty suspension



The New Survey and Sanctions Rule

- 77 Fed. Reg. 67068 (November 8, 2012)
- Codifies HHA survey process
- Establishes intermediate sanctions
 - Civil money penalties and payment suspensions effective 7-1-14
 - Other sanction effective 7-1-13
- Establishes Informal Dispute Resolution process
 - Effective 7-1-14



Alternative Sanctions: 488.800 et seq.

- Condition-level deficiencies only
 - Repeat standard-level deficiencies may trigger condition-level finding
- CMS developing detailed guidance on sanction process in SOM
 - Progressive action approach
- Sanction determinations made by CMS RO
 - Survey recommendations
 - State agency recommendations
- No CMP funds can be used to finance survey activities
 - Avoids "bounty hunter" risk



General Provisions: 488.810

- Sanctions imposed only for condition-level deficiencies
- Accrediting Organizations report condition-level findings to CMS RO
 - Sanctions lead CMS and SA to take over oversight and enforcement
- Branch deficiencies counted against parent
- Subunit deficiencies do not apply to parent
- All deficiencies require a Plan of Correction
 - CMS approval required
- Written notification of intent to impose sanction
- Appeal rights under 42 CFR Part 498
 - Penalties accrue during appeal, but collection delayed



Sanction Factors: 488.815

- Choice reflects "the impact on patient care and the seriousness of the HHA's patterns on noncompliance
- Whether deficiencies pose immediate jeopardy to patient health and safety
- The nature, incidence, degree, manner, and duration of the deficiencies
- The presence of repeat deficiencies; compliance history in general and specific to cited deficiencies
- Whether deficiencies directly relate to patient care
- Whether the HHA is part of a larger organization with documented problems
- Whether the deficiencies indicate system wide failure



Available Sanctions: 488.820

- Civil Money Penalties (CMP)*
 - Suspension of payment on new admissions*
 - Temporary management*
 - Directed plan of correction**
 - Directed in-service training**
- * required by statute
- ** required by regulation



Civil Money Penalties: 488.845

- Per instance CMPs: \$1000-\$10,000
 - Per day CMPs: \$500-\$10,000; three tiers
 - Factors considered
 - 488.5 factors
 - Size of the HHA
 - Accurate and credible resources such as PECOS, cost reports, claims information providing information on operations and resources of HHA
 - Evidence of built-in, self-regulating quality assessment and performance improvement system
 - Discretion to increase or decrease CMP at revisit



Civil Money Penalties: 488.845

- **Penalty start**
 - Per-day: day of the survey that identified noncompliance
 - **Penalty ends:** date of correction of all deficiencies/date of termination
 - Correction=revisit survey finding date



Civil Money Penalties: 488.845

- Appeal Rights: 42 CFR Part 498
 - CMPs held pending outcome, but still accruing during appeal
 - Payment due 15 days after final administrative decision
 - Written request for hearing w/in 60 days of notice
 - Waiving right to appeal reduces CMP 35%
 - Payment due w/in 15 days of waiver request receipt
 - IDR option
 - Request w/in 10 days of notice of penalty
 - CMP may be offset against Medicare or Medicaid payments



PECOS

- ACA and regulation requires all home health certifying and ordering physicians be enrolled in Medicare
- Medicare requires an approved enrollment record in PECOS
 - HHAs only have access to “ordering and referring” file
- Physician name and NPI as they appear in PECOS on the claim
- Edit effective with SOC January 6, 2014
 - Watch for expanded enrollment focus in claims reviews

PECOS

- Full Implementation of Edits Set for January 6, 2014.
- <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1305.pdf>
- See also
- 8441 : Home Health Agency Reporting Requirements for the Certifying Physician and the Physician Who Signs the Plan of Care - Effective July 2014
- <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2789CP.pdf>
- 8356:Handling of Incomplete or Invalid Claims once the Phase 2 Ordering and Referring Edits are Implemented
- <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R2767CP.pdf>

Medicare coverage guidelines

- *Jimmo v Sebelius* settlement
- <http://www.medicareadvocacy.org/wp-content/uploads/2012/12/Jimmo-Settlement-Agreement-00011764.pdf>.
- Focused on illegal “improvement” standard
- CMS is clarifying existing guidelines; provider education will follow
- Permit coverage of skilled maintenance therapy
- Permit coverage of chronic care/terminal patients
- Existing guidelines recognize such coverage but MACs changed the “rules”

Implementation Game Plan

- CMS clarified guidelines with specific prohibition of an improvement standard (w/in 6 months) <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM8458.pdf>
- Training of Medicare contractors and providers (following issuance of guidelines)
- Reopening of select claims denied since 1/11
- Ongoing oversight of claim determinations

Medicare Home Health Oversight Target Areas

- False Claims
- Homebound
 - Absences documented or reported by patient
 - Conflicting documentation
- Medical Necessity
 - Therapy is a big target
 - Improper “improvement” standard
 - Documentation weakness on skilled nature of care
- Coding
 - diagnoses
- Face-to-Face Encounter
- Therapy Assessments

Medicare Home Health: OIG Focus

- Workplans
 - Home health Prospective Payment System requirements
 - Employment of individuals with criminal convictions
 - Home health face-to-face physician encounter requirements
 - Missing OASIS
 - Trends in Revenues and expenses

Recent Enforcement Activity

- DOJ very active in certain states, including MI, IL, FL, and TX
- Indictment of Texas physician and 6 HHAs for false claims and billing for unnecessary or non-provided care
- Indictment of FL owners, administrators, nurses, and physicians for billing unnecessary care
- Indictment of IL owners and marketers for referral kickbacks

Claims

- MAC, RAC, ZPIC
- MAC
 - Pre-payment review for new providers
 - Pre-payment edits
 - Target providers
 - High volume services
 - High cost
 - RAC, OIG, CERT, GAO identify vulnerability

Claims

- Data analysis to target providers
 - Claims
- Aberrant patterns outside the norm
 - Statistical deviation
 - Percent increase billing, payment, number visits/services
- High utilization services/items
- High cost services/items

RAC Approved HH Issues

- Region C: Connolly, Inc.
- States: AL, AR, CO, FL, GA, LA, MS, NM, NC, OK, SC, TN, TX, VA, WV, Puerto Rico and U.S. Virgin Islands
 - Home Health Agency - Medical Necessity and Conditions to Qualify for Services: Complex
 - RAP claim without corresponding home health claim: Automated
 - Incorrect billing of Home Health Partial Episode Payment claims: Automated
 - Validation of late episode timing: Automated
 - Core-based statistical area: Automated
 - Hospice related services billed with Condition code 07-Home Health: Automated
 - Non-Routine Medical Supplies and Home Health Consolidated billing: Automated

HHABN

- No change in policy
- ABN CMS-131 for financial liability protection
 - Replaces Option Box 1
- Home Health Change of Care Notice (HHCCN)
 - prior to reducing or discontinuing care related HHA reasons
 - Prior to reducing or discontinuing care related to physician orders
 - New form replaces Option BOX 2 and Option Box 3
- Mandatory December 9, 2013
- <http://www.cms.gov/Medicare/Medicare-General-Information/BNI/HHABN.html>

Confined to the Home

- Change Request 8444
- Clarifies that homebound must met both:
 - 1) The individual has a condition due to an illness or injury that restricts his or her ability to leave their place of residence except with the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance of another person; or if leaving home is medically contraindicated.
 - AND
 - (2), the condition of the patient should be such that there exists a normal inability to leave home and, consequently, and leaving home would require a considerable and taxing effort.

Moratorium on New HHAs

- January 31, 2014---6 months
 - Miami – Dade, FL and Cook County (Chicago area) extended
 - Fort Lauderdale, Detroit, Dallas, and Houston added
 - New providers
 - Branches included



HIPAA Breach

- Home Health and Hospice agencies are particularly vulnerable to breaches due to the nature of the business
 - Stolen and lost lap tops /records



Program Integrity Proposals

- Implement a targeted, temporary moratorium on new home health agencies
- Require credentialing of home health agency executives
- Expedite refinements to the Medicare home health payment system to eliminate incentives to over-utilize care
- Require all Medicare participating home health agencies to implement a comprehensive corporate compliance plan
- Strengthen admission standards for new Medicare home health agencies through probationary initial enrollment , prepayment claims review, increased initial capitalization requirements, and early-intervention oversight by Medicare surveyors

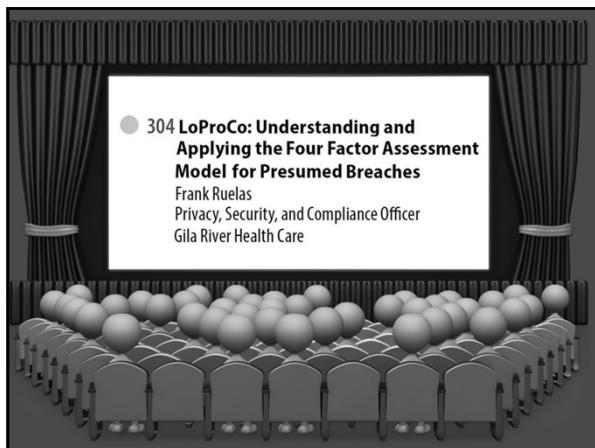


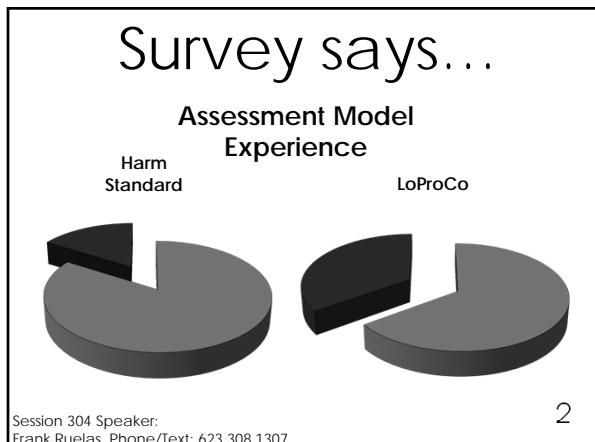
Program Integrity Proposals

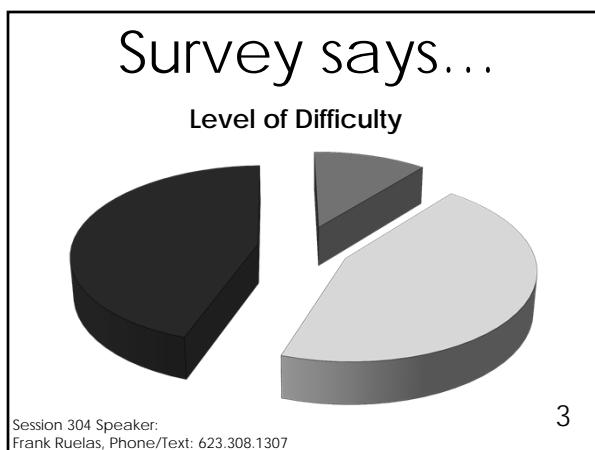
- Establish targeted systemic payment safeguards focused on abusive utilization of home health services
- Create a joint Home Health Benefit Program Integrity Council to provide a forum for partnering in program integrity improvements with Medicare, Medicaid, providers of services, and beneficiaries
- Require criminal background checks on home health agency owners, significant financial investors, and management
- Establish authority for a self-policing compliance entity to supplement and complement federal and state oversight
- Enhance education and training of health care provider staff, regulators and their contractors to achieve uniform and consistent understanding and application of program standards

CONCLUSION

- Home Care and Hospice is diverse
- Range of legal/regulatory issues is endless
 - Significant regulatory energy directed towards home care and hospice
 - Compliance issues/concerns
- Center of innovation in care is home care; change triggers action

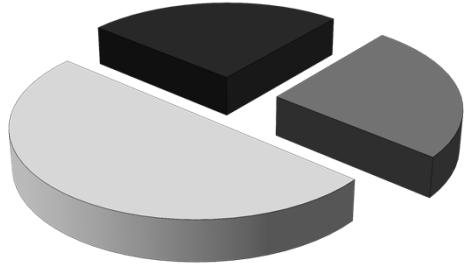






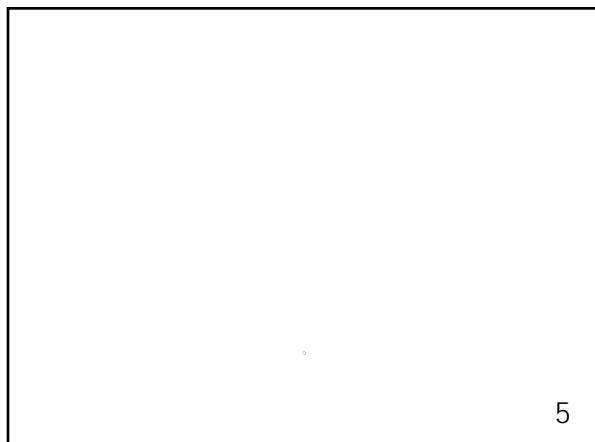
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Skill Level



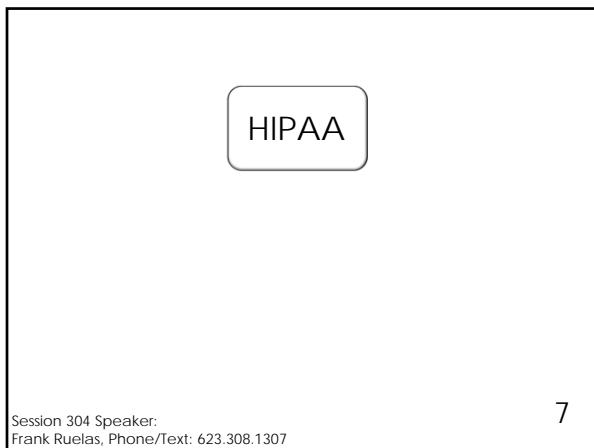
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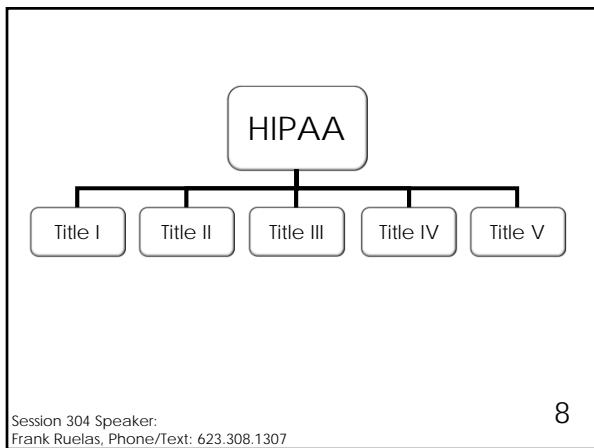
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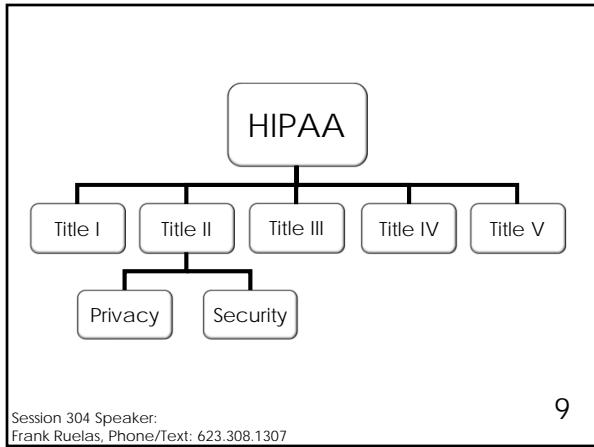


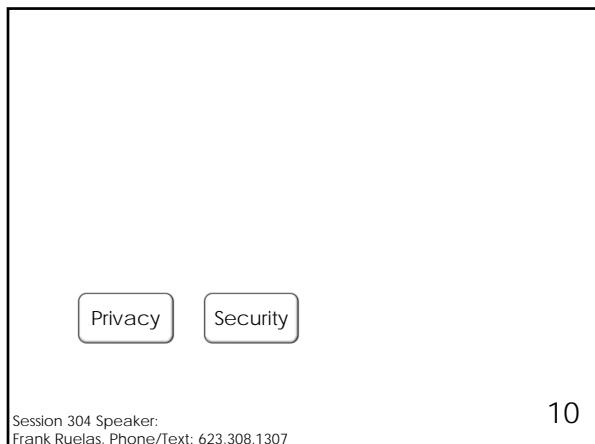
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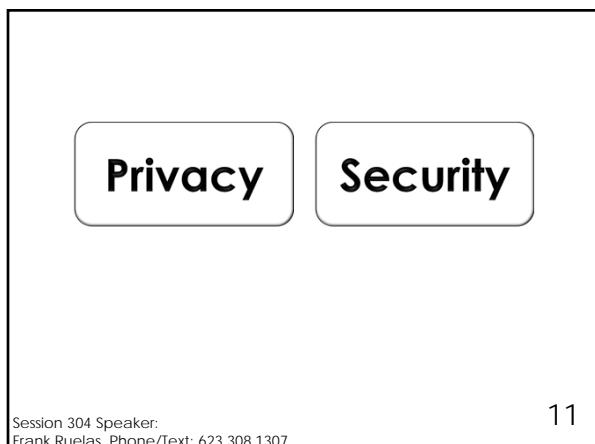




Privacy Security

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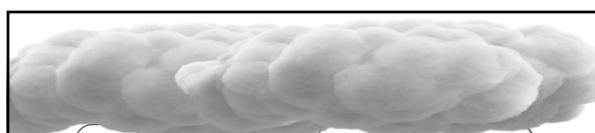
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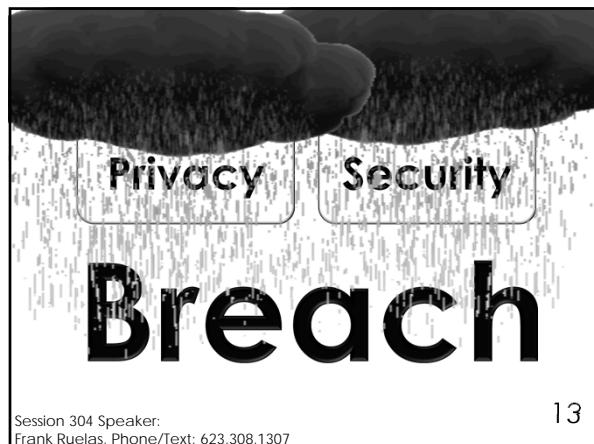


Privacy Security

Breach

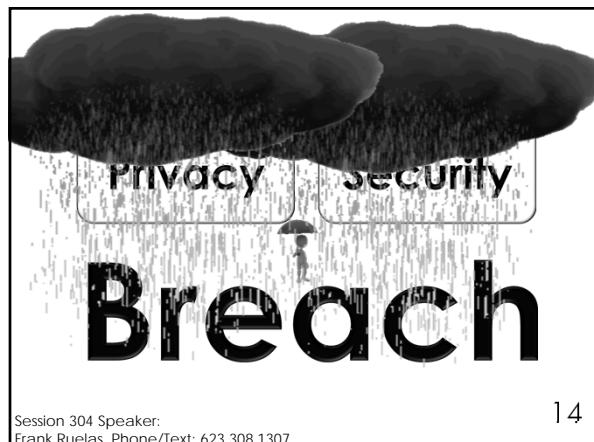
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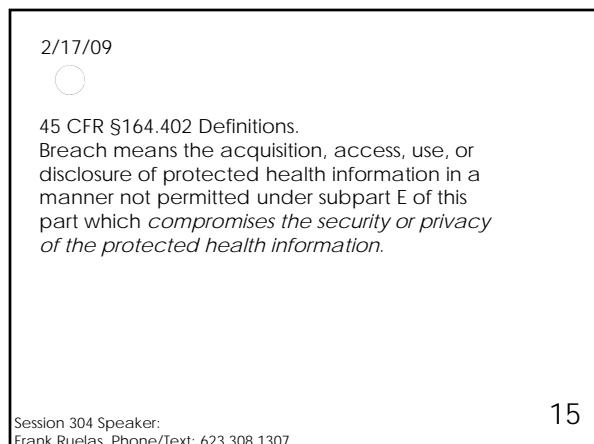
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2/17/09	8/24/09	
45 CFR §164.402 Definitions. <i>Breach</i> means the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E of this part which <i>compromises the security or privacy of the protected health information</i> .		
<i>compromises the security or privacy of the protected health information</i> means poses a significant risk of financial, reputational, or other harm to the individual.		
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2/17/09	8/24/09	1/25/13
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2/17/09	8/24/09	1/25/13	????
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<i>compromises the security or privacy of the protected health information</i> means...????			
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(2) Except as provided in paragraph (1) of this definition, an acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the protected health information has been compromised based on a risk assessment of at least the following factors:

- (i) The nature and extent of the protected health information involved, including the types of identifiers and the likelihood of re-identification;
 - (ii) The unauthorized person who used the protected health information or to whom the disclosure was made;
 - (iii) Whether the protected health information was actually acquired or viewed; and
 - (iv) The extent to which the risk to the protected health information has been mitigated.

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(2) Except as provided in paragraph (1) of this definition, an acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E is presumed to be a breach unless the covered entity's business associate, as applicable, demonstrates that there is a low probability that the protected health information has been compromised based on a risk assessment of at least the following factors:

- (i) The nature and extent of the protected health information involved, including the types, identifiers and the likelihood of re-identification;

(ii) The unauthorized person who used the protected health information or to whom disclosure was made;

(iii) Whether the protected health information was actually acquired or viewed; and

(iv) The extent to which the risk to the protected health information has been mitigated.

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(2) Except as provided in paragraph (1) of this definition, an acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E is presumed to be a breach unless the covered entity or business associate, as applicable, demonstrates that there is a low probability that the protected health information has been acquired and retained in a risk assessment of at least three factors:

Before the advent of the personal health information involved, however, the risk of identifying an individual's likelihood of infection; the author, a person who used to protect their health information or to whom the disclosure was made.

- (iv) The extent to which the risk to the protected health information has been mitigated.

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Enter LoProCo



Low
Probability of
Compromise

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22

Enter LoProCo

Low infers a
range...

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Enter LoProCo

Low infers a
range...often
described using
3 levels.



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Our Starting Point

An Identified Impermissible Use or Disclosure

Our Mission:
The decision is to move forward with an assessment to determine if it is a breach

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Factor 1 Factor 2 Factor 3 Factor 4

Probability of Compromise

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Time for Hands On Training (no notes needed)

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Review

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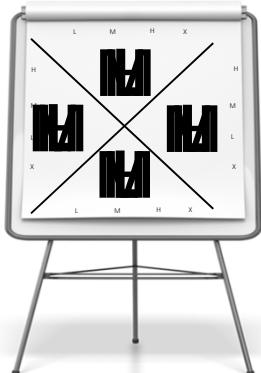
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Compromise

To make known to an unauthorized person.
- Frank Ruelas

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Factor 1
Factor 2
Factor 3
Factor 4

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Tick-Tock.... The Clock Is Ticking

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Disclaimer

- This material is designed to offer basic information for coding and billing and is presented based on the experience, training and interpretation of the author. Although the information has been carefully researched and checked for accuracy and completeness, the presenter does not accept any responsibility or liability with regards to errors, omissions, misuse, or misinterpretation. This presentation and handout is intended as an education guide only.

2

Presentation Outline

1. E/M Services
2. Critical Care Services
3. Prolonged Care Services
4. Psychotherapy
5. Infusions
6. Smoking Cessation
7. Physical Therapy
8. Resources & Links

3

E/M Visits

E/M Visit When Time is Controlling Factor

Using time as controlling factor for E/M when counseling or coordination of care dominates the visit.

Code	Typical Time For E/M
99211	5
99212	10
99213	15
99214	25
99215	40

- Established Office Visit:
- Total E/M visit = 55 min
 - Counseling Time = 30 minutes (more than 50% of total)(description).
 - What should be billed and documented?**
 - EM code?
 - Both E/M & Prolonged Care (CPT 99354-99355)?
 - Extra time Monitoring versus Counseling?
 - What if Resident & Teaching Physician?

5

Hospital Discharge Services

- Do not confuse:**
reporting requirements for physician coding and Hospital's requirements
- Discharge management includes:
 - Final exam of patient
 - Discussion of hospital stay
 - **Discharge instructions (including time to instruct family or other caregivers)**
 - Preparation of discharge records, prescriptions and referral forms
 - CPT 99238 Hospital discharge day management; 30 min or less
 - CPT 99239 Hospital discharge day management; **more than 30 min**
 - **Must document time**
 - Include all time even if not continuous on the same date

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Discharge Services Nursing Facility

- ▶ CPT 99315 Nursing Facility Discharge, day management; **30 minutes or less**
- ▶ CPT 99316 Nursing Facility Discharge, day management; **more than 30 minutes**
 - **Must document time**

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Discharge Documentation

- ▶ Reason for hospitalization
- ▶ Significant findings
- ▶ Summary of procedures and treatment provided
- ▶ Patient's discharge condition
- ▶ Patient and family instructions (as appropriate)
- ▶ Attending physician's signature
- ▶ **Time, if more than 30 minutes**
 - “**40 minutes spent in D/C management**”
 - “**More than 30 minutes spent in D/C management**”

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Death Pronouncement

- ▶ Use Discharge Day Management codes (CPT 99238-99239)
 - Only physician who performs the pronouncement
 - Use date pronouncement occurred even if the paperwork is delayed to a subsequent date
 - Completion of the death certificate alone is not sufficient for billing
 - Physician must “examine” the patient, thus satisfying the “face to face” visit requirement
- ▶ Document the cumulative time when reporting **99239 or 99316 (greater than 30 minutes)**

Source: CMS' Medicare Claims Processing Manual, Pub. 100-04, Chapter 12, §30.6.9.2E

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Adult Critical Care Services

Adult Critical Care Codes

- ▶ Hourly codes (CPT 99291-99292) used for:
 - Over 71 months of age
 - Outpatient pediatric/neonates

Code	Descriptions	Fee Office (POS 11)	Fee Facility (POS 22)
99291	Critical care, E/M of the critically ill or critically injured patient; first 30-74 minutes	\$272.18	\$217.75
99292	Critical care, each additional 30 minutes (Separately in addition to CPT 99291)	\$120.78	\$109.55

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Neonate & Pediatric Critical Care Codes (Daily)

- ▶ Used as long as the neonate/infant/young child qualifies for critical care services during the hospital stay

Neonate Critical Care Codes (28 days of age or younger):
 ▶ **99468-99469:** Inpatient critical care services provided to neonates 28 days of age or younger

Pediatric Critical Care Codes (29 days of age to 71 months):
 ▶ **99471-99476:** Inpatient critical care services provided to infants 29 days through 71 months of age

Note: These codes have specific guidelines, not covered in this presentation.

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Critical Care Requirements

1. Reasonable and medically necessary;
 2. Clinical condition – critically ill;
 3. Critical care work; and
 4. Documentation of time
- If the services are reasonable and medically necessary but do not meet the criteria for Critical Care services, they should be coded as another appropriate E/M service (e.g., subsequent hospital care, CPT codes 99231–99233)

(Critical Care is defined in Medicare Claims Processing Manual: Pub.100-04, Ch.12,30.6.12)

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Critically Ill

The criteria for defining a critical care condition:

- High probability of sudden, clinically significant or life threatening deterioration in the patient's condition
- The condition requires the highest level of physician preparedness for urgent intervention.

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Critical Care Work

- Require a physician's direct personal supervision and management of life- and organ-supporting interventions that may require frequent manipulation by the physician
 - Withdrawal of or failure to initiate these interventions on an urgent basis would likely result in sudden, clinically significant, or life-threatening deterioration in the patient's condition.
 - The physician must devote his or her full attention to the patient and therefore cannot render E/M services or other services to another patient during the same time period.

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Special Considerations

- ▶ Warranted versus unwarranted Critical Care
- ▶ Chronic Illness & Critical Care
- ▶ Bundled Procedures*
- ▶ Separately Billable Procedures (Unbundled)*
- ▶ Covered versus non covered activities
- ▶ Family Discussion
- ▶ Teaching Time
- ▶ Non Physician Practitioners & Shared Visits
- ▶ Medical Students
- ▶ *See Resource section

Time

- ▶ Physician **must document time** (per date/calendar day)
 - Start/Stop times vs. Total time?
- ▶ Time counted:
 - Must be exclusively devoted to patient
 - Does not have to be continuous
 - Includes time spent on bundled procedures
 - Excludes teaching time
- ▶ Critical Care Services are not restricted to a fixed number of days

Best Practices – Documentation

- ▶ Time-based service, must include the total time spent performing critical care services:
 - “*Total critical care time, excluding procedures, 1 hour and 40 minutes*”
- ▶ Additionally, each daily note should include:
 - Specific diagnoses supporting critical illness
 - Details of the patient’s condition and critical care work to support the ongoing critical illness and the high complexity of decision-making

Reporting Critical Care CPT 99291 -99292

- ▶ CPT 99291 (Critical Care, first hour) is used to report physician services that provide constant attention to a critically ill patient for a total of **30-74 minutes** on a given day.
 - A physician may bill only one unit of CPT code 99291 for a patient on a given date
- ▶ If the total duration of Critical Care provided by the physician on a given day is **less than 30 minutes**, the appropriate E/M code should be used. (Usually 99221-99223 – initial encounter or 99231-99233 – subsequent encounters)
- ▶ Additional Critical Care services over 74 minutes should be billed with CPT add on code of 99292 **for each additional 30 minutes beyond 75 minutes**

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Counting Units

Total Duration CC (minutes)	Total Duration CC (hr & min)	Code(s)
Less than 30 minutes		99232 or 99233
30-74 minutes	30min- 1hr 14min	99291 x 1
75-104 minutes	1hr 15min- 1hr 44min	99291 x 1 and 99292 x 1
105-134 minutes	1hr 45min- 2hr 14min	99291 x 1 and 99292 x 2
135-164 minutes	2hr 15min- 2hr 44min	99291 x 1 and 99292 x 3
165-194 minutes	2hr 45min- 3hr 14min	99291 x 1 and 99292 x 4
195 minutes or longer	3 hr 15min- etc.	99291-99292 as appropriate (per above illustrations)

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Single Physician

- ▶ The initial Critical Care service (CPT 99291) must be met by a single physician or qualified NPP.
- ▶ Physicians in group practice of the **same specialty**.
 - Considered single physician for billing and reporting
 - Should not each report CPT 99291 on the same date
- ▶ Physicians in group practice of **different specialty**.
 - Considered without regard to membership in same group
 - Can each report 99291, if providing care that is **unique to specialty and managing at least one of the patient's critical illnesses**
 - Cannot report 99291, if providing "staff coverage" or "follow up"

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CPT 99292 Each Additional 30 Minutes

- ▶ Subsequent Critical Care services performed on the same calendar date:
 - Report CPT code 99292 (Critical Care, each additional 30 minutes)
 - 15–30 minutes beyond the first 75 minutes of critical care on a given day.
- ▶ The service may represent aggregate time met by a single physician or physicians in the same group practice with the same medical specialty in order to meet the duration of minutes required for CPT code 99292.

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Prolonged Care

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Prolonged Care

- ▶ Beyond the usual service & reported in addition to another service
- ▶ Initial (CPTs 99354, 99356, 99358)
 - First hour once per day (30-60 min)
 - Less than 30 min total duration is not reported (included in E/M code)
- ▶ Add on (CPTs 99355, 99357, 99359)
 - Each additional 30 min beyond first hour (and final 15-20 min on a given date)
 - Less than 15 minutes beyond the first hour or less than 15 minutes beyond the final 30 minutes is not reported separately.

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Prolonged Care With Face-to-Face Care

- ▶ **Office /Other Outpatient Setting (99354-99355):**
 - CPT 99354 Prolonged service in the office or other outpatient setting required direct patient contact beyond the usual service; first hour
 - +99355 each additional 30 minutes
- ▶ **Inpatient /Observation Setting (99356-99357):**
 - CPT 99356 Prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour
 - +99357 each additional 30 minutes

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Prolonged Care Without Face-to-Face Care

- ▶ CPTs 99358 and 99359 are used when a physician provides prolonged service not involving direct (face-to-face) care that is beyond the usual service in either the **inpatient or outpatient setting.**
 - CPT 99358 is used to report the first hour of prolonged service on a given date
 - CPT 99359 is used to report each additional 30 minutes beyond the first hour

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Inpatient/Observation Setting: Medicare and CPT Differ

- ▶ Medicare only allow providers to report Inpatient codes (CPTs 99356 & 99357) if the time was spent face-to-face with the patient.
 - *"In the case of prolonged hospital services, time spent reviewing charts or discussion of a patient with house medical staff and not with direct face-to-face contact with the patient, or waiting for test results, for changes in the patient's condition, for end of a therapy, or for use of facilities cannot be billed as prolonged services."*
- ▶ AMA's CPT description does not include "face-to-face" in description.
 - CPT 2012 defines direct patient contact as face-to-face, but also counts "additional non face-to-face services on the patient's floor or unit of the hospital or nursing facility during the same session"

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CPT 99354 & 99355 Times & Units

Total Duration Prolonged Service	Codes Reported
Less than 30 minutes	Not reported separately
30–74 minutes (1/2 hr – 1 hr 14 min)	99354 x1
75–104 minutes (1 hr 15 min – 1 hr 44 min)	99354 x1 and 99355 x1
105–134 minutes (1 hr 45 min – 2 hr 14 min)	99354 x1 and 99355 x2
135–164 minutes (2 hr 15 min – 2 hr 44 min)	99354 x1 and 99355 x3
165–194 minutes (2 hr 45 min – 3 hr 14 min)	99354 x1 and 99355 x4

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CPT 99354 & 99355 Threshold Outpatient New Visits

Code	Typical Time For E/M	Threshold Time to Bill 99354	Threshold Time to Bill 99354 & 99355
99201	10	40	85
99202	20	50	95
99203	30	60	105
99204	45	75	120
99205	60	90	135

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Prolonged Care -Documentation

- ▶ Can be billed with most E/M codes; consults, admits, new, established, subsequent, discharge day management.
- ▶ NPP's can also bill for prolonged care
- ▶ Documentation should include
 - Time spent above and beyond the documented level of E/M service
 - Total ALL time spent with the patient face-to-face
 - Medical necessity
 - Description of the reason for prolonged time (i.e. prolonged due to patient dementia)

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E/M Visits Based On Time & Prolonged Care

- ▶ When time is the controlling factor for billing the E/M service then prolonged care **should only be billed when the service has exceeded 30 minutes beyond the highest level of E/M in the appropriate category.**
 - The time approximation must meet or exceed the specific CPT code billed (determined by the typical/average time associated with the E/M code) and should not be "rounded" to the next higher level.
- ▶ When the E/M service is billed based on the elements (history, exam & MDM) an indication of the time spent on the E/M is not required.

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Prolonged Care Examples

- ▶ A physician performed a visit that met the definition of visit code 99233 and the total duration of the direct face-to-face contact (including the visit) was 115 minutes.
 - *The physician bills codes 99233, 99356, and 1 unit of code 99357*
- ▶ A physician performed an office visit to an established patient that was **predominantly counseling**, spending 75 minutes (direct face-to-face) with the patient.
 - *The physician should report CPT code 99215 and one unit of code 99354*

Source: Medicare Claims Processing Manual (Pub.100-04, Ch12, Section 30.6.15.1.H)

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Psychotherapy Services

Psychoterapy without E/M

- ▶ • 90832: Psychotherapy, 30 minutes with patient and/or family member,
- ▶ • 90834: Psychotherapy, 45 minutes with patient and/or family member, and
- ▶ • 90837: Psychotherapy, 60 minutes with patient and/or family member

Psychotherapy with E/M

- ▶ • +90833: Psychotherapy, 30 minutes with patient and/or family member when performed with an E&M service (list separately in addition to the code for primary procedure)
- ▶ • +90836: Psychotherapy, 45 minutes with patient and/or family member when performed with an E&M service (list separately in addition to the code for primary procedure), and
- ▶ • +90838: Psychotherapy, 60 minutes with patient and/or family member when performed with an E&M service (list separately in addition to the code for primary procedure).

Counting Time

Must document time

- ▶ 90832: and 90833 -- 16 to 37 minutes,
 - ▶ • 90834 and 90836 -- 38 to 52 minutes, and
 - ▶ • 90837 and 90838 -- 53 minutes or longer
- ▶ **NOTE:** Document specific psychotherapy time not including E/M time for 90833, 90836 and 90838

Medicare PHP Payments

- ▶ Effective January 1, 2014, when E&M services are paid under Medicare's Partial Hospitalization Program (PHP) and not in the physician office setting, the CPT outpatient visit codes 99201-99215 have been replaced with one Level II HCPCS code - G0463.

Psychotherapy Services

- ▶ CMS MLN Matters®Number: SE1407 (Jan2014):
- ▶ The Comprehensive Error Rate Testing (CERT) identified many improper payments for :
 - Failure to document the time spent on the E&M service separately from the time spent on the add-on psychotherapy service.

Infusions

IV Hydration Infusions

- ▶ 96360 Intravenous infusion, hydration; initial, 31 minutes to 1 hour
- ▶ + 96361 each additional hour

IV Infusions Therapy, Prophylaxis or Diagnosis

- ▶ 96365 Intravenous infusion for therapy, prophylaxis or diagnosis; initial, up to 1 hour
- ▶ + 96366 each additional hour
- ▶ + 96367 additional sequential infusion of a new drug/substance, up to 1 hour

IV Infusions Therapy, Prophylaxis or Diagnosis

- ▶ 96369 Subcutaneous infusion for therapy or prophylaxis; initial, up to 1 hour, including pump set-up and establishment of subcuraneous infusion site(s)
- ▶ + 96370 each additional hour

IV Infusions Chemotherapy

- ▶ 96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
- ▶ + 96415 each additional hour

Documentation

- ▶ Document start time of infusion (do not include the time to establish the IV site)
- ▶ Document finish time of infusion (do not include the time to remove the IV needle)
- ▶ If new drug or same drug given as a "push" requiring 15 minutes or less, code with add-on CPT 96375 or 96376 as applicable

Smoking Cessation

Smoking Cessation

- ▶ 99406 Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes
- ▶ 99407 intensive, greater than 10 minutes

▶ **Must document time**

Best practices – document patient response to counseling and ordering of nicotine patch, etc.

Physical Therapy

Modalities – Constant Attendance

- ▶ 97032 – 97039
 - Each modality consists of 15 minutes per unit

▶ **Must document time**

Reporting of total time/units depends on LCD of payer

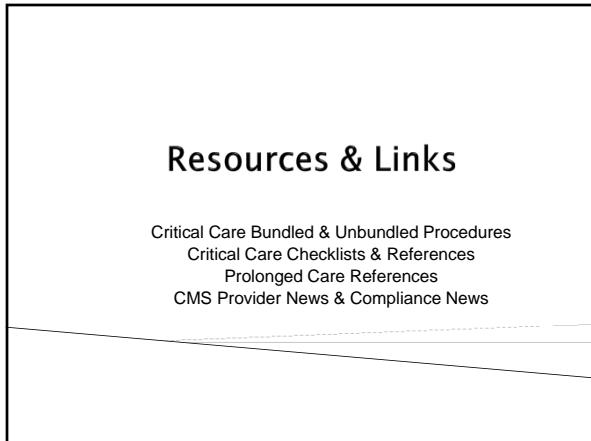
Therapeutic Procedures – Direct one-on-one patient contact

- ▶ 97110 – 97124
- ▶ 97140
- ▶ 97530 – 97542
 - Each procedure consists of 15 minutes per unit
- ▶ 97545 – Work hardening – initial 2 hours
- ▶ + 97546 each additional hour

Must document time

Reporting of total time/units depends on LCD of payer





Resources & Links

Critical Care Bundled & Unbundled Procedures
Critical Care Checklists & References
Prolonged Care References
CMS Provider News & Compliance News

Critical Care Bundled Procedures

- Interpretations of cardiac output measures (93561, 93562)
- Chest x-rays, professional component (71010, 71015, 71020)
- Blood gases and information data stored in computers (93000, 99090, 82800-82810) (e.g., ECGs, blood pressures, hematologic data—CPT 99090)
- Pulse oximetry (94760, 94761, 94762)
- Gastric intubation (43752, 43753)
- Temporary transcutaneous pacing (92953)
- Ventilation management (94002-94004, 94660, 94662)
- Vascular access procedure (36000, 36410, 36415, 36591 36600)

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Separately Billable Procedures (Unbundled Procedures)

- Some of these separately billable services include:
 - Endotracheal intubation (31500)
 - Insertion/placement of Swan Ganz (93503)
 - Cardiopulmonary resuscitation (92950)
 - Central venous lines (36556)
 - Arterial lines (36620)
- The physician's progress notes should document that time involved in the performance of separately billable procedures was not counted toward critical care time

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Critical Care Checklist

AUDIT CHECKLIST:		CRITICAL CARE SERVICES	
Month:	Physician:	Met criteria:	Payer:
Patient:	Reviewer:		
ACCOUNT:	DOCUMENTATION TASK	YES	NO
Critical Care (CPT 99291-99291) If the answer is "no" to any of the questions, do not report critical care 99291-92.			
Clinical criterion	Does the patient have acute impairment of one or more organ systems and have a high probability of imminent or life threatening deterioration?		
Treatment criterion	Documentation not limited to direct medical management, frequent assessment and interventions not limited to a single decision-making process?		
	Does the record demonstrate work performed during the encounter that is more intense than the work for other E/M codes? High-complexity decision making to assess, manipulate and support vital system function(s) to treat single or multiple organ system failure and/or prevent further life threatening deterioration in the patient's condition?		
Time	Is time specifically documented 99291 30-74 minutes? Is time specifically documented 99292, additional 30 minutes? 75 to 104 minutes?		
	Is time documented reasonable considering the documented work performed? If time includes spent with family, was family member operating as surrogate decision-maker because the patient is unable to make decisions?		

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Critical Care Checklist Cont.

Bundled procedures	Bundled procedures (included in critical care time) are not billed for separately: <input type="checkbox"/> Interpretation of cardiac measures (93364,93365) <input type="checkbox"/> Blood gases and information data stored in computers (93000,99990,82800-82810) <input type="checkbox"/> Endotracheal intubation (94760, 94761, 94762) <input type="checkbox"/> Gastric intubation (43732, 91103) <input type="checkbox"/> Temporary transcutaneous monitoring (99313) <input type="checkbox"/> Venous access procedure (94657, 94660, 94662) <input type="checkbox"/> Vascular access procedure (96000, 36410, 36413, 36410, 36600)	
Separately billable procedures	Does time documented as critical care exclude time spent performing procedures for which separate payment is made? <input type="checkbox"/> Endotracheal intubation (31500) <input type="checkbox"/> Insertion and removal of Sputum Gauze (93503) <input type="checkbox"/> CPR (92950) <input type="checkbox"/> Central venous lines (86556) <input type="checkbox"/> Nasogastric tube (36600-36620) <input type="checkbox"/> Sheldon catheter	
NPP	If the PA or NP performed critical care, is this billed under the NPP's number for Medicare? The shared visit rule does not apply to critical care services.	
Residents	Did the physician document that he/she was present during the entire patient assessment? "Available documentation: "I was present with the NPP during the history and exam. I discussed the case with the NPP and agree with the findings and plan as documented in the NPP's note."	
Medical necessity	If the services are reasonable and medically necessary but they do not meet the criteria for critical care services, then the services should be re-coded as another appropriate E/M service (e.g., hospital visit CPT 99231-99233).	

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Critical Care Services References

- ▶ CMS' Medicare Claims Processing Manual, Pub. 100-04, Chapter 12, §30.6.12
www.cms.gov/manuals/downloads/clm104c12.pdf
- ▶ CMS' Medicare Benefit Policy Manual, Pub. 100-02, Chapter 15, §30E
www.cms.gov/manuals/Downloads/bp102c15.pdf
- ▶ CMS Transmittal 1548, CR 5993, July 9, 2008;
www.cms.gov/Transmittals/Downloads/R1548CP.pdf &
 CMS MLN Matters MM5993, CR 5993, July 9, 2009;
www.cms.gov/MLNMattersArticles/downloads/MM5993.pdf
- ▶ American Medical Association's Current Procedural Terminology (CPT) Manual, Professional Edition 2013
- ▶ AMA's CPT Assistant February 2013, Volume 23, Issue 2, Pages 17-18:
 "Prolonged E/M Services (99354-99359)"

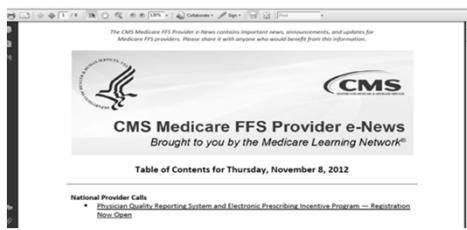
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Prolonged Care Services References

- ▶ CMS Medicare Claims Processing Manual 100-4, 12-§30.6.15.1 & §30.6.13F
<http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf>
- ▶ CMS Transmittal 2282, CR 7405, 8/26/11: "Clarification of Evaluation and Management Payment Policy"
<http://www.cms.gov/transmittals/downloads/R2282CP.pdf>
 & CMS MLM Matter: 7405, 8/26/11:
<https://www.cms.gov/MLNMattersArticles/downloads/MM7405.pdf>
- ▶ American Medical Association's (AMA)s Current Procedural Terminology Manual, Professional Edition 2013
- ▶ AMA's CPT Assistant August 2012, Volume 22, Issue 8, Pages 3-5:
 "Prolonged E/M Services (99354-99359)"

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CMS – FFS Provider e-News

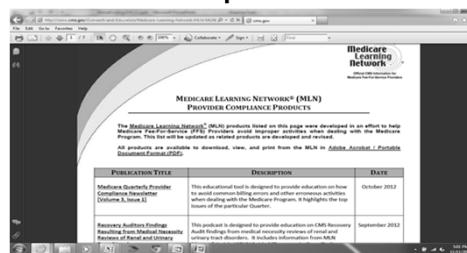


Use this Link To sign up for CMS e-News:

https://public.govdelivery.com/accounts/USCMS/subscriber/new?pop=t&topic_id=USCMS_7819

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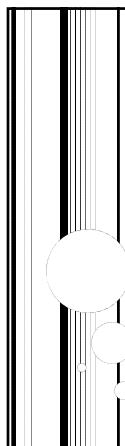
Provider Compliance Products



http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/ProvCmpl_Products.pdf

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Questions

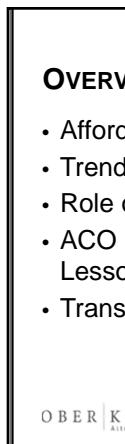


ACO FORMATION, OPERATION AND COMPLIANCE

HCCA Compliance Institute 2014

Sarah E. Swank
OBER | KALER
Washington, DC

Christine Worthen
Board and Cassel
Fort Lauderdale, FL

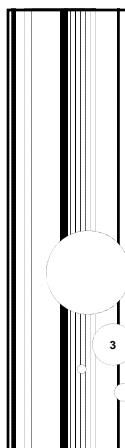


OVERVIEW

- Affordable Care Act and ACOs
- Trends in Integration
- Role of Compliance
- ACO Formation and Operation
- Lessons Learned
- Transferring Skills

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INTRODUCTION

THE PROGRAM AND INTEGRATION

PROGRAMS AND GOALS

- Affordable Care Act
 - ACOs
 - CMS Innovation Center
 - Bundled Payments
 - Insurance Exchanges
 - Fraud and Abuse and Waste
- Three Aims
 - Better care for individuals
 - Better care for populations
 - Lower growth of expenses

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TRENDS IN INTEGRATION

- You have to know where we have been to know where we are going . . .
 - Consolidation and movement in the market
 - Focus on primary care as gatekeepers
- We do not want to make the same mistakes we made in the past

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WHAT IS DIFFERENT THIS TIME AROUND?

- Increased focus on quality
- The need for IT solution
- Shifting of care settings away from the hospital to lower cost settings
- Focus on primary care but now also on specialists
- Both private and public payors
- Care coordination and population health

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COMMON THEMES

Opportunities

- Improved outcomes
- Cost efficiency
- Patient satisfaction
- Market advantage
- Affiliation rather than consolidation

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Potential Pitfalls

- Connectivity issues
- Fraud and abuse issues
- Reimbursement
- Remedial measures and credentialing
- HIPAA privacy and security



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WHAT IS AN ACO?

Accountable Care Organization (ACO)

- Participate in Medicare
- ACO participants
- 5,000 beneficiaries
- Tax identification number (TIN)
- Legal entity and governance
- Shared savings/losses
- Quality measures
- Application and CMS Agreement

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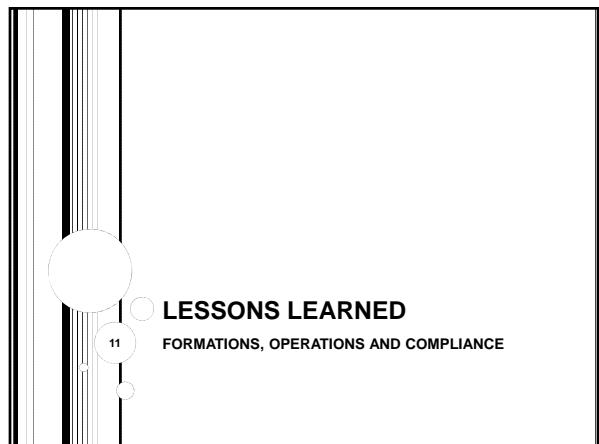
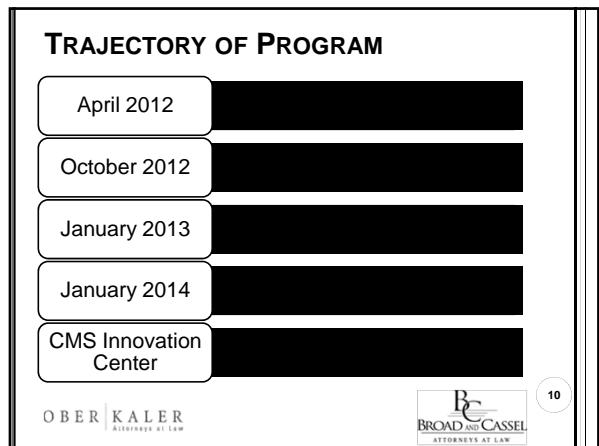
KEY ACO DEADLINES FOR 2014

Applications posted on CMS website	Coming Soon
NOIs accepted	May 1, 2014 - May 30, 2014
CMS User ID forms accepted	May 6, 2014 - June 9, 2014
Applications accepted	July 1, 2014 - July 31, 2014
Application approval or denial decision	Fall 2014
Reconsideration review deadline	Fall 2014

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LESSON: ACOs ARE NOT LIKE THE OTHERS

- ACO rules are a game changer for corporate and transactional principals
 - Governance
 - Tax exemption
 - Conflict of interest
- At the same time, remember your transaction basics:
 - Legal entity often is LLC, but look to state law Super majority powers
 - Voting rights, composition and quorum
 - Corporate practice of medicine may dictate structure

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GOVERNANCE

- Governing bodies must have the following characteristics:
 - Oversight
 - Transparency
 - Fiduciary Duty
 - Conflict of Interest Policy
 - Composition and Control

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GOVERNANCE

- ACO participants must have at least 75 percent control of the governing body
- ACO will remain provider-driven
- Medicare beneficiaries served by the ACO and representatives of entities that are not enrolled in Medicare constitute remaining 25 percent
 - Health plans
 - Investment companies
 - Others

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LESSON: FOCUS ON GOVERNANCE SOONER THAN LATER

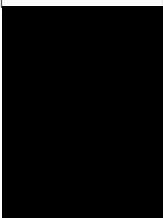
- Start with governance
- Ownership does not have to tie to governance rights
- Put thought into your Medicare Beneficiary
- You can use existing structures but governance is a good reason to start clean with a new entity
- Prepare for the first meeting of the governing body after your start date
- Set up a structure you can grow into

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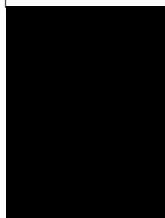
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LEADERSHIP

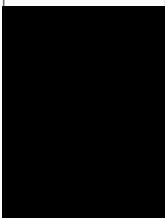
Manager



Medical Director



Compliance Officer

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THE ROLE OF COMPLIANCE

- Compliance officer a required position for an ACO
 - Reports directly to governing body
 - Can be a lawyer but not the lawyer
 - May be a current compliance officer
 - Responsible for compliance plan (or program)
- Certification requirements by leadership

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LESSON: YOU HAVE CHOSEN WISELY

- Leadership is key to an ACO's success and ACOs will need the attention of the leadership selected
 - Leadership is often "contributed" or paid by contractual arrangement
 - Must include a compliance officer that is not the attorney and a compliance plan
 - Stepping away from cookie cutter approach is okay, but you need a plan that will be detailed in the application
 - Rarely find employees in early adopter ACO, but some are moving in that direction



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LESSON: COMPLIANCE

- Report suspected violations to law enforcement (part of policies)
 - Compliance Program (can leverage existing programs)
 - Compliance Policies and Procedures (NPP; access to PHI; patient complaints, retention/disposal of PHI/records; COI; licensure and verification; training/education; patient incentive waivers for in kind - preventive care/advance clinical goal, e.g., blood pressure monitor)
 - Monitor CMS claims to ensure opt-outs' data not flowing?
 - FISMA Considerations



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COMPLIANCE

- Compliance Training (Centralized? At Participant Level?)
 - Code of Conduct
 - Compliance officer
 - Mechanism for reporting issues (Hotline?)



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LESSON: ORGANIZATIONAL STRUCTURE

- Entity formation documents/amendments (own EIN, shared governance, distribute shared savings, etc.)
- State licensing (if necessary, e.g., risk bearing)
- Org charts with position descriptions/reporting (Background checks? Exclusion screening? COI?)

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LESSON: ORGANIZATIONAL STRUCTURE

- Compliance Officer – independent; reporting relationship – direct access to the top; COI
- Patient/Consumer Advocate
- Network participation agreements
- Clinical/administrative systems to: promote evidence-based medicine and patient engagement; quality measures reporting; care coordination across continuum; patient-centeredness (e.g., individual care plans)
- Senior level medical director (board certified) – clinical oversight, part of ACO

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LESSON: BENEFICIARY OPT OUT/DATA SHARING/MARKETING

- Initial opt out notice; subsequent notice at time of visit
- Signage and written notices to explain data sharing and opt out right
- All subject to CMS' marketing requirements – approval process
- CMS approval process – guard against coercion, misleading information
- Marketing materials defined broadly – when in doubt, submit for CMS approval
- ACO information publicly available on its website (Update regularly)
- If provider leaves – need to opt out or get patient consent, even though still aligned

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LESSON: ACO PARTICIPANTS AND PROVIDERS / SUPPLIERS

- Medicare provider/supplier bills under ACO participant TIN (i.e., physician in large group practice which practice is in ACO as participant)
 - Agreements in place – mandate compliance with ACO program compliance, but ACO ultimately responsible – distribute copy of agreement
 - TIN/NPI list – correct? Notify CMS within 30 days of changes? Notify providers/suppliers 30 days prior to submission?
 - Process to ensure not on exclusion list
 - Termination issues/process? (consider: must maintain 5,000 beneficiaries)
 - Business plan for selection of new participants and/or providers/suppliers?



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LESSON: ACO PARTICIPANTS AND PROVIDERS/SUPPLIERS

- Compliance with beneficiary notification? Marketing?
 - Quality reporting – accurate? Timely? Meeting targets? Performance improvement plan?
 - Follow care management policies and procedures of ACO? Local policies with ACO reporting/oversight?
 - ACO EHR access – for data analytics, quality improvement



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SHARING SAVINGS TRACKS

- Two Tracks (participants choose):
 - **Track 1:** ACOs achieving a specified minimum savings rate can share in up to 50 percent of savings based on quality performance, and there is no downside risk for the full three-year agreement period
 - **Track 2:** ACOs that achieve a specified minimum savings rate can share in up to 60 percent of savings, but this model includes downside risk. ACOs not meeting the minimum savings rate will share in losses (not exceeding 60 percent)



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SHARING SAVINGS TRACKS

One-sided Model

- No downside risk
 - Share in up to 50% of savings
 - Performance payment limit of 10% of benchmark expenditures

Two-sided Model

- Downside risk
 - Share in up to 60% of savings
 - Performance payment limit of 15% of benchmark expenditures

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SELECTING A TRACK

- **NOW:** Pick a track and either no down side risk or risk in later years of the agreement
 - **FUTURE:** After three year agreement, ACOs likely to be required to go at risk



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QUALITY

- Quality Assurance Program
 - Committee not required
 - Still physician led
 - Include method in application
 - Must meet the Quality Performance Standards to be eligible for shared savings program
 - Must completely and accurately report data on all program measures
 - Possible sanctions or termination for failure to comply

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QUALITY

Year 1: pay-for-reporting

- Complete and accurate data reporting on all program measures

Year 2: mix

- 8 measures pay-for-reporting
- 25 measures pay-for-performance

Year 3: pay-for-performance

- Except survey results

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LESSON: DON'T JUST GO WITH THE FLOW

- Quality can change throughout the program, but not each performance year
- New focus on high quality and population management
- You may want to select or incentivize other quality measures
- "Meaningful use" of EHR double counted quality measure not a requirement, but likely need one
- Quality committee not required, but still physician led

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DATA COLLECTING, SHARING & REPORTING

- Data reporting to CMS
 - Financial data
 - Quality data (including patient/caregiver experience)
- Data from CMS
 - "De-identified" data
 - Identifiable beneficiary data
- Data sharing among ACO Participants
 - Quality driven based on incentives
 - Now setting their own clinical protocols and measures

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LESSON: DATA IS KING, BUT HIPAA RULES

- Beneficiary opt out may affect data received
- HIPAA applies
 - ACOs are likely business associates of ACO participants, rather than covered entities themselves
 - If set up as a physician group or health system that is billing Medicare could be a covered entity
- The HIPAA rules changed and they affect your ACO
 - Downstream contractors as business associates
 - Breach reporting

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REMEMBER YOU HAVE SEVERAL AGENCIES TO NAVIGATE

- CMS
 - ACO Final Rule – establishes program requirements
- CMS and OIG
 - Fraud and abuse interim final rule – 5 waivers
 - Waivers apply to the MSSP and ACOs participating in it
 - No waiver, even for MSSP participants, for analogous state fraud and abuse laws
- FTC and DOJ
 - Antitrust statement – movement onto the commercial market
- IRS
 - Tax exempt hospital and health care organization notice – 5 factor test but many still look to FMV for comfort

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5 CMS AND OIG FRAUD AND ABUSE WAIVERS – LAWS WAIVED

- Stark Law (Physician self-referral)
- Federal Anti-Kickback Statute (criminal statute that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of federal health care program business)
- Gainsharing CMP (prohibits hospital payments to physician to reduce/limit care to Medicare beneficiary under his/her direct care)
- Beneficiary Inducements CMP (prohibits inducements to Medicare beneficiary likely to influence choice of provider/practitioner/supplier)
- Need to post on website (redact economic terms)

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FIRST WAIVER: PRE-PARTICIPATION WAIVER

- ACO or its participants/providers/suppliers can fund ACO development services for benefit of all (i.e., hospital or referring physician); must be able to unwind; protects outside parties
 - Does NOT include agreements for funding with home health agencies, DME suppliers, drug or device manufacturers
 - Governing body must approve – reasonably related to CMS program purposes (i.e., triple aim)
 - Prepare documentation of waived relationships at time of transaction; retain for 10 years; make available to CMS upon request



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FIRST WAIVER: PRE-PARTICIPATION WAIVER

- ACO must be likely to participate by next application date
 - Use once; waiver applies to pre-participation period only
 - Waiver of Stark, Anti-Kickback, Gainsharing CMP
 - Examples: Funding for IT, legal/consulting, staff hiring, capital contributions



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SECOND WAIVER: PARTICIPATION WAIVER

- Starts when agreement with CMS begins
 - Protects all parties to the arrangement (must involve participant/providers/and/or suppliers; protects outside parties)
 - Governing body approval – see pre-participation
 - Document preparation – see pre-participation
 - Generally ends when program participation ends
 - Waiver of Stark, Anti-Kickback, Gainsharing CMP



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THIRD WAIVER: STARK LAW WAIVER

- Antikickback and Gainsharing CMP are waived for financial relationships among ACO/participants/providers and suppliers that implicate Stark Law
- Eligible if in good standing under ACO program; financial relationship is reasonable related to the ACO program; and financial relationship complies with Stark Law DHS, ownership/investment or compensation exceptions
- Generally ends when program participation ends

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FOURTH WAIVER: SHARED SAVINGS DISTRIBUTION WAIVER

- Protects shared savings distribution methods (EXCEPT: hospital distribution to physician knowingly made to reduce/limit medically necessary services/items HOWEVER protects incentives for alternative evidence-based care that is medically necessary)
- No particular requirements must be met
- No particular duration

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FIFTH WAIVER: PATIENT INCENTIVE WAIVER

- Waives Beneficiary inducements CMP and Kickback Law
- Applies to free/reduced items or services to beneficiaries
- Must be preventive care items or services or advance clinical goal (i.e., adherence to treatment/drug regime)

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AUDIT CONSIDERATIONS

- CMS audit – review the slides on Final Rule requirements for general scope. Address gaps now
- Keep documentation (marketing materials, beneficiary forms, etc.)
- Update agreements as relationships change – maintain current documentation
- Ask for extension if needed – meet deadlines and communicate
- Project lead to ensure organized process – compliance/legal review suggested

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TRANSFERRING SKILLS

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TRANSFERRING THE ACO EXPERIENCE

- Commercial Payors
- Patient Center Medical Home (PCMH)
- State Programs
- Regulation of Provider Risk

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COMMERCIAL PAYORS



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COMMERCIAL PAYORS

- Some start with the MSSP ACO Program and move into commercial while others start with commercial
 - Skill set can be transferred
 - Number crunching for cost savings
 - Population management and quality assurance
 - Leverage existing resources
 - Shifting care settings
 - Movement toward point of care solutions

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COMMERCIAL PAYORS

- Fraud and abuse issues related to risk sharing, whether in the form of:
 - Incentives and bonuses
 - Capitation and taking on risk
 - State insurance laws
 - Risk sharing laws
 - Managed care contracting requirements
 - Driven by data
 - Look at HIPAA provisions although often allowed for “health care operations” and “payment” of the covered entity

- Look for data



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TRANSFERABLE SKILLS TO COMMERCIAL MARKET

- Leveraging population health management across continuum – beyond PCMH and traditional insurer disease management programs; challenge: pay ACO PMPM to cover operations
 - Quality metrics – leverage CMS and identify commercial metrics (not all CMS metrics are applicable)
 - Low hanging fruit – easy to tackle – need long term, sustainable plan to manage population and get paid for services; policies and procedures to manage population – NCQA? Segment patient population by disease state?
 - Physician compensation – new payment models to reward value (shared savings not long term solution)
 - Data warehouses; predictive modeling; dashboards

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LEGAL CONSIDERATIONS FOR COMMERCIAL ARRANGEMENTS

- Do not share pricing information among participants; joint contracting for risk arrangements with shared savings/loss vs. negotiating fee for service
 - Read the commercial contracts – understand cost targets, trend, minimum risk corridor, minimum savings rate, upside/downside caps, etc. Engage outside experts for assistance
 - No mandatory antitrust review under CMS program – keep on radar for commercial lines (focus on shared savings/loss contracts to mitigate)

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QUESTIONS ?

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Drug Billing Compliance in Provider Settings: Auditing Strategies

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San Diego, California
March 31, 2014

Goals

- Learn the benefits, opportunities, and challenges to conducting a drug billing risk assessment
 - Understand and evaluate accepted approaches for reviewing complex unknown risk in an active government audit environment
 - Assess the distinct stages of assessment and review which are unique to drug billing compliance

Presentation Sections

- 1. Topics in drug billing compliance
 - 2. Conducting a drug billing audit
 - 3. Possible outcomes for a drug billing audit
 - Note 1: This lecture will focus on the principles of pharmacy billing compliance in a provider setting and not retail pharmacies – though principles discussed can be used in retail pharmacy compliance
 - Note 2: This lecture will principally use Medicare reimbursement principles as a guide for pharmacy billing compliance

Themes

1. Compliance begins with the order
2. An audit should review the life cycle:
 - From order to remittance
3. Not all deficiencies in an audit result in an “overpayment”

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Topics in Drug Billing Compliance

- HHS OIG Workplan 2013 & 2014:

Payments for Outpatient Drugs and Administration of the Drugs

Billing and Payments. We will review Medicare outpatient payments to providers for certain drugs (e.g., chemotherapy drugs) and the administration of the drugs to determine whether Medicare overpaid providers because of incorrect coding or overbilling of units. Context—Prior OIG reviews have identified certain drugs, particularly chemotherapy drugs, as vulnerable to incorrect coding. Providers must bill accurately and completely for services provided. (CMS's *Claims Processing Manual*, Pub. No. 100-04, ch. 1, §§ 70.2.3.1 and 80.3.2.2.) Further, providers must report units of service as the number of times that a service or procedure was performed. (Chapter 5, § 20.2, and ch. 26, § 10.4.) (OAS; W-00-12-35576; various reviews; expected issue date: FY 2014; work in progress)

*2014 Work Plan Reference: Pg. 22, Medicare Part A and Part B

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Topics in Drug Billing Compliance

- HHS OIG Workplan 2014

Covered Uses for Medicare Part B Drugs (New)

Quality of Care and Safety. We will review the oversight actions CMS and its claims processing contractors take to ensure that payments for Part B drugs meet the appropriate coverage criteria. We will also identify challenges contractors face when making coverage decisions for drugs. Context—If Part B MACs do not have effective oversight mechanisms, Medicare and its beneficiaries may pay for drugs with little clinical evidence of the drugs' safety and effectiveness. Medicare Part B generally covers drugs when they are used to treat conditions approved by the Food and Drug Administration, referred to as "on-label" uses. Part B may also cover drugs when an "off-label" use of the drug is supported in major drug compendia or when an off-label use is supported by clinical evidence in authoritative medical literature. (Social Security Act, § 1861(t).) (OEI; 03-13-00450; expected issue date: FY 2014; work in progress)

*2014 Work Plan Reference: Pgs. 22-23, Medicare Part A and Part B

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Topics in Drug Billing Compliance

1. Is there a written drug order?
2. Is there documentation of administration of the drug?
3. What are the billing units per amount of drug?
4. Are the units billed equal to the amount administered?
5. Is wastage billing allowed?
 - (Does the wastage amount need to be identified on the claim?)
6. If there is a billing error, did it result in an overpayment?

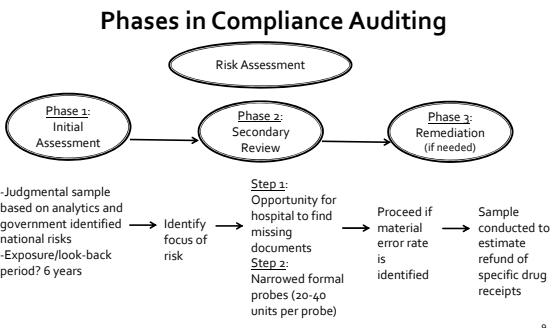
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Conducting a Drug Billing Audit

- Questions to consider:
 - **Which drugs will be audited?**
 - Consider: specific high-volume and high-value drugs
 - Drugs identified in OIG Workplan and national audits (e.g., Herceptin)
 - **What time period?**
 - Baseline audit ("are we doing it correctly today?"): within current fiscal year
 - Routine not-for-cause: within current fiscal year or consider two fiscal years to analyze what happens when changes in pharmacy chargemaster occur
 - Clean-up not-for-cause ("this is a high risk area; what is our exposure?"): consider statute of limitations period (generally 6 years)
 - For-cause: time period errors are suspected or consider statute of limitations period
 - **How large is the sample?**
 - Probe review: 20-40 similar units
 - Probes for each drug? Each year? Patients per year?
 - Local circumstances will drive sample size and design

8

Conducting a Drug Billing Audit



9

Conducting a Drug Billing Audit

- Drug billing audits may need to be conducted in several phases
- For the first phase, generally use a "no assumptions" approach
 - "If it isn't documented, then it didn't happen"
 - This approach will provide a window into immediate risk exposure from an external audit, how well documents are provided, and allow the broadest recommendations for improvement
- For the second phase, dig deeper to find missing documents or confirm with clinicians what is implied in medical record but not explicit
- For the third phase, determine whether error caused a financial impact

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Conducting a Drug Billing Audit

- Documents needed:
 - Medical record
 - Physician's order
 - Administration of drug
 - Shadow charts?
 - Claim forms
 - Detailed charges captured for generating claim form
 - Remittance advice (what was paid)
 - Miscellaneous?
 - Pharmacy reconciliation reports

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Conducting a Drug Billing Audit

- Understand the documentation landscape
 - Audit identifies missing documents associated with drugs often not known to be missing until audited
- Are records electronic or paper? Or combination of both?
- If crossing time period into EMR, when did EMR go live? Did it go live for all departments or was it staged?
- If records are in EMR, do auditors have access to the right parts of the EMR?
 - Is there access to the e-medication administration records (MARS)?
- Are there legacy issues relating to:
 - Stamped signatures on physician order forms?
 - Possible shadow charts outside of EMR?
 - Series accounts billed consistently though dosage dropping?

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Conducting a Drug Billing Audit

- Items to know about the drug being audited:
 - Drug J Code (HCPCS)
 - Generic Drug Name
 - Proprietary Drug Name
 - On Label Indication
 - Off Label and/or Compendial Listing
 - How Supplied
 - Units for Billing
 - Any applicable NCDs or LCDs?

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Conducting a Drug Billing Audit

▪ Notes on Billing Units:

- When billing drugs, units of service must be billed in multiples of the dosage specified in the full HCPCS descriptor.
- If the dosage given is not a multiple of the HCPCS code, the provider rounds to the next higher unit in the HCPCS description for that code.
- For example, if 2.5 milligrams of Zoledronic Acid is administered, it is appropriate to bill for 3 units, as the HCPCS defines the unit for Zoledronic Acid as 1 milligram.

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Conducting a Drug Billing Audit

▪ Notes on Billing for Wastage:

- If after administering the prescribed dosage of any given drug, the provider must discard the remainder of a single-use vial or other package, Medicare may cover the amount of the drug discarded along with the amount administered. The following elements must be followed in order for the discarded amount to be covered.
 - 1. The vial must be a single use vial. Multi-use vials are not subject to payment for any discarded amounts of the drug.
 - 2. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient.

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Conducting a Drug Billing Audit

▪ Notes on Billing for Wastage:

- Example:
 - HCPCS J0152, Injection, adenosine for diagnostic use, 30 mg
- Doses available from the manufacturer include:
 - 6 mg, 12 mg, and 60 mg
- The amount prescribed for the patient is 70 mg. If the provider uses two 60 mg vials to administer the dose, the provider may only bill 3 units (rather than 4 units) as the doses available from the manufacturer allow the prescribed amount to be administered with a 60 mg vial (2 units) and a 12 mg vial (additional unit).

16

Possible Outcomes for a Drug Billing Audit

- *Think through the potential errors and implications ahead of time*
- Not all errors result in “overpayment”
- Distinction between:
 - Condition of Participation error – usually no overpayment
 - Condition of Coverage/Payment error – possible overpayment

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Possible Outcomes for a Drug Billing Audit

- Conditions of Participation:
 - Administrative requirements for participating in a federal health care program
 - Often organizational requirements rather than payment or service specific
 - *Example:* All documents must be completed (including signed) within 30 days after discharge
 - Noncompliance with conditions of participation risk administrative sanctions, but noncompliance usually does not result in a payment impact
- Conditions of Coverage/Payment:
 - Requirements in order to receive reimbursement for specific items and services
 - Often very detailed rules about specific items and services
 - *Example:* Payment for drug only allowed when it is ordered for a medically accepted use
 - Noncompliance with conditions of coverage/payment may result in receiving an “overpayment” if item or service should not have been billed

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Possible Outcomes for Drug Billing Audit

- What could be specific dispositions within a drug billing audit?
 - Missing order
 - Unsigned verbal order
 - Unapproved use
 - No evidence of administration
 - Not administered as ordered
 - Over-billed units
 - Under-billed units
 - Missing record
 - MISCELLANEOUS (always leave room for the unknown!)

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Possible Outcomes for Drug Billing Audits

- Are the errors conditions of participation or conditions of coverage/payment errors?
- If conditions of participation error, then identify documentation improvement needs
- If conditions of coverage/payment error, then check remittance advice:
 - Did the provider receive a bundled payment?
 - If so and no outlier payment, then likely no overpayment (assuming drug is not driving the bundled payment)
 - If so and received an outlier payment, then drug billing error may have contributed to receiving outlier payment
 - Did the provider receive a pass-through payment?
 - If so, then drug billing error may have contributed to receiving outlier payment

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- Questions/Discussion

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Not a Quality Expert? How Do you Integrate Quality into Your Compliance Program

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2014 HCCA Compliance Institute
March 31, 2014 – San Diego, California

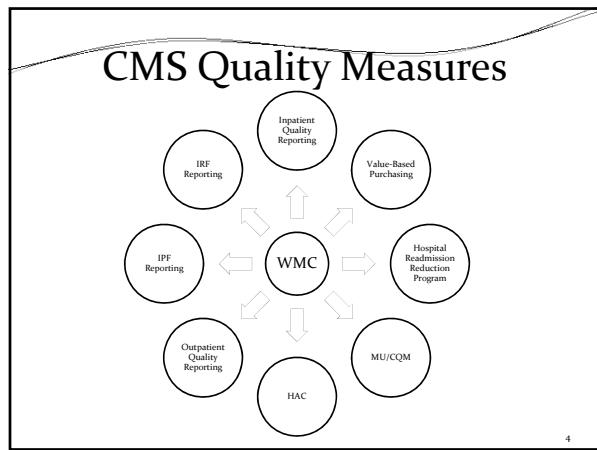
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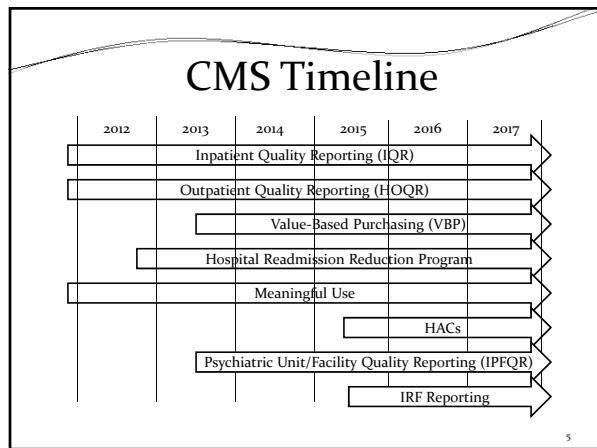
- What is Quality?
- Overview of national quality reporting requirements.
- NY State compliance program requirements related to Quality.
- Quality and Compliance: What does all this mean?
- Identification of internal data collection and reporting.
- Data Integration
- Quality and Compliance Program Integration
- Compliance monitoring and reporting

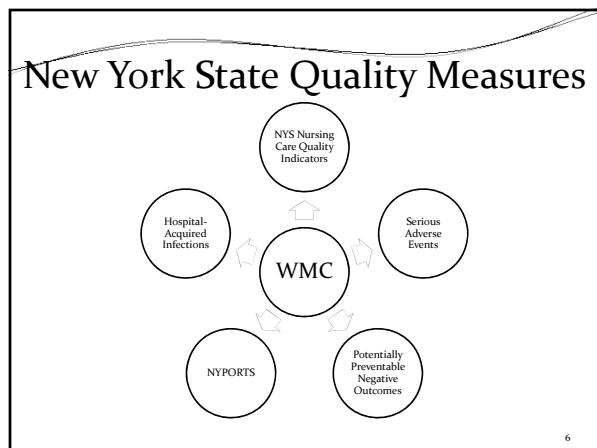
What is Quality?

- The Institute of Medicine (IOM) has defined health care quality in six parts in *Crossing the Quality Chasm*¹:
 - Safe
 - Effective
 - Patient-centered
 - Timely
 - Efficient
 - Equitable

¹ *Crossing the Quality Chasm*, Institute of Medicine, 2001







Compliance Programs in NY State

- May 2012 – OMIG published Compliance Program Guidance for General Hospitals.
- Compliance role/expectations with Quality referenced in several compliance program elements:
 - Element 1: Written policies and procedures
 - Element 2: Designation of Compliance Officer
 - Element 7: Responding to compliance issues

7

Written Policies and Procedures

- Code of conduct identifies compliance expectations relating to quality of care.
- Policies and procedures address compliance expectations for quality of care and quality and adverse incident reporting to the DOH.
- Policies and procedures address reporting and attesting for payment through Medicaid and Medicaid Electronic Health Records Incentive Programs.

8

Designation of Compliance Officer

- Compliance Officer attends meetings or receives reports on compliance matters in areas that may include quality.
- Compliance Officer promotes quality.
- Information regarding patterns or concerns relating to quality of care are reported to the Compliance Officer.
- Compliance Officer attends QI meetings.

Responding to Compliance Issues

- Compliance Officer attends and participates in Quality Improvement and other committees.

9

Quality and Compliance: What Does All This Mean?

- Competing initiatives
- Leadership support
- Staff expertise?
- How do we choose?
- Staff buy-in?
- What do we do with the information?

10

First Steps to Consider to Integrate Quality & Compliance

- Look at your hospital structure
- What is your relationship with the Director of Quality?
 - How is compliance viewed in the Quality arena?
- Is there buy in at your senior management level?
- Have you had a discussion with your CEO
 - Program expectation as a whole;
 - How is Quality and Compliance viewed at the CEO level;
 - Is there buy in?

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Westchester Medical Center Structure

- Quality committee, sub councils on quality
- Sub-councils on Quality that report to the Quality Committee
 - Children's Hospital
 - Behavioral Health Hospital
 - Acute Care Hospital
- Team members
 - Quality , Nursing, Administrator, Chairman, UR, Individual Department reps
- Quality Committee of the Board

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WMC Integration Steps

- Alignment with Director of Quality
- Discussion with CEO
- Meeting with Director of Quality, CMO and CEO
 - Determine boundaries, if any
 - How will data and information be disseminated
 - Compliance Officer Role
- Presentation at Executive Compliance Committee
 - Senior Management Team

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Integration Process

- Member of the Quality Committee
 - Attend sub-committees as needed
- All reports copied to compliance officer for review
- Sentinel Events
- Root Cause Analysis (RCA)
- Corrective Action Plans (CAPs)
 - Monitored to completion
- Data transformed to Compliance Dashboard
 - CEO & Senior Management Team
- Data included in Audit Status Report to Board Audit & Compliance Committee

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Data Review by Compliance

- Target areas
 - Value-Based Purchasing (VBP) – Clinical Care & Patient Experience Measures
 - Meaningful Use
 - Hospital Acquired Conditions (HACs)
 - Never Events
- Analysis
- Reports

15

Value-Based Purchasing

- 12 Clinical process measures; (IQR) program
 - AMI, HF, PN, etc.
- 9 Patient experience measures; (HCAHPS)
- Status and Oversight
- Outcomes Management

16

Meaningful Use

- Medicare/Medicaid
 - Steps Taken
 - Measurement
 - Status

17

Never Events

- Occurrence
- Reporting
- Root Cause Analysis (RCA)
- Corrective Action Plans (CAP's) and/or Quality Improvement (QI) Program
- Follow up and Monitoring

18

Hospital Acquired Conditions (HACs)

- Report Review
 - MIDAS (data capture system)
- Case Review
- Multidisciplinary Team Review
- Financial Effect
- Quality Initiative

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Report Reviews

- Quality committee
 - Reviews reports from sub council
 - Data analysis reports reviewed
 - Respective discussion
- Compliance Reports integrate Quality Reports
 - Create quality summary report (publisher)
 - List Scores on Value-Based Purchasing (VBP)
 - List Never Events
 - List Hospital Acquired Conditions (HACs)
 - Corrective Action Plans (CAPs)
 - Discuss Plan
 - Timelines

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The Dashboard Report

- Use word document or publisher;
- Categorize your own related quality indicators to report out based on your quality team objectives;
- List the timeline and responsible manager for the completion of the corrective action plan (CAP);
- Use traffic light indicators that show status improvement;
- Finalize the document in PDF format and attach to your dashboard via SharePoint;
- Update bi-weekly or monthly; and
- Message your senior management team every time the dashboard is updated

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Dashboard

- Compliance and Quality interface on dashboard for:
 - Senior Management access for review
 - Required actions and follow up information
 - Executive Compliance Committee Discussions
 - Encourage interactive discussions on SharePoint
 - Audit & Compliance Committee of the Board
 - Interactive discussions on SharePoint; no paper documents
 - Committee meeting status discussions
 - Requested report out by responsible manager

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Questions



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Westchester Medical Center

Corporate Compliance Dashboard

Information Current As of April 1, 2013

Program Component	Next milestone/Activity	Comments	Status
Training & Education:			
• 2013 Mandatory Annual Education	Rollout Date: April 1, 2013		
Communications:			
• Compliance Tips	Quarterly publication		
• Newsletter	Quarterly publication		



Action Items Current



Action Items Due Within 2 Weeks



Action Items Overdue

2012—2013 Corporate Compliance Work Plan

Program Component	Audit Name	Audit Stage	Responsible VP	Senior Mgmt.	Action Items	Date Due	Status
Auditing—Work Plan	Inpatient Rehab (IRF) Coding & Documentation Audit	Draft Report			.		
	Inpatient Cardiac Defibrillator Documentation Audit	Deferred to 2nd Q 2013					
	OB/GYN ultrasound and E/M services	Field Work					



Action Items Current



Action Items Due Within 2 Weeks



Action Items Overdue

2012—2013 Corporate Compliance Work Plan

Program Component	Audit Name	Audit Stage	Responsible VP	Senior Mgmt.	Action Items	Date Due	Status
Auditing—CAP(s)							

Program Component	Audit Name	Audit Stage	Responsible VP	Senior Mgmt.	Action Items	Date Due	Status
Auditing—Special Request							

 Action Items Current Action Items Due Within 2 Weeks Action Items Overdue

Quality Monitoring Program	Monitored Pro-	Identified Variance	Var-	Responsible VP	Senior Mgmt.	Action Items	Date Due	Status
VBP								
MU								
HACs								
Never Events								



Action Items Current



Action Items Due Within 2 Weeks



Action Items Overdue

 Health Care
Compliance
Association
HCCA
Compliance Institute
San Diego, CA
April 1, 2014

Assessing and Mitigating Risk Under the HIPAA Omnibus Rule

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Chief Legal & Compliance Officer
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Agenda

2

- Omnibus Rule – Critical Elements
 - Disclosures to Health Plans
 - Business Associates
 - Breach Notification
- Addressing Risk
- Assessing Risk
 - Risk Assessment Documents
- Mitigating Risk
 - Corrective Action Plans
- Monitoring
- Summary/Q & A

HIPAA Omnibus Rule - Changes

3

- Business Associates and subcontractors
- Breach notification
- Marketing
- Sale of PHI
- Fundraising
- Notice of Privacy Practices
- Individual access to ePHI
- Third party designation for receipt of PHI
- Research
- Decedent PHI
- Student Immunization Records
- Restriction on health plan disclosures



Review of Critical Elements

4

Restrictions on Health Plan Disclosures:

- New Rule – Patients may restrict information provided to health plans if:
 1. If the patient requests the restriction;
 2. The patient has paid in full for the service or healthcare item;
 3. The disclosure would have been for payment or healthcare operations and is not required by law.

Application – Breach Notification Requirements

5

The Challenges of Restrictions on Disclosures to Health Plans:

- How do you flag requests?
- Are staff trained on how to respond to requests?
- Does your record system have a mechanism to flag these disclosures?

Review of Critical Elements

6

Business Associates and Subcontractors:

- “Maintains” now included in the definition of Business Associate
 - Anyone who stores PHI, even if it is not accessed, is a BA
- Privacy protection requirements are now extended to subcontractors of business associates
- All Business Associates must comply with the Security Rule requirements for safeguards:
 - Administrative
 - Physical
 - Technical
- BAs now have Civil and Criminal liability
- Covered Entities are responsible for breaches of BAs through “Agency Liability”

Application – Business Associate Agreements

7

The Impact of BA Changes to Covered Entities:

- The Covered Entities (CE) does not need a BAA with a subcontractor
 - The BA must have a BAA with the subcontractor
 - The subcontractor must agree to the same restrictions and conditions as the BA
- CEs should:
 - Revise their BAA to require subcontractor compliance
 - Obtain **assurances** (in the BAA) that the BA monitors compliance by the subcontractor
 - Consider **indemnification** clause in the BAA
 - * CEs are responsible no matter what...try to protect yourself

Review of Critical Elements

8

Breach Notification Rules:

- Old Rule – A reportable breach occurs if 3 elements are present:
 1. Violation of the Privacy Regulations
 2. Unsecured PHI
 3. Substantial risk of financial, reputational, or other harm to the individual
- New Rule – A reportable breach is **PRESUMED** to have occurred if:
 1. There is a violation of the Privacy Regulations that includes
 2. Unsecured PHI

Unless ... “low probability” that PHI has been compromised

Review of Critical Elements

9

Breach Notification (Continued):

- “Low Probability” is based on 4 factors:
 - What was the nature and extent of the protected health information (PHI) involved, including the types of identifiers in the information and the likelihood of re-identification?
 - To whom was the unauthorized information disclosed?
 - Was the PHI actually acquired or viewed?
 - What was the extent to which the risk to PHI has been mitigated?

Application – Breach Notification Requirements

(10)

The Impact of Breach Notification changes:

- Change your risk assessment to evaluate the 4 factors
- As a practical matter...
 - The outcome of your assessment may not change
 - Obtain **assurances** (in the BAA) that the BA monitors compliance by the subcontractor
 - Consider **indemnification** clause in the BAA
 - * CEs are responsible no matter what...try to protect yourself

Addressing Risk

(11)

Assessing Risk – Required by the Security Regs:

- Conduct an accurate and thorough assessment of the potential risks and vulnerabilities...of [ePHI]" 45 CFR 164.308(a)(1)(ii)(A)

Mitigating Risk – Required... by the Security Regs:

- Security Regs: "...mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity;" 45 CFR 164.308(a)(6)(ii)
- Privacy Regs: A covered entity must mitigate...any harmful effect that is known to the covered entity of a use or disclosure of [PHI]..." 45 CFR 164.530(f)

Addressing Risk

(12)

Monitoring Risk – Compliance Program Guidance:

- An ongoing evaluation process is critical to a successful compliance program. The OIG believes that an effective program should incorporate thorough monitoring of its implementation and regular reporting to senior hospital or corporate officers. (Compliance Program Guidance for Hospitals, Section F)

Disclosures to Health Plans

(13)

- Are we assessing, mitigating, or monitoring?
 - Step 1: Assess the process
 - Step 2: Identify deficiencies
 - Step 3: Develop corrective action
 - Step 4: Report completion of corrective action
 - Step 5: Monitor/Test the new process

Disclosures to Health Plans

(14)

- Look at Risk Assessment Document:

Risk Area:	Patient request for restriction on PHI disclosed to health plans.
Description:	Under the HIPAA Omnibus Rule, a patient may request that a covered entity restrict the information that is provided to a health plan IF 3 conditions are satisfied: <ol style="list-style-type: none">1. The patient specifically requests the restriction of PHI;2. The patient has paid in full for the restricted services; and3. The disclosure to the health plan would otherwise be permitted for payment or health care operations.

- Who completes this document?
- What level of detail is required?
- What is the purpose of this document?

Disclosures to Health Plans

(15)

- For our purposes, assume a process is in place...now what?
 - Testing – Depends on the level of risk
 - Mitigation?
 - Monitoring?

Disclosures to Health Plans

(16)

- Assume there is no process because, “We can’t track it”:
 - Why? Why? Why? Why? Why?
 - Who’s job is this?
 - What is your role in this?
- Don’t forget the practical...
 - How often does this happen?

Business Associate Agreements/Subcontractors

(17)

- Are we assessing, mitigating, or monitoring?
- Look at the Risk Assessment document:

Risk Area:	Extension of BAA to subcontractors of business associates
Description:	The HIPAA Omnibus Rule extended to covered entities liability for uses and disclosures of PHI by subcontractors of business associates. Business associates must obtain reasonable assurances from all subcontractors that use, disclose, receive, transmit, or store PHI that privacy and security protections have been implemented.

Business Associate Agreements/Subcontractors

(18)

- Look at the Business Associate Disclosure Form
- Who’s responsibility is this?
- What is your role?
- What is the next step?

Business Associate Agreements/Subcontractors

(19)

- If no list or no confidence of subcontractor compliance...
 - Mitigation
 - Audit/Test
 - Sample of contracts – both BAA and non-BAA
 - Follow-up with Business Associates
 - Make sure there is a process
 - Monitor
 - Annual Sample testing
 - Don't forget WHY?

Breach Notification

(20)

Breach Notification has 2 components:

1. Process in place for breach notification
2. Methodology to avoid breaches

Avoid = Assess, then Mitigate

How do you avoid a breach?

- Know how a breach could occur:
 - PHI leaving the organization

Breach Notification

(21)

Breach Notification has 2 components:

1. Process in place for breach notification
2. Methodology to avoid breaches

Avoid = Assess, then Mitigate

How do you avoid a breach?

- Know how a breach could occur:
 - PHI leaving the organization

Breach Notification

(22)

- Risk areas for data to leave the organization:

- | | |
|---------------------------------------|-----------------------------------------|
| <input type="radio"/> Employees | <input type="radio"/> Laptops |
| <input type="radio"/> Jump Drives | <input type="radio"/> CD/DVD |
| <input type="radio"/> Hard Drives | <input type="radio"/> External Storage |
| <input type="radio"/> Copies | <input type="radio"/> Paper Records |
| <input type="radio"/> Fax Machines | <input type="radio"/> e-mail |
| <input type="radio"/> Misdirected VPN | <input type="radio"/> Hacking/Intrusion |

Media Re-Use and Disposal

(23)

- Look at Risk Assessment for hard drives

Risk Area:	Media Re-Use and Disposal
Description:	Media that is no longer in use but contains PHI must be destroyed or the retained data rendered unusable.

Media Re-Use and Disposal

(24)

- Is this automatically a problem?
- What happens if it is?
 - Who's job is it?
 - What is your role?
 - Provide the standard/Policy Development
 - Identify the risk
 - Quantify the risk
 - Request updates
 - Report



[COVERED ENTITY]
Business Associate Disclosure Form

Pursuant to the Business Associate Agreement ("BAA") between **[COVERED ENTITY]** and your company, and as a result of changes to the HIPAA Privacy regulations resulting from the Omnibus Rule, we request that you answer these questions, sign the form below, and return the form to the address/fax/e-mail listed below.

Question		
1.	Do you intend to use subcontractors for any service contemplated under the contract between your company and [COVERED ENTITY] ?	<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	If the answer in Question 1 is "yes", will the subcontractors use, disclose, transmit, receive, or store protected health information?	<input type="checkbox"/> Yes <input type="checkbox"/> No
3.	If the answer in Question 2 is "yes", is there a BAA in place between your company and all subcontractors?	<input type="checkbox"/> Yes <input type="checkbox"/> No
4.	If the answer in Question 3 is "no", please list the date by which a BAA will be in place for all subcontractors: (note, this is required by our existing BAA)	
5.	If the answer to Question 2 is "yes", have you obtained reasonable assurances from the subcontractor that it has implemented a HIPAA privacy and security program to mitigate the risk of inappropriate disclosure of PHI?	<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	If the answer to Question 5 is "no", please list the date by which reasonable assurances from the subcontractors will be obtained: (note, this is required by our existing BAA)	
7.	If the answer to Question 2 is "yes", have you validated that the subcontractors have a HIPAA privacy and security program to mitigate the risk of inappropriate disclosure of PHI?	<input type="checkbox"/> Yes <input type="checkbox"/> No
8.	If the answer to Question 7 is "no", please list the date by which you will validate that subcontractors have implemented a HIPAA privacy and security program to mitigate the risk of inappropriate disclosure of PHI: (note, this is required by our existing BAA)	

I understand that **[COVERED ENTITY]** will rely on the representations made in this document to demonstrate its compliance with the HIPAA Privacy and Security Regulations as amended.

Company: _____

Signature

Date

Printed Name

Title

Information Security	No. IS-018
Title:	Page: 1 of 1
<u>Media Re-use and ePHI Disposal</u>	Effective Date: June 1, 2013
<u>Citation:</u> 45 CFR §164.310(d)	Review Date: June 1, 2014
	Previous Versions Dated: N/A
	Approved By: Chief Legal & Compliance Officer

SCOPE: All Employees

PURPOSE: Establish and maintain procedures addressing final disposition of ePHI and/or hardware or electronic media on which ePHI is stored.

POLICY: PlusDelta Technologies, LLC (“PlusDelta”) will implement required device and media control procedures to ensure that all media that contains ePHI is rendered unusable prior to being re-deployed within or outside of PlusDelta OR destroyed prior to disposal of the media.

REQUIRED PROCEDURE

1. The Security Officer or designee is responsible for final disposal of ePHI to determine and document appropriate methods to dispose of hardware, software, and ePHI.
2. On an annual basis, the Security Officer will identify removable storage devices and current use assuring that ePHI on removable, reusable media such as tapes, CDs, hard drives and file servers is properly destroyed, e.g., degaussed, and cannot be recreated.
3. The Security Officer, in conjunction with outsourced IT partners, are responsible for overseeing the appropriate reuse of electronic media, ensuring that ePHI previously stored on electronic media cannot be accessed and reused.
4. Employee training will address security and risks to ePHI when reusing software and hardware.
5. The Security Officer will maintain records of hardware, media, and assign personnel to ensure that ePHI is not inadvertently released or shared with any unauthorized party and that appropriate personnel are assigned responsibility to record receipt and removal of hardware/software containing ePHI.

2014 HIPAA Risk Assessment

Risk Area:	Extension of BAA to subcontractors of business associates	
Description:	The HIPAA Omnibus Rule extended to covered entities liability for uses and disclosures of PHI by subcontractors of business associates. Business associates must obtain reasonable assurances from all subcontractors that use, disclose, receive, transmit, or store PHI that privacy and security protections have been implemented.	
No.	Workstep	Response
Confidentiality		
1.	What is the process to identify the contracts in which the contractor will use, disclose, receive, transmit, or store PHI?	
2.	Have all Business Associates who use, disclose, receive, transmit, or store PHI been identified?	
3.	Have all Business Associates completed, signed and returned a Business Associate Disclosure Form?	
Integrity		
1.	Is there a system to identify which contractors receive a BAA?	
Accessibilty		
1.		
Scalability		
1.	Is there a system in place that identifies all contracts, a notation of whether the contract requires a BAA, and a brief description of the contract services?	

2014 HIPAA Risk Assessment

Risk Area:	Patient request for restriction on PHI disclosed to health plans.	
Description:	<p>Under the HIPAA Omnibus Rule, a patient may request that a covered entity restrict the information that is provided to a health plan IF 3 conditions are satisfied:</p> <ol style="list-style-type: none"> 1. The patient specifically requests the restriction of PHI; 2. The patient has paid in full for the restricted services; and 3. The disclosure to the health plan would otherwise be permitted for payment or health care operations. 	
No.	Workstep	Response
Confidentiality		
1.		
Integrity		
1.	Are technical safeguards in place to ensure that records are properly flagged as restricted from disclosure?	
Accessibilty		
1.	Do current policies and procedures define how to receive, document and respond to requests for restrictions of PHI?	
2.	Have staff been trained on how to respond to requests for restrictions of PHI to health plans?	
Scalability		
1.	Does the current medical record system have the capability to document requests for restrictions?	
2.	Does the current medical record system have the capability to restrict information disclosed to health plans for payment or health care operations?	
3.	If not, what steps are in place to comply with this requirement?	

2014 HIPAA Risk Assessment

Risk Area:		Media Re-Use and Disposal
Description:		Media that is no longer in use but contains PHI must be destroyed or the retained data rendered unusable.
No.	Workstep	Response
Confidentiality		
1.	What is the process to identify whether media that is no longer in use contains PHI?	
2.	What is the process to inventory media to ensure that unused media no longer contains PHI?	
3.	What is the process to ensure unused media no longer contains PHI?	
Integrity		
1.		
Accessibilty		
1.		
Scalability		
1.		


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ATTORNEYS AT LAW



Social Media in the Hospital Setting: So Much Not to “Like”

Susan Childs, RN, BSN, CPHRM
Dayton Children's Hospital
Liz Stock, Esq.
Bricker & Eckler LLP
Chris Bennington, Esq.
INCompliance Consulting



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Say Cheese!



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One Little Facebook Post...

“Just performed my first circumcision. I'll be pouring one out tonight for all the lost foreskin.... #rip”

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... Can Result in Big Problems



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What We'll Cover Today

- Social Media Overview
- Employment Issues
- Social Media and HIPAA
- Real world examples and tips
- Q&A

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Disclaimer

This presentation does not constitute legal advice, and you should consult with a lawyer before relying on any statement in this presentation.

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Social Media

- Social Media is a “conversation” your hospital may or may not be engaged in formally – but the conversation is going on – and most likely includes your employees
- 2013 survey showed that 67% of online American adults have a profile on a social media site (83% in 18-29 age group)

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Social Media



- ▶ Uses internet and web-based technologies to transform broadcast media *monologues* (one to many) into social media *dialogues* (many to many).
- ▶ Transforms people from *content consumers* into *content producers*.

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Facebook



- ▶ More than 1.23 billion active monthly users (Jan. 2014)
- ▶ 757 million users log into Facebook daily (Jan. 2014)
- ▶ 945 million mobile users (Jan. 2014)
- ▶ Every day: 4.5 billion “likes”; 350 million photos added (May 2013)
- ▶ Size of Facebook database: Over 300 Million GB (Nov. 2013)

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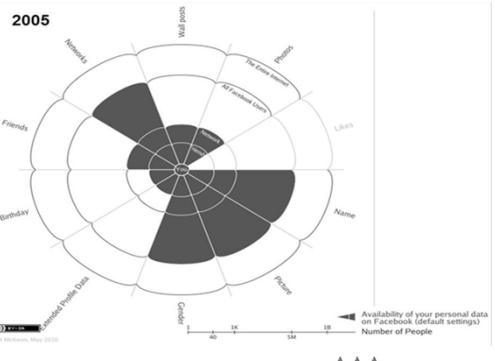
Facebook's Default Privacy Settings

- ▶ A brief year by year history – reflecting society's trend of becoming "more open?"
- ▶ The Evolution of Facebook's Privacy Settings" by Matt McKeon from Visual Communication Lab (@mattmckeon).

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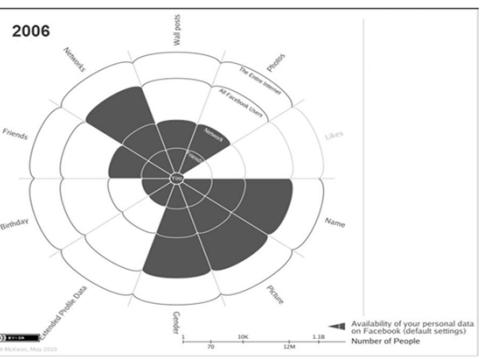
10



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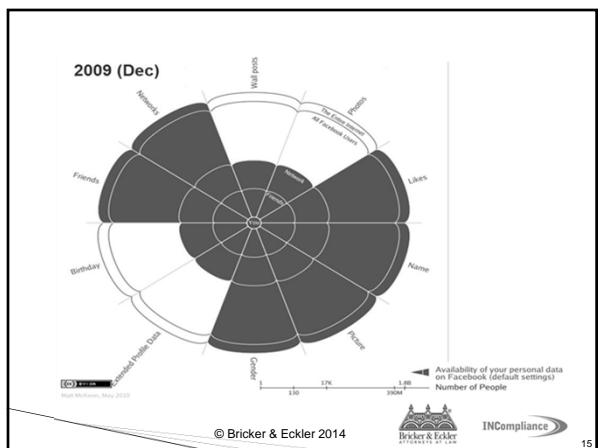
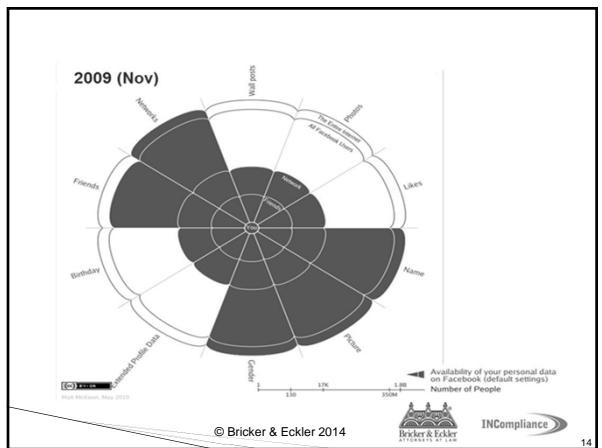
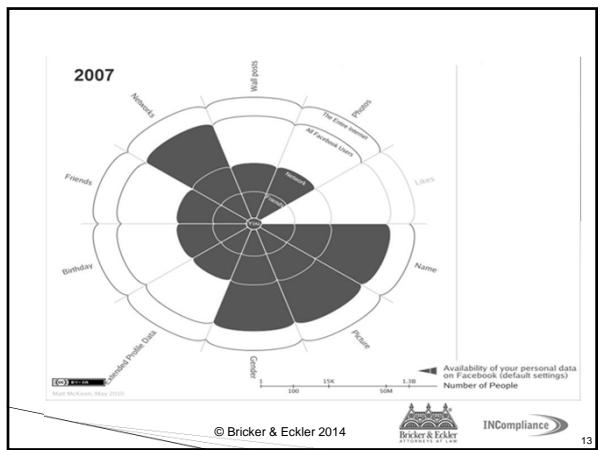
11

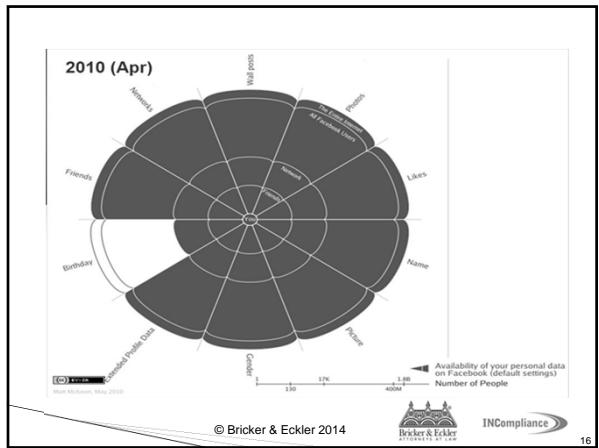


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Employers Are Asking:

- ▶ “I can’t believe one of our employees posted *that* on her Facebook page! Can I fire her?”
- ▶ “I Googled that applicant. Can I/should I use the information I found as grounds for not hiring him?”
- ▶ “Should my supervisors be posting recommendations for former employees on LinkedIn?”

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Social Networking and the Employment Lifecycle

- ▶ Potential impact of social media on your hospital from an employment perspective:
 - The Potential Employee
 - The Former Employee
 - The Current Employee

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The Potential Employee

- ▶ Should you use social media to make hiring decisions?

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The Potential Employee

- ▶ Pay Dirt: online disclosures vs. résumé, application, or job interview disclosures
- ▶ Risk becoming “pregnant” with information that would be unlawful to use in making a hiring decision (e.g., religious beliefs, medical history, prior workers’ compensation claims, etc.)

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The Potential Employee

- ▶ Limit searches to public information
- ▶ Do not obtain user’s or another person’s password to obtain access to non-public data
- ▶ Segregate the searchers from the employment decision-makers

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The Potential Employee

- ▶ Some States have laws that prohibit:
 - Asking applicants or employees for their social network password
 - Taking adverse employment action for lawful conduct outside the workplace

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The Former Employee

- ▶ LinkedIn: provides a unique opportunity to make recommendations regarding current or former employees
- ▶ But, supervisor may create evidence of “pretext” regarding the reason for a termination

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The Current Employee

- ▶ Use of social media on work time/equipment:
 - What do your current policies say?
 - What are your *actual* practices?
 - Consider extent of hospital use of social media and guidance needed for those posting on hospital's behalf

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Dayton Children's

- ▶ www.twitter.com/daytonchildrens
- ▶ www.youtube.com/daytonchildrens
- ▶ www.facebook.com/wally.b.bear
- ▶ www.twitter.com/SKGreaterDayton
- ▶ www.facebook.com/daytonchildrens
- ▶ www.facebook.com/safekidsgreaterdayton
- ▶ www.facebook.com/womensboard
- ▶ www.facebook.com/twigaux
- ▶ www.facebook.com/carehousedayton
- ▶ www.Pinterest.com/daytonchildrens
- ▶ blog.childrensdayton.org
- ▶ Instagram – Username : Dayton Childrens

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The Current Employee

- ▶ Main problem area: Off-duty use by employees
- ▶ Just One Example
 - Anonymous report on compliance hotline
 - Nurse posed for photos in OR wearing medical bra over scrubs
 - Posted photos to Facebook

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Physicians

- ▶ Must be careful not to jeopardize professional ethics and/or patient privacy
- ▶ Federation of State Medical Boards recently issued guidance on the appropriate use of social media in the medical practice.
<http://www.fsmb.org/pdf/pub-social-media-guidelines.pdf>

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Ob-gyn Vents on Facebook

- ▶ New York Daily News article – Feb. 7, 2013
- ▶ Ob-gyn rants on Facebook about a patient she claims was repeatedly late for appointments

"So I have a patient who has chosen to either no-show or be late (sometimes hours) for all of her prenatal visits, ultrasounds and NSTs. She is not 3 hours late for her induction. May I show up late to her delivery?"

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The Current Employee

Consider a policy to prohibit:

- ▶ Disclosure of PHI (more later)
- ▶ Unauthorized disclosure of confidential information
- ▶ Posting content that is false, obscene, threatening, defamatory, illegal
- ▶ Posting information disruptive to your hospital's ability to operate effectively and efficiently

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The Current Employee

- ▶ Violation of applicable law or other policies (discrimination, harassment, HIPAA, etc.)
- ▶ Friending patients
- ▶ Speaking or posting on behalf of your hospital without express authorization
- ▶ Providing medical advice via social media

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The Current Employee

CAUTION!

- ▶ There are various legal limitations on an employer's ability to prohibit certain employee activity.
- ▶ Ensure policies are not overly restrictive of employee rights under the law.

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National Labor Relations Act

- ▶ Prohibits discrimination or retaliation against non-supervisory employees who engage in "protected concerted activity"
 - Includes discussions of wages, benefits, dress code, assignments, and other work responsibilities amongst employees.
 - Does not include "mere griping" or employee's activity for purely personal interest.

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National Labor Relations Act

- ▶ Example:
 - Caseworker employed by non-profit social services provider threatens to complain to supervisor about co-workers not working hard enough
 - Coworker posts: "My fellow co-workers, how do you feel?"
 - Other coworkers respond:
 - "Try doing my job. I have five programs."
 - "What the hell, we don't have a life as is."
 - Coworkers fired for harassment
 - NLRB decision: Terminations unlawful

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National Labor Relations Act

► Example:

- Bartender unhappy about not receiving a raise for 5 years complains on Facebook:
 - Calls customers “rednecks” and says he hopes they choke on glass as they drove home drunk
- Bartender fired
- NLRB: Termination lawful; personal venting and not “concerted activity”

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National Labor Relations Act

► What about:

- Nurse posts that hospital provides poor patient care?
- Nurse goes on to criticize nurse-patient ratio and benefits paid to nursing staff?
- Other nurses join the discussion?

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Other Laws

- Whistleblower protections
- State laws prohibiting termination for lawful conduct outside of work
- First Amendment (public employers only)
- Invasion of privacy
- Stored Communications Act

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HIPAA

FierceHealthcare
ONLY NEWS FOR HEALTHCARE EXECUTIVES
Published on FierceHealthcare (<http://www.fiercehealthcare.com>)

Photos of dying patient posted to Facebook get four hospital workers fired

By Amy M. Williams
Created April 9, 2012 - 1:20pm
Instead of treating a 60-year-old stabbing victim after his initial arrival at St. Mary Medical Center's ER, nurses and other staff took photos of the man and posted them on Facebook, the Los Angeles Times reports.

William Wells, the patient, had been stabbed more than 12 times by a fellow nursing home resident. His death was ruled a homicide.

Police arrested his suspected attacker.

The breach of patient privacy, which occurred on April 7 at the Long Beach, Calif.-area hospital, is the fourth such case in California this year, according to Chuck Idelson, a spokesman for the Times. Neither of the two nurses involved was fired.

Nurses and staff posted a photograph of Wells on their public Facebook accounts for about two days before someone at Cedars-Sinai Medical Center, an employee who saw the photo and reported it to the hospital told the Times. Hospital staff also downloaded the photo attached to text messages, the employee said.

The hospital has since removed the photo from its website.

A spokesman for the California Nurses Association, which represents nurses, said he believes it's rare for nurses to post unauthorized patient photographs online.

"Nurses are very private people. They are not like other health care providers who post patient-related information online, because they view sites as 'an open book,'" Chuck Idelson, the spokesman told the Times.

Deborah Child, an ER at Cedars-Sinai's emergency room, told the Times that she knows many nurses who write about patients on Facebook. Some even do it while they're on the job.

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HIPAA

- The Health Insurance Portability and Accountability Act of 1996.
- Privacy Rule - regulates the use and disclosure of "Protected Health Information (PHI)" held by "Covered Entities."
- **This includes PHI disclosed via Social Media.**

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Who is covered?

Covered Entities: Providers, Health Plans, and Health Care Clearinghouses

Workforce: HIPAA applies to a Covered Entity's workforce, which includes: employees, volunteers, trainees, and other persons whose conduct, is under the direct control of the Covered Entity

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What is PHI?

- Information that relates to:
 1. the individual's past, present or future physical or mental health or condition
 2. the provision of health care to the individual
 3. the past, present, or future payment for the provision of health care to the individual
- Identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual

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What is PHI?

- Names, addresses, dates, phone numbers, Social Security numbers, account numbers, etc.
- Full face photographic images and any comparable images
- "Any other unique identifying number, characteristic, or code"

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Connecting Social Media and HIPAA

- Privacy Rule - Provides federal protections for PHI held by Covered Entities.
- Gives patients a right with respect to that information.
- Covered Entities may still disclose and use PHI for certain permitted purposes. Examples:
 - Treatment – Disclosures to other providers
 - Payment – Disclosures to insurers
 - Health Care Operations – Disclosures for Quality Improvement
 - Other – Disclosures to public health agencies

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Connecting Social Media and HIPAA

- **General Rule:** Patient authorization is required for disclosures
 - **Exceptions:** Treatment, payment, health care operations, and certain special categories (i.e., public health, law enforcement)
 - **If an exception does not apply, we cannot disclose without authorization.**

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Connecting Social Media and HIPAA

There is no Facebook exception.



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Connecting Social Media and HIPAA

- Common question: If there is no Facebook exception, why can the hospital post all kinds of patient information on its page?
 - Answer: The hospital obtains HIPAA compliant authorizations before posting patient information to its page (we hope!).

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Consequences

- Internal Investigation
- Disciplinary action
- Professional reputation
- Professional licensure
- Organizational reputation
- Notifications to patient, media, government
- Government Investigation
- Fines

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Social Media Breaches

CONFIDENTIAL
An impermissible use or disclosure of PHI that compromises the security or privacy of the PHI. Unless an exception applies, a use or disclosure of PHI in a manner not permitted under the Rules is presumed to be a breach unless a covered entity demonstrates that there is a low probability that the PHI has been compromised based on a risk assessment including certain factors.

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Social Media Breaches

- If a breach is “reportable,” a Covered Entity must notify the patient and Health & Human Services (HHS).
- If the breach involved 500 or more patients, the Covered Entity must also notify local media.
- HHS investigates self-reported breaches.
- HHS imposes fines for self-reported breaches.
- Most social media-related breaches will be reportable.

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Social Media Breaches

- Examples of Social Media- related breach investigations
 - Nursing student takes picture of baby having a PICC line placement and posted to Facebook
 - Employee notified of a former patient's death on Facebook
 - Anonymous report that hospital website contains photo showing patient information

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Enforcement

- HHS also learns of breaches through complaints, which may be filed by anyone.
- Fines vary; up to \$1.5 million per year.
- Associated costs can surpass \$15 million
- Patients affected may now receive part of the fine/settlement paid by the Covered Entity (Regulations forthcoming).



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Common Pitfalls

Post-Treatment: "The surgery was weeks ago. I can talk about it on Facebook now!"

WRONG. Providers have a continuing obligation to protect PHI both during and after treatment.



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Common Pitfalls

Responding to patients: "I need to defend the hospital against what this patient is saying on Facebook!"

WRONG. The HIPAA obligations are not negated by a patient's own disclosures through social media.



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Common Pitfalls

- ▶ **High Profile Patients:** "I can tell my Facebook friends that Sasha Obama was just admitted to my facility. It will be in the news anyway."
- ▶ **WRONG.** Public figures have the same HIPAA protections as everyone else. Let the news break the story.



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HIPAA/Social Media - Discipline

	Level 1 Human Error Carelessness	Level 2 At Risk Behavior Fails to follow Procedure	Level 3 Reckless Behavior Curiosity, Personal Use or Malicious Intent
Coaching/ Counseling			
Written/Final Written Warning			
Termination			

HIPAA/Social Media - Discipline			
KEY to Levels	LEVEL 1	LEVEL 2	LEVEL 3
	<ul style="list-style-type: none"> Lack of care or attention to process or procedure Carelessness that makes confidential information susceptible to being overheard, accessed or revealed to unauthorized individuals Non-intentional or inadvertent act to access or disclose confidential info without a work-related reason Failure to report disclosures 	<ul style="list-style-type: none"> Action that fails to comply with HIPAA or hospital policy or procedure resulting in potential or actual breach of information privacy 	<ul style="list-style-type: none"> Employee willfully accesses a record out of curiosity or concern; personal use or malicious intent Accesses, reviews or discloses confidential information without documented authorization

The Right Way to Use Social Media

► Provide staff with guidance on how to interact with official social media sites. Examples:

- Any photo or patient information posted by Hospital has been done so with written consent by the patient.
- You may "like" or "share" items posted on our official sites. This connects your post to our site and assures viewers we have proper authorization.
- Never post patient information or photos that were not originally posted on the official sites.
- Never provide more patient information than was posted on the official site.
- Never "friend" a person when your only relationship with that person is health care provider-patient.

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Thank you for your attention!

**Please Visit Us In
The Exhibit Hall – Booth 404**



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Challenges And Helpful Hints For Turning Low Performers Into Compliant Performers: A Road Map For Success

HCCA 18th Annual Compliance Institute

March 31, 2014

**Dr. Robert Ossoff, Special Assistant to the Vice Chancellor of Health Affairs,
Vanderbilt University Medical Center**

**Lori J. Strauss, Chief Corporate Compliance & Privacy Officer,
University of Virginia Health System**

How To Succeed As A Compliance Professional

Objectives:

1. Learn how to break down silo's through appropriate initial education.
2. Learn how to implement a monitoring program that encourages compliance.
3. Appreciate how changing the image of the Compliance Office may help to change organizational culture.
4. Learn how to recruit physician champion(s).

Quality Patient Care

The patient is the center of health care.

Health care providers – clinicians, organizations, all of those involved in healthcare – ultimate goal is to provide quality care to the patient.

- Documentation quality helps to achieve this.

Quality care is expected by our patients and our payers.

Health care organizations must deliver quality care to remain financially viable.

Compliance & Quality

Compliance complements health care providers' (HCPs) mission to deliver quality patient care by developing effective internal controls that promote compliance with applicable federal and state laws and the program requirements of federal, state, and private health plans.

- Silos focus on areas of expertise and quality patient care requires breaking down the silos.

The OIG Compliance Program Guidance documents tell us that compliance programs help to prevent fraud, waste, and abuse.

- Helps to fuse compliance and quality initiative into one.

Compliance & Quality

Compliance programs are becoming more integrated with quality of care.

Health care organizations are expected to be in full compliance with all laws and regulations that govern their businesses.

Documentation and documenting patient outcomes is critical to evaluate quality patient care.

Education & Training

Appropriate education and training are key to achieving compliance.

- Establish a culture within our organizations that promotes prevention, detection and resolution of events that do not conform to federal and state laws or the hospitals' policies and procedures.
- Education, training, and retraining are important tools to achieve a culture of compliance.

Education & Training

Challenges:

- Different backgrounds and roles
- Varying knowledge of the regulations and rules
- Multiple demands
- Engagement
- Unpredictable behavior and response to training

Successful Strategies

Help to meet training requirements

Help to transform low performing physicians and HCPs into compliant performers

Develop policies and procedures on provider education

Monitor training and compliance

Consistently apply and enforce consequences for providers that do not complete the training

Successful Strategies

Timing – critical for most situations, “timing is everything”, education should be provided at the time of employment and ongoing.

Educate physicians, other licensed independent practitioners (LIPs), billing and coding employees, nursing and ancillary service employees, finance and health information management employees, human resource staff, administrative support staff, the organizations entire workforce.

Successful Strategies

Make training meaningful – focus content pertinent to the employees role.

Offer continuing education credits to provide additional benefits to training if possible.

Successful Strategies

Content suggestions for new hires:

The entire workforce should be educated on:

- your compliance program,
- how to report suspected misconduct, and
- your non-retaliation policy for reporting in good faith.

Successful Strategies

Content suggestions for newly hired physicians and other LIPs that bill for their services:

- principles of government and private payer reimbursement
- diagnosis coding
- amending medical records,
- documenting rendered services,
- teaching physician rules where appropriate
- laws governing non-physician practitioners
- supervision and documentation requirements
- pertinent policies and procedures

Successful Strategies

More content suggestions for newly hired physicians and other LIPs that bill for their services:

- role of the Compliance Officer
- credentialing
- legibility of documentation
- with EMRs – cutting, pasting, cloning
- incident to billing requirements
- shared visit rules
- use of nursing or medical student documentation
- physician orders and verbal orders
- basic evaluation and management billing rules

Successful Strategies

The compliance training and education policy need to include ongoing education and training to maintain high compliance standards.

Auditing and monitoring is another element of effective compliance programs.

Auditing and monitoring can complement your organization's training and education.

Successful Strategies

Impacts of Auditing & Monitoring on Training:

Have staff with expertise in federal and state health care laws, regulations, statutes, and other coding, documentation, rules, and guidelines, audit the medical records and work with the providers, coding and billing staffs, and others as applicable on compliant documentation or other identified issues.

Utilize trends identified from the auditing and monitoring in your retraining programs.

Successful Strategies

- Audit policy vetted and approved by physicians' practice group executive committee

Buy-in at the top is important for success of programs. Effective compliance programs require leadership and Board level support.
- Initial education and training session upon hire

Live interactive sessions.

Successful Strategies

- Early complimentary audits

After ~60-80 outpatient clinic visits, review ~10-15 randomly selected encounters for each billing provider.
- Detailed feedback and extensive education regarding billing and documentation pertinent to the providers specialty

One-on-one feedback.

Successful Strategies

- Spend time & develop relationships

Initial meetings typically last 1-2 hours to allow for education, answering questions, and to develop trusting relationships.

Establish contacts and relationships with the behind the scenes billing and management staffs as it is often these individuals that have a direct relationship with the billing provider and a better knowledge of the clinic's operations.

Successful Strategies

- Provide feedback

Compliment and encourage good practices and share opportunities for improvement – provide rationales and benefits.

- Follow-up audits

Timing, process, education, and follow-up.

Successful Strategies

- Consequences & accountability

“Three strikes”, \$, and action plans.

- Feedback on audits and meetings

Distribute an audit review questionnaire to get ideas on how to improve the monitoring system and meetings to benefit the providers more effectively.

Goal - improve processes to achieve desired results.

Successful Strategies

Helpful hints to change organizational culture.

Relationships are critical for all compliance professionals particularly during training, education, auditing and monitoring projects:

- Know your audience.
- Be engaging.
- Have a positive attitude.
- Avoid confrontation.
- Information should flow both ways.
- Compliment and highlight areas of compliance.
- Communication skills are extremely important.
- Know your stuff – must be knowledgeable in billing and coding rules and regulations.

Successful Strategies

It is critical for the compliance message to be received in the manner in which it was intended – helpful and supportive.

This helps to change an organizations' culture.

Successful Strategies

Recruit Physician Champion(s)

- Identify potential physician leaders who may be supportive to compliance efforts.
- Ask key questions.
Please share any suggestions to improve our compliance program and/or process.
- Don't make promises.
- Listen.
- Take notes.
- Get back to physicians or HCPs with response(s) for good to great ideas.
- Recruit the physician or HCP to help to implement their suggestion – they are now part of the team.

Compliant Workforces

Having an effective compliance program that assists low-performing individuals to turn into high performing ones is an ongoing process.

It requires a substantial commitment of time, energy, resources, and ability to constantly change and adapt to the ever changing health care landscape.

If at first you don't succeed - reevaluate, make some changes, and try again.

How To Succeed As A Compliance Professional

Summary:

Break down silo's through appropriate initial education.

Implement a monitoring program that encourages compliance.

Change the image of the Compliance Office to help change the organization's culture.

Recruit physician champion(s).

Questions

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Critical Change: Enterprise Risk Management Meets Healthcare

18TH Annual Compliance Institute
San Diego, CA
March 31, 2014

Marie Moseley, JD, MPH, BSN, NNP-C, CHC, CHC-P

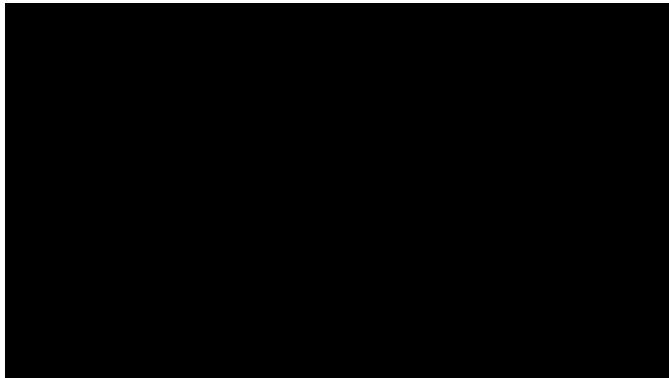
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Objectives

- 1** Understand ERM Basics and how it applies to Health Care
- 2** Identify key components
- 3** Lessons learned

2



ERM Meets Healthcare

- ERM...What is it?
 [A] process, effected by an entity's board of directors, management and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives.

(Committee of Sponsoring Organizations of the Treadway Commission (COSO))

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ERM Meets Healthcare

- Enterprise Risk Management (ERM) defined:
 • A broad-based interdisciplinary process through which an organization identifies, analyzes, prioritizes, and addresses the risks and opportunities (in other words, the uncertainties) than can affect its achievement of strategic objectives, whether in positive or negative ways.

American Health Lawyers Association, *Enterprise Risk Management for Healthcare: Where & How to Begin*

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ERM Meets Healthcare

Traditional Risk Management <ul style="list-style-type: none"> • Risk = Negative outcome • Risk driven • Silo approach 	Enterprise Risk Management <ul style="list-style-type: none"> • Risk = any issue affecting the organization's ability to meet its objectives • Value driven • Holistic approach 
----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

ERM Meets Healthcare

Key Components:

1. Enterprise-wide risk analysis
2. Enterprise-wide oversight
3. Strategic risk ranking
4. Accountability & Monitoring

ERM Meets Healthcare

Core Elements:

1. Education	5. Risk response
2. Objective setting	6. Controls
3. Event identification	7. Communication
4. Risk assessment	8. Monitoring

ERM Meets Healthcare

The diagram illustrates various risks facing healthcare organizations, represented by a balance scale and several boxes:

- Loss of/Reduction in Revenue Sources
- Loss of Accreditation
- Competition/Market Share/Reputation
- Regulatory Issues
- Technology
- Accountability/Transparency
- OIG/CMS

The Economist
This is going to hurt

ERM Meets Healthcare

Key Components:

- 1. Enterprise-wide risk analysis
- 2. Enterprise-wide oversight
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ERM Meets Healthcare

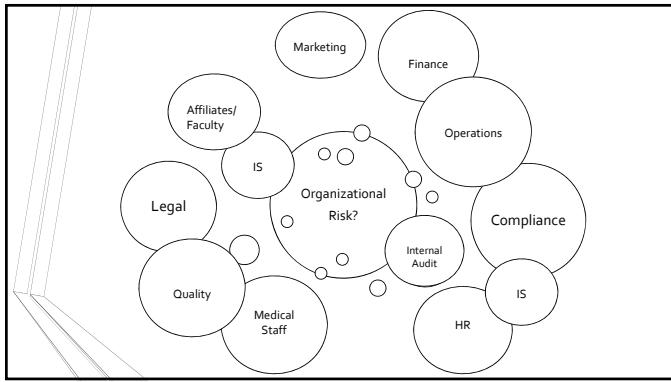
Risk Domains

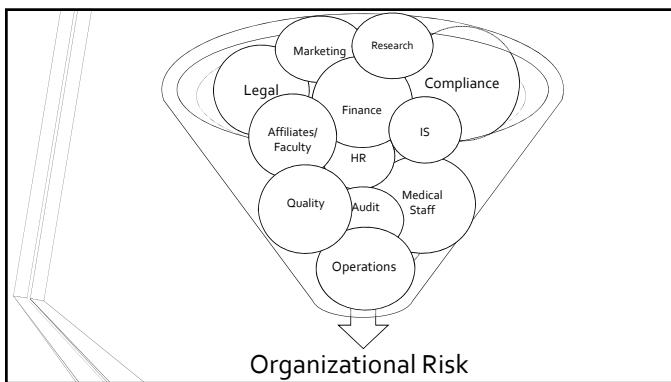
Strategic	Operational
Financial	Regulatory/ Legal
Human	Technological
Project Specific	

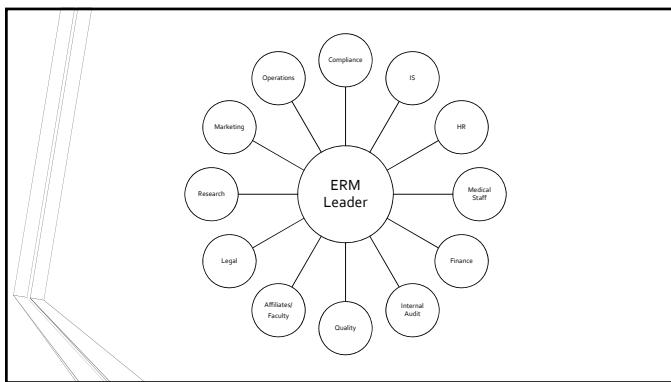
ERM Meets Healthcare

Key Components:

- 1. Enterprise-wide risk analysis
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ERM Meets Healthcare

Key Components:

1. Enterprise-wide risk analysis
2. Enterprise-wide oversight
3. Strategic risk ranking
4. Accountability & Monitoring

ERM Meets Healthcare

Likelihood	Consequences				
	Insignificant	Minor	Moderate	Major	Severe
Almost certain	M	H	H	E	E
Likely	M	M	H	H	E
Possible	L	M	M	H	E
Unlikely	L	M	M	M	H
Rare	L	L	M	M	H

ERM Meets Healthcare

Key Components:

1. Enterprise-wide risk analysis
2. Enterprise-wide oversight
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ERM Meets Healthcare

- Management Response (Red & Yellow)
 - Avoid
 - Control/Mitigate
 - Accept
 - Transfer



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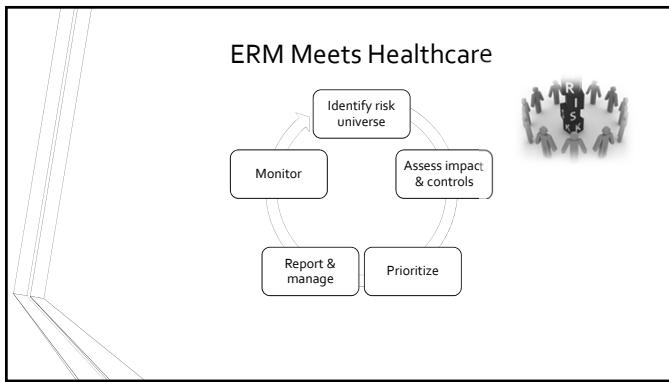
ERM Meets Healthcare

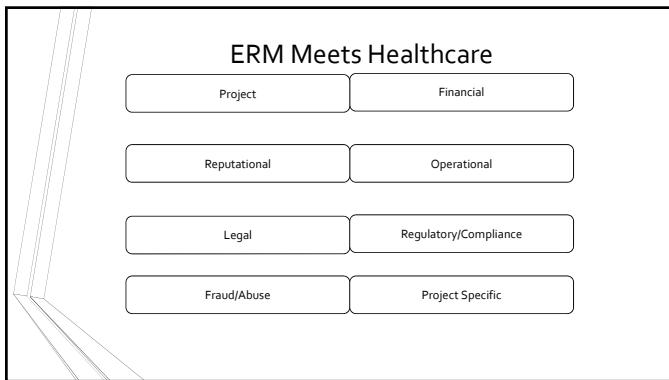
- Identify and focus on top risks
 - Critical business unit
 - Critical risk

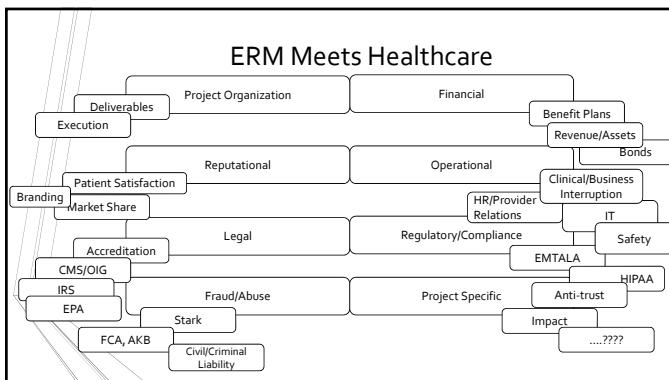


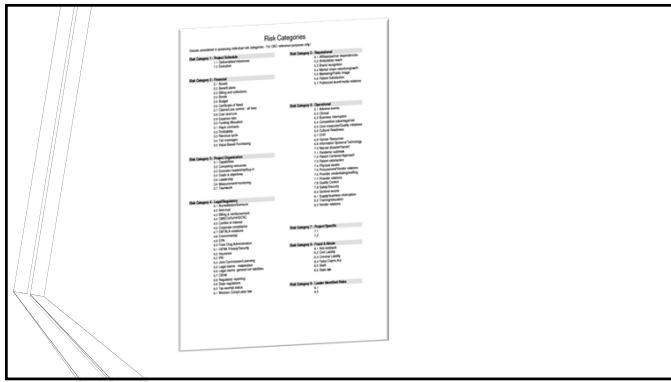
ERM Meets Healthcare

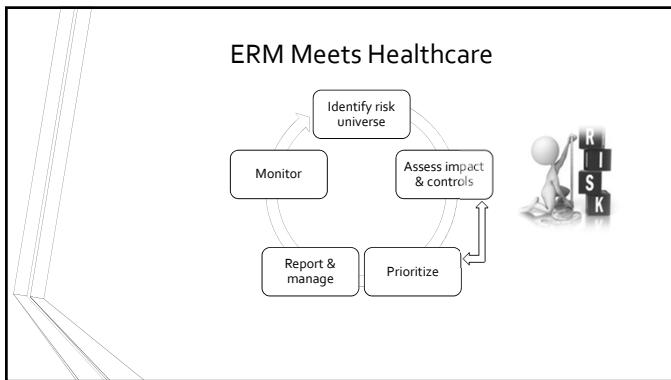


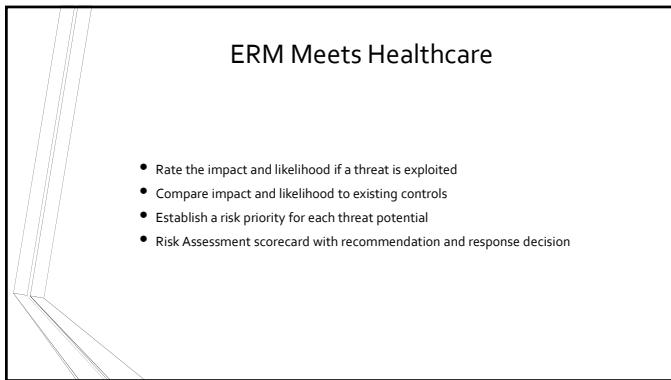




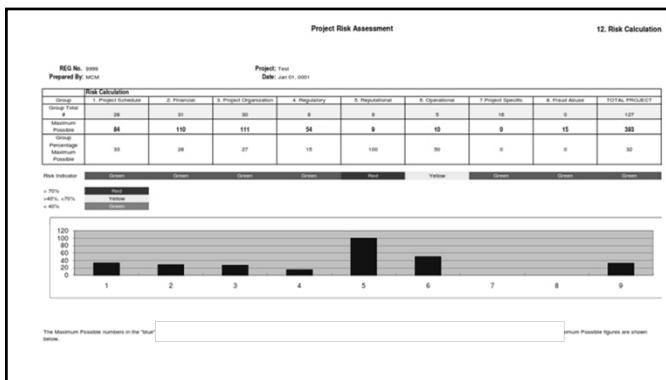
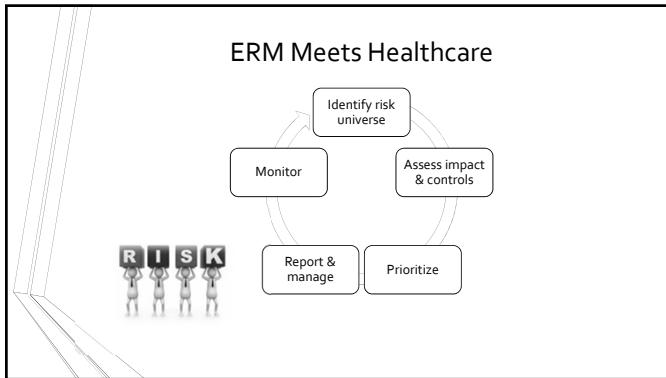


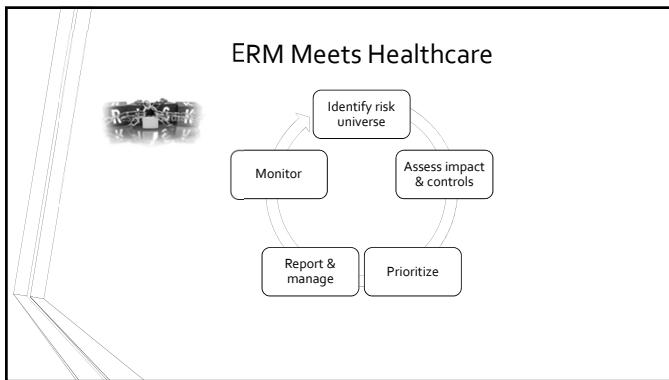






Descriptor	Negligible (WHITE)	Minor (GREEN)	Moderate (YELLOW)	Major (AMBER)	Extreme (RED)
Paramedic	Result of a single minor adverse event or clinical outcome directly related to delivery of care.	Minor adverse event or clinical outcome, short term effects	Minor adverse event or clinical outcome, long term effects	Major adverse event or clinical outcome, continuing ongoing effects	Critical outcome, continual ongoing effects
Healthcare Business Interruption	Interruption in service which does not affect patient care	Short term disruption to service with minor impact on patient care	Some disruption in service with temporary loss of ability to provide care	Extended loss of service with significant impact on patient care	Permanent loss of core service or function, unable to provide care resulting in major community impact
Patient Safety & Staff Factor	Minor injury or illness, first aid treatment required	Minor injury or illness, first aid treatment required	Temporary loss of ability to provide care	Significant system consequences	Failure leading to death or major impairment
Financial	Negligible organizational financial loss	Minor organizational financial loss	Significant organizational financial loss	Major organizational financial loss	Severe organizational financial loss





Lessons learned

- Slow, painful & time consuming
- Requires top-down commitment
- Baby steps
- Strong leader, C-suite engagement
- Build on existing resources
- Communicate
- Not about the tools

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Objectives

- 1 Understand ERM Basics and how it applies to Health Care
- 2 Identify key components
- 3 Lessons learned

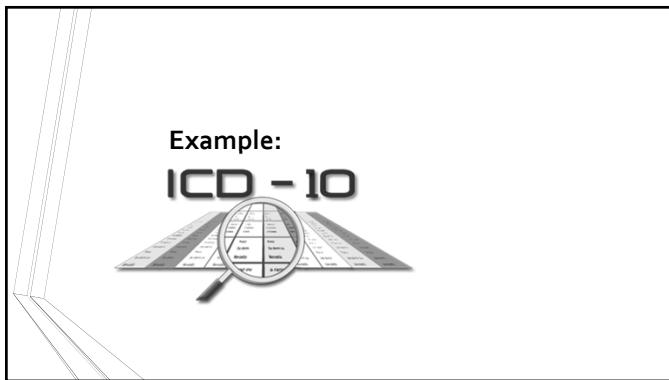
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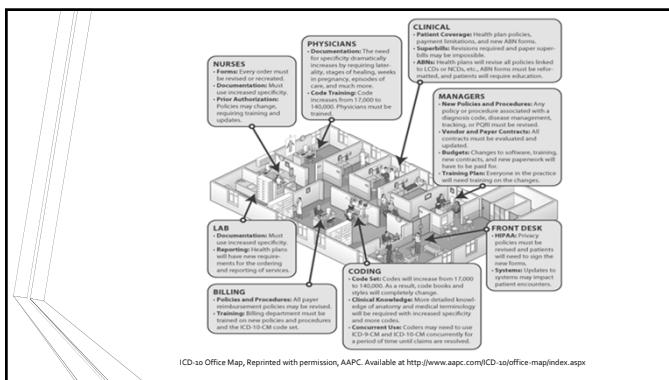
Example:

Meaningful Use



1. EHR functionality
2. Clinical work flows
3. Untimely adoption
4. Reimbursement
5. Audit defense







Risk Categories

(Issues considered in assessing individual risk categories - For OAC reference purposes only)

Risk Category 1 - Project Schedule

- Deliverables/milestones
- Execution

Risk Category 2 - Financial

- Assets
- Benefit plans
- Billing and collections
- Bonds
- Budget
- Certificate of Need
- Claims/Loss control - all lines
- Cost overruns
- Expense ratio
- Funding Allocation
- Payor contracts
- Profitability
- Revenue cycle
- Tail coverages
- Value Based Purchasing

Risk Category 3 - Project Organization

- Capabilities
- Competing resources
- Executive leadership/buy-in
- Goals & objectives
- Leadership
- Measurement/monitoring
- Teamwork

Risk Category 4 - Legal/Regulatory

- Accreditation/licensure
- Anti-trust
- Billing & reimbursement
- CMS/CoPs/HHS/OIG
- Conflict of Interest
- Corporate compliance
- EMTALA violations
- Environmental
- EPA
- Food Drug Administration
- HIPAA Privacy/Security
- Insurance
- IRS
- Joint Commission/Licensing
- Legal claims - malpractice
- Legal claims -general tort liabilities
- OSHA
- Regulatory reporting
- State regulations
- Tax-exempt status
- Workers Comp/Labor law

Risk Category 5 - Reputational

- Affiliate/partner dependencies
- Ambulatory reach
- Brand recognition
- Market share retention/growth
- Marketing/Public Image
- Patient Satisfaction
- Publicized event/media relations

Risk Category 6 - Operational

- Adverse events
- Clinical
- Business interruption
- Competitive advantage/risk
- Core measures/Quality initiatives
- Cultural Readiness
- EHR
- Human Resources
- Information Systems/Technology
- Natural disaster/hazard
- Pandemic outbreak
- Patient Centered Approach
- Patient satisfaction
- Physical assets
- Procurement/Vendor relations
- Provider credentialing/staffing
- Provider relations
- Quality Control
- Safety/Security
- Sentinel events
- Supply/business interruption
- Training/education
- Vendor relations

Risk Category 7 - Project Specific

Risk Category 8 - Fraud & Abuse

- Anti-kickback
- Civil Liability
- Criminal Liability
- False Claims Act
- Stark
- State law

Risk Category 9 - Leader Identified Risks

Office of Inspector General (OIG) Medicare Compliance Reviews

HCCA 2014 Compliance Institute
Session 402, 4:30-5:30
March 31, 2014

Facilitators

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Agenda

- Engagement Process
Tips and Tools
- The OIG Hospital Risk Areas
- Revamping controls



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Session 402
March 31, 2014

The Engagement Process: Tips

- Entrance Conference – Represent!

- Is this an audit or an investigation?
- Is the sample selected in a way that is statistically valid or was the sample judgmentally selected?

- Record Request List –

- Does each section represent a sample or an entire population for a period? If a sample, how many more claims might you select?
- Ask for information necessary to enable you to obtain information efficiently. If you submitted the data to CMS, the OIG should have access to it.
 - Patient account number
 - Medical record number
 - DRG or HCPCS, etc.

The Engagement Process: Tips

- Assembling the Team:

- Finance, Compliance, Coding, Case Management/ Physician Advisor, Patient Accounts, Chargemaster, Health Information Management
 - Who will assess the inpatient cases?
 - Who will assess the outpatient cases?
 - Who will obtain claims and remits?
 - Who is going to send information to the OIG?
 - How are spreadsheets going to be completed for submission to the OIG? What level of QC/discussion will occur prior to submission?

The Engagement Process: Tips

- Self-Assessment –

- OIG will ask the entity to review the cases and report
- OIG will typically describe what they are focusing on and will not have you necessarily verify every line item of claim.
- Identify claim error with payment impact vs. no payment impact. (i.e., CC or MCC change but no DRG change or CPT change but same APC).
- Make sure internal assessment methodology is consistent if multiple individuals are involved in evaluating the same types of cases. Document the individuals reviewing each case in case follow up discussions are needed.
- Be sure to loop in clinicians for clarifications as needed (i.e., mod 25 use) prior to initial response.
- Review similar cases together (same DRG).

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Session 402
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Provider experiences with OIG Hospital
Compliance Reviews – Management Tools

Sample Number	Adm Day of Week	Claim From Date	Claim Thru Date	Claim Payment Amount	DRG	DRG Description	DRG Reviewed by RAC	RAC Outcome?	P/MO Order (Y/N)	Review Outcome
A-201	Sat	12/18/10	12/19/10	\$ 6,359.97	069	TRANSIENT ISCHEMIA	Y	2/3 ok	Y	IP
A-202	Sat	04/23/11	04/24/11	\$ 5,495.90	101	SEIZURES W/O MCC	Y	3/3 ok	Y	IP
A-203	Sun	10/24/10	10/24/10	\$ 5,114.67	123	NEUROLOGICAL EYE DISORDERS	Y	1/1 ok	Y	IP

The Engagement Process: Tips

- Submission of Information –

- Send electronically, create folders that mirror what is sent and on what date.
- Label cases, one PDF per patient, naming conventions, MR vs claim info, complete your assessment before sending record.
- Section titles do not limit assessment focus.
- Surgical admissions, include prior MD notes. Medical admission, include ED physician notes.
- Spot check information prior to submission.
- Hospital comments should support your position for that case and provide enough rationale to help them come to the same conclusion
- Send in section by section once completed in an effort to manage the back and forth.

The Engagement Process: Tips

- Rebuttal/Appeal Processes – OIG & CMS

- Try to handle related cases at the same time during a rebuttal period with OIG. Ask for regulatory guidance used by OIG as a basis for their determination.
- Identify other audit outcomes or communications that support your interpretation or coding/admission decisions
- Certain types of cases may go to external review
- Understand what appeal processes will be available to you through the OIG and CMS and how entity initiated reprocessing of claims will impact your organization's appeal rights.
 - Identify which claims may be sent to a 3rd party reviewer.

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The Engagement Process: Tips

- **Objective Attributes Recap Sheet (OARS)**
 - Do you concur with all, some or none of the findings per section/risk area.
 - Opportunity to explain why errors occurred and what has been done to prevent future errors.
 - Some of OARS information will appear in draft/final report.
- **Exit Conference Conference – Represent!**
 - Administrative finality to review process. Allows access to OIG Audit Team for high-level comments.
- **Draft and Final Reports**

The Engagement Process: Tips

- **Communicating with Sr. Leadership**
 - Communicate regularly the status of the engagement.
 - Identify dollars at risk by review area
 - IP Short stay = delta between IP and OP payment
 - Psych admission source D code = \$80 per admission
 - DRG validation, delta between two DRGs that may be very similar.
 - Device Credits = amount of credit received (IP) vs APC reduction % on OP claim.
 - Outpatient E&M with Modifier 25 = refund of E&M payment = \$60 - \$100 per CPT.

Provider experiences with OIG Hospital Compliance Reviews - Management Tools

Section	Topic	# of claims	Medicare Claim Payments	Claims requiring correction	Estimated Over-payment*	Teams looking at this section	Comments
G	Psych Admissions	82	\$975,000	82	\$ 6560	Case Management	OIG would argue that it is all or nothing. They would not allow us to retain the cases as OP. Still working through these accounts. 1st batch of claims sent to OIG on 1/29/12.
F	IP Device Credits	10	\$286,000	2	\$ 1,000	Cardiology	Sent file to OIG on 12-17-12. OIG requested a 1/5% refund of the total with two cases to be refunded and agreed that the other 8 cases did not require a refund. Two lead credits were not reprocessed.
	Total Medicare payments	595	\$ 4,285,334	339	\$500,000		
	Inpatient Medicare payments	238	\$ 3,002,934	90	\$200,000		
	Outpatient Medicare payments	357	\$ 1,282,400	249	\$300,000		

Draft as of x/xx/xx – For discussion purposes

Total overpayments as % of payments
Inpatient overpayments as a % of payments
Outpatient overpayments as % of payments

11.2%
4.6%
25.8%

The Engagement Process: Tips

- Communicating with Sr. Leadership (cont'd)
 - Timeline of report and reprocessing of claims.
 - Ask for input on cases that may need to be appealed.
 - Provide updates on corrective actions put in place operationally and from a controls perspective:
 - Education on documentation or coding issues
 - Charge master updates
 - Establishment of routine data monitoring and assessment

**OIG Hospital
Compliance Review -
Risk Areas**

OIG Hospital Compliance Reviews –
Inpatient Risk Areas



- Short hospital stays (0 and 1 day)
- High-severity level MS-DRGs
- Same day discharge and readmission
- Transfers to post-acute care providers
- Transfers to inpatient hospice care
- Manufacturer medical device credits
- Claims paid amount in excess of claims charged amount
- Claims with payments greater than \$150,000
- Blood-clotting factor drugs
- Hospital-acquired conditions and present on admission
- Outlier payments

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OIG Hospital Compliance Reviews –
Outpatient Risk Areas

- Observation outlier payments
- Facility E&M coding and “new” vs. “established” patient
- Manufacturer medical device credits
- Services billed with modifier 59
- E&M services billed with surgical services (modifier 25)
- Claims paid amount in excess of claims charged amount
- Outpatient services billed during inpatient stays
- Three-day payment window rule
- Surgeries billed with units greater than one
- Services billed during skilled nursing facility stays
- Outpatient dental services

Other OIG Risk Areas

- Inpatient psychiatric facility interrupted stays
- Inpatient psychiatric facility emergency department adjustments
- Skilled Nursing Facility payments for ultra high therapy
- Inpatient Rehabilitation Facility documentation requirements
- Outpatient brachytherapy reimbursement
- Outpatient claims billed using “J” codes
- Observation services during outpatient visits
- Hemophilia services and septicemia services
- Intensity modulated radiation therapy planning services
- Outpatient claim payments greater than \$25,000



OIG Hospital Compliance Reviews –
Inpatient Risk Areas – Operational Challenges

- Short stay admissions on weekends with medical DRGs, including transfers for medical and surgical admissions
- Outpatient services rendered while the beneficiary was an inpatient /resident at another facility
- Admission Source Code “D” for psychiatric admissions
 - Operationally a significant challenge if the admission source code from the medical admission is brought over into the psychiatric admission.

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OIG Hospital Compliance Reviews –
Outpatient Risk Areas – Operational Challenges

- Outpatient dental services
 - Medicare does not have edits in place to reject claims or request medical record documentation prior to payment of claims with dental procedure codes (i.e., D7140 – tooth extraction)
- Pegaspargase (J9266)
 - Purchased in a single use vial containing 3750 international units
 - Paid by Medicare per vial, patients typically receive less than 1 vial but we can bill for one rounding up.
 - Charging was set up resulted in belief that each vial contained only 750 international units.
 - So, when only 1 unit was supposed to have been billed to Medicare, the number of units submitted was 5 (5 x 750), resulting in an overpayment.

OIG Hospital Compliance Reviews –
Outpatient Risk Areas – Operational Challenges

- E&M services billed with surgical services (modifier 25)
 - 38242 – Allogenic lymphocyte infusions - New AMA CPT language in 2013, “these procedures (38240-38243) include physician monitoring of multiple physiologic parameters, physician verification of cell processing, evaluation of the patient before, during and after the HPC/lymphocyte infusion, physician presence during the HPC/lymphocyte infusion with associated direct physician supervision of clinical staff, and management of uncomplicated adverse events (e.g., nausea, urticaria) during the infusion, which is not separately reportable.”
 - Joint injections
 - A patient evaluation prior to a decision to administer an injection, if documented well , supports both.
 - An E&M provided during the same session as a planned injection is questionable unless other things are evaluated.

OIG Hospital Compliance Reviews –
Outpatient Risks – Controversial Interpretations

- Modifier 59
 - Right heart cardiac catheterization (93451, formerly 93501)and endomyocardial heart biopsy (93505)
- Observation Outlier Payments - start and end time was disputed as well as what documentation in the medical record constitutes a physician order. Carving out time for procedures was also evaluated but had less of an impact on outlier payments compared to start and stop times.

OIG Hospital Compliance Review - Revamping Controls

HCCA 2014 Compliance Institute
Session 402, 4:30-5:30
March 31, 2014

OIG Hospital Compliance Reviews – Outpatient Risk Areas – Pre-Billing Controls

- **New Pre-Billing Controls resulting from OIG reviews:**
 - Dental Procedures – Claim hold for all Medicare claims with dental services. Evaluated by for medical necessity prior to billing.
 - Herceptin – claim hold 44, 88 or 132 units and evaluate units.
 - Emend – claim hold to evaluate the appropriateness of billing Medicare Part B vs. Medicare Part D.
 - Pegaspargase – more than 1 unit will be stopped for review.

OIG Hospital Compliance Reviews – Post-Billing Controls – OP Drug Unit Billing

- Identify the most common dosing guidelines for the particular drugs in question.
- Develop your own weight and height assumptions which will combine with dosing guidelines to provide you with an upper and lower norm/threshold.
 - For drugs billed based on weight, calculated the dosage and number of billable units for patients weighing more than 250 lbs. or less than 100 lbs.
 - 250lb = 113kg (398.08g)
 - 100lb = 45kg (359.23g)
 - For drugs billed based on body surface area, (i.e., square centimeters, calculated the dosage and number of billable units for patients weighing more than 250 lbs. and 6' 2" or less than 100 lbs and 4' 11"
 - <http://www.halls.md/body-surface-area/bsa.htm>
- Convert the dosing upper and lower threshold to Medicare billable units based on your assumptions for each drug

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OIG Hospital Compliance Reviews –
Post-Billing Controls – OP Drug Unit Billing

- Sample: *Alpha 1-Proteinase Inhibitor (Aralast) (J0256)*
 - Alpha 1-proteinase inhibitor is used to treat alpha 1-antitrypsin deficiency in people who have symptoms of emphysema.
 - The HCPCS code for this drug is J0256 and is described as "Injection, alpha 1-proteinase inhibitor - human, 10 mg"
 - Typical dosing instructions per FDA is: 60 mg per kg
- Calculation:
 - For a 250 pound patient, the units needed would be calculated as:
 - $113 \text{ kg} * 60 \text{ mg per kg} = 6780 \text{ mg}$
 - Billable units then are $6780 / 10 \text{ mg} = 678 \text{ units (not mg)}$
 - For a 100 pound patient, the units needed would be calculated as:
 - $45 \text{ kg} * 60 \text{ mg /kg} = 2700 \text{ mg}$
 - Billable units then are $2700 / 10 \text{ mg} = 270 \text{ units}$
- So the range of "normal" billable units for aralast (J0256) would be:
 - $<= 680 \text{ units or } >= 270 \text{ units}$

OIG Hospital Compliance Reviews –
Post-Billing Controls – OP Drug Unit Billing

Drug Unit Billing Example:

- Identified a charge master setup error which was causing the hospital to underreport the number of units being billed while, at another facility, the units exceeded the "normal" range.

Provider	Patient Name	Medical Record Number	CPT Code	Units	Charge Covered Charge	Service From Date	Service Through Date	Payment
Hospital B	James, Stephen	654321	J0256	6010	\$91,712	06/25/2013	06/25/2013	\$1,847
Hospital B	James, Stephen	654321	J0256	610	\$3,308	06/11/2013	06/11/2013	\$1,874
Hospital B	James, Stephen	654321	J0256	606	\$9,247	04/23/2013	04/23/2013	\$1,862
Hospital B	James, Stephen	654321	J0256	606	\$9,247	05/14/2013	05/14/2013	\$1,862
Hospital A	Gillis, Stephen	12345	J0256	001	\$10,145	04/12/2013	04/12/2013	\$3
Hospital A	Gillis, Stephen	12345	J0256	001	\$10,145	04/26/2013	04/26/2013	\$3

- The acceptable range for this drug, based on clinical dosing guidelines, is between 270 and 680 units.

OIG Hospital Compliance Reviews –
Post-Billing Controls – OP Drug Unit Billing

- Sample: *Rituximab (J9310)*
 - Rituximab is used to treat a variety of conditions, including Non-Hodgkin's lymphoma and rheumatoid arthritis.
 - The HCPCS code for this drug is J9310 injection, rituximab, 100 mg
 - Typical dosing instructions per FDA are: $375 - 500 \text{ mg/m}^2$ (milligrams per square meter)
- Calculation using a Body Surface Area Calculator:
 - For a 250 pound patient 6'2", units would be calculated as:
 - The body surface area would be equal to 2.43 m^2
 - $2.43 \text{ m}^2 * 500 \text{ mg} = 1215$
 - Billable units then are $1215 / 100 \text{ mg} = 12 \text{ units (not mg)}$
 - For a 100 pound patient 4'11", units would be calculated as:
 - The body surface area would be equal to 1.37 m^2
 - $1.37 \text{ m}^2 * 375 \text{ mg} = 513.75$
 - Billable units then are $513.75 / 100 \text{ mg} = 5 \text{ units (not mg)}$
- The range of "normal" billable units for rituximab (J9310) is:
 - $<= 12 \text{ units or } >= 5 \text{ units}$

HCCA 2014 Compliance Institute

Session 402

March 31, 2014

OIG Hospital Compliance Reviews – Post-Billing Controls – OP Drug Unit Billing

Logic around drug unit billing plan: Drug unit billing thresholds calculated for each drug based on clinical dosing guidelines.

HCPCS	Name of Drug	Upper Threshold	Lower Threshold
J0152	Adenosine injection	8	2
J0256	Alpha 1 proteinase inhibitor	680	270
J0475	Baclofen 10 MG	8	2
J1459	Privigen 500 mg	226	36
J1561	Gammunex-C/Gammaked	226	36
J1568	Immune globulin, powder	115	12
J1568	Dtagam injection	226	36
J1745	Infliximab Remicade injection	100	14
J9095	Bevacizumab injection	113	23
J9041	Bortezomib injection	35	15
J9043	Cabazitaxel injection	61	54

HCPCS	Name of Drug	Upper Threshold	Lower Threshold
J9055	Cetuximab injection	122	35
J9171	Docetaxel injection	200	50
J9217	Leuprolide acetate suspension	Not equal to:	1, 3, 4
J9305	Pemetrexed injection (alimta)	122	69
J9310	Rituximab injection	12	5
J9266	Pegasparagase (oncaspar)	Greater than 1	
J9355	Herceptin (Trastuzumab)	Equal to:	44, 88 or 132

These sample thresholds are for illustrative purposes only. Each organization should develop their own assumptions regarding typical patient height & weight ranges and should confirm typical dosing guidelines used by their own clinicians for their own patients.

OIG Hospital Compliance Reviews – Post-Billing Controls – Outlier Payments

- Data Monitoring and Assessment Plan:
 - IP and OP populations
 - Created sub-criteria to narrow down the list of cases eligible for review (i.e., IP cases with LOS greater than 14 days)
 - Make sure your data is accurate
 - Things to look for:
 - Duplicate charges
 - Charge master set up issues (wrong conversion multipliers)
 - Credits that turn into debits

OIG Hospital Compliance Reviews – Post-Billing Controls – Payments Greater than Charges

- Payments Greater Than Charges
 - IP and OP
 - Created sub-criteria to narrow down the list of cases eligible for review (i.e., payment is 150% of charge, claim payment greater than \$2,500)
 - Make sure your data is accurate
 - Things to look for:
 - Late charges
 - Charge master set up issues (unit vs. charge)
 - Debits that turn into credits

Office of Inspector General
(OIG)

Medicare Compliance Reviews:
A Look Inside the Audit
Process

Gloria A. Jarmon, Deputy Inspector General for Audit Services
HCCA 2014 Compliance Institute
Session 402, 4:30-5:30
March 31, 2014

Quick Overview

- OIG Program Overview
- Operational Items
- How the Audit Process Works
- How a Hospital Can Prepare to Ensure Compliance
- Looking Forward

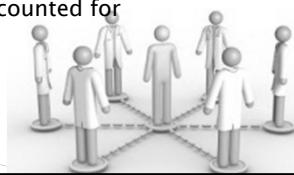
The Hospital Compliance Initiative

- Who are the auditors?
- Why focus on Hospitals?
- Too many hospitals, too little time
- Review internal controls and disseminate best practices



Operational Items

- Goal = improve billing practices and reduce errors
- Collaboration between the hospital and OIG auditors
- Hospital variance is accounted for



How the Audit Process Works

- Hospitals are selected based on several different criteria
- When and how statistical sampling is utilized
- Medical opinions are given by an independent physician reviewer



What Can Be Done to Ensure Compliance?

- Involvement from the Board of Directors
- Effective Communication Across the Organization
- Continually Review Procedures and be Proactive
- Read the OIG Workplan *prior* to Audit
- Be Organized
- Most Common Issues Found in Audits



Looking Forward to Building Strong Compliance Programs

- Financial Managers are Encouraged to Build Strong Compliance Departments
- Be Aware of Changes Implemented by the ACA
- Be Flexible!



Thank you & Questions

<http://oig.hhs.gov/>

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HCCA
2014 Compliance Institute

**Review of the OIG 2014 Work Plan
For Post-Acute Providers**

Paula G. Sanders, Esquire
Gavin J. Gadberry, Esquire
Session 403

http://www.hms.com/our_services/services_program_integrity.asp

2

What is an OIG Work Plan?

- Provides an indication of OIG enforcement activities for the coming year.
- Don't--
- What happened in the previous year???

³ POST & SCHELL, PC

OIG Recoveries FY 2013

- > \$5.8 billion expected recoveries
 - ~ \$850 million in audit receivables
 - ~\$5 billion in investigative receivables
- ~ \$19.4 billion in savings on the basis of prior- period legislative, regulatory, or administrative actions based on OIG recommendations

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OIG FY 2013 Actions

- 3,214 exclusions of individuals and entities
- 960 criminal actions of individuals and entities
- 472 civil actions

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Investigative Letters: Medicare MAC

Dear Compliance Officer:

As the Medicare Administrative Contractor (MAC)...regularly monitors billing and claim submission data for unusual patterns and data aberrances...As such, the enclosed data are intended to provide you with information based on your facility's claim submissions, and to serve as an educational tool to assist you in the evaluation of your billing patterns.

A recent OIG data analysis on SNF RUG billing trends from 2006 to 2008 indicates that

(1) SNFs increasingly billed for higher paying RUGs, even though beneficiary characteristics remained largely unchanged.

(2) For-profit SNFs were far more likely than nonprofit or government SNFs to bill for higher paying RUGs.

Based on these findings, OIG recommended that MACs strengthen monitoring of the SNF billing and conduct additional review of SNFs that bill high paying RUGs excessively.

...We identified claims with the high paying RUG codes from your facility. Enclosed is a summary of the RUG claims billed by your facility as compared to the J12 average...Though we recognize that not all of these claims may represent payment errors, we are asking, in light of the OIG findings, for you to review the data closely and conduct a self audit of the associated claims. If you determine any claims were paid in error, you should submit the appropriate refund...

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OIG Outlook (2/6/2014)

- Goal: promote quality, safety and value
 - Key focus on quality and care of nursing homes & how often beneficiaries are harmed during their stay
- Compliance work in home health agencies
- Office of Evaluations & Inspections' focus
 - Quality of care, accuracy of payments & access to care

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OIG Outlook 2014

- Adverse events in SNFs
 - Preventable?
 - Medicare cost impact
- Data analytics
 - Trends, spikes, decreases
- Home health & personal care services
 - Are services delivered, are they necessary, are patients homebound, kickbacks

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OIG Outlook 2014

- Office of General Counsel
 - Proposed regulations on civil money penalties (CMPS), exclusions and safe harbors
 - New guidance for health care boards of directors

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OIG Work Plan (WP): Focus on Providers

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Hospitals

- New hospital inpatient admission criteria (new)
 - Focus on impact of new inpatient admission criteria on hospital billing, Medicare payments, and beneficiary payments; variations among hospitals
 - 2 day inpatient stay/observation stays
- Analysis of salaries included in hospital cost reports (new)
- Compare reimbursement for swing bed at Critical Access Hospitals to the same level of care at SNFs

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LTCHs

- Long-term-care hospitals (LTCHs)—Billing patterns associated with interrupted stays
 - Focus on readmission patterns to determine the extent of new stays instead of interrupted stay billings,
 - Extent to which co-located LTCHs readmit patients from the providers with which they are co-located
 - Extent of improper LTCH payments for readmissions in 2011

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Hospitals

- Selected inpatient and outpatient acute care billing requirements (ongoing)
 - Determine hospitals' compliance with selected billing requirements and recommend recovery of overpayments
 - Survey or interview hospitals' leadership and compliance officers to provide contextual information related to hospitals' compliance programs

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Hospitals

- Hospital participation in projects with quality improvement organizations (QIOs) (ongoing)
 - Focus on extent and nature of hospitals' participation in quality improvement projects with QIOs
 - Extent to which QIOs' quality improvement projects in hospitals overlap with projects offered by other entities
 - CMS spending \$1.3 billion for current 3 year QIO contract

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IRFs

- Inpatient rehabilitation facilities (IRFs)—Adverse events in post-acute care for Medicare beneficiaries
 - Adverse and temporary harm events
 - Factors contributing to events
 - Preventable?
 - Medicare cost impact
- IRFs provide 11 % of post acute facility care
 - \$7 billion annually

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Nursing Homes

- SNF Medicare Part A billing facilities (new)
 - Describe SNF billing practices in selected years & variation in billing among SNFs in those years
 - Prior OIG work found SNFs increasingly billed for highest level of therapy even though beneficiary characteristics remained largely unchanged
 - OIG also found SNFs billed one-quarter of all 2009 claims in error, resulting in \$1.5 billion in inappropriate Medicare payments
 - Quality of care on-going focus

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Nursing Homes

- Questionable billing patterns for Part B services during nursing home stays
 - Focus on questionable billing patterns associated with nursing homes and Medicare providers for Part B services provided to residents during stays not paid under Part A
 - Series of studies examining several broad categories of services, such as foot care
 - Congress explicitly directed OIG to monitor Part B billing for abuse during non-Part A stays

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Nursing Homes

- State agency verification of deficiency corrections
 - Determine whether State survey agencies verified correction plans for deficiencies identified during nursing home recertification surveys.
 - Prior OIG review found one State survey agency did not always verify that nursing homes corrected deficiencies identified during surveys in accordance with Federal requirements

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Nursing Homes

- Program for national background checks for long-term-care employees
 - Review procedures implemented by participating States for long-term-care facilities or providers to conduct background checks on prospective employees and providers who would have direct access to patients and determine the costs of conducting background checks
 - Determine outcomes of States' programs and determine whether the programs led to any unintended consequences.
 - Mandated by Affordable Care Act, § 6401

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Nursing Homes

- Hospitalizations of nursing home residents for manageable and preventable conditions
 - Determine hospitalization rates of SNF residents as a result of conditions thought to be manageable or preventable in the nursing home setting
 - 2013 OIG review found that 25% of Medicare beneficiaries were hospitalized for any reason in FY 2011.
 - Premise: hospitalizations of SNF residents are costly to Medicare and may indicate quality-of-care problems in the nursing homes

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Hospices

- Hospice in assisted living facilities (ALFs)(new)
 - Focus: extent to which hospices serve Medicare beneficiaries who reside in ALFs
 - Length of stay, levels of care received, and common terminal illnesses.
 - Goal: provide HHS with data to support payment reform and quality measures pursuant to ACA § 3132
 - Concern: ALF residents have the longest lengths of stay in hospice care
 - Medicare Payment Advisory Commission has said that these ALF long stays bear further monitoring and examination

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Hospices

- Hospice general inpatient care (GIP)
 - Focus on use of hospice GIP
 - Assess appropriateness of GIP claims and the content of election statements for hospice beneficiaries who receive GIP
 - Review hospice medical records to address concerns that GIP is being misused

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Home Health Services

- Home health prospective payment system requirements
 - Review compliance with various aspects of the home health prospective payment system (PPS), including the documentation required
 - Determine whether home health claims were paid in accordance with Federal laws and regulations.
 - Prior OIG report found that one in four HHAs had questionable billing.
 - CMS designated newly enrolling HHAs as high-risk providers, citing their record of fraud, waste, and abuse
 - Since 2010, ~ \$1 billion in improper Medicare payments and fraud has been identified relating to the home health benefit

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Home Health Services

- Employment of individuals with criminal convictions
 - Determine extent to which home health agencies (HHAs) are complying with State requirements for conducting criminal background checks on HHA applicants and employees
 - Prior OIG review found that 92 % of nursing homes employed at least 1 individual with at least 1 criminal conviction but review could not determine whether the nursing home employees should have been disqualified from working in nursing homes
 - Nearly all states have laws prohibiting certain health-care-related entities from employing individuals with prohibited criminal conviction

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Ambulances

- Ambulance services—Portfolio report on Medicare Part B payments (new)
 - Analyze and synthesize OIG evaluations, audits, investigations, and compliance guidance related to Medicare Part B ground ambulance transport services
 - Identify vulnerabilities, inefficiencies, and fraud trends and offer recommendations to improve detected vulnerabilities and minimize inappropriate payments for ambulance services
 - Prior OIG work identified fraud schemes and trends indicating overutilization and medically unnecessary payments
 - Premise: ambulance services are covered “where the use of other methods of transportation is contraindicated by the individual’s condition....” when a beneficiary’s medical condition at the time of the transport is such that using other means of transportation would endanger the beneficiary’s health.

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Ambulances

- Ambulance services—Questionable billing, medical necessity, and level-of-transport
- Examine Medicare claims data to assess the extent of questionable billing for ambulance services, such as transports that potentially never occurred or potentially medically unnecessary transports to dialysis facilities
- Determine whether Medicare payments for ambulance services were made in accordance with Medicare requirements
- Prior OIG work found that Medicare made inappropriate payments for advanced life support emergency transports

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Lab Tests

- Laboratory tests—Billing characteristics and questionable billing
 - Review billing characteristics for Part B clinical laboratory (lab) tests and identify questionable billing
 - Lab payments in 2008 represented an increase of 92 % over payments in 1998
 - In 2010, Medicare paid ~ \$8.2 billion for lab tests, 3 % of all Medicare Part B payments
 - Premise: Medicare should pay only for those lab tests that are ordered by a physician or qualified nonphysician practitioner who is treating a beneficiary

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Physical Therapists

- Physical therapists—High utilization of outpatient physical therapy services
 - Review outpatient physical therapy services provided by independent therapists to determine whether they were in compliance with Medicare reimbursement regulations
 - Prior OIG work found that claims for therapy services provided by independent physical therapists were not reasonable or medically necessary or were not properly documented
 - Focus is on independent therapists who have a high utilization rate for outpatient physical therapy services

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Portable X-Ray

- Portable x-ray equipment—Supplier compliance with transportation and setup fee requirements (new)
 - Review Medicare payments for the transportation and setup of portable x-ray equipment to determine whether payments were correct and were supported by documentation
 - Assess the qualifications of the technologists who performed the services and determine whether the services were ordered by a
 - Prior OIG work found that Medicare improperly paid portable x-ray suppliers for return trips to nursing facilities (i.e., multiple trips to a facility in 1 day) and for services ordered by nonphysicians that are not covered by Medicare

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Prescription Drugs

- Covered uses for Medicare Part B drugs (new)
 - Review the oversight actions CMS and its claims processing contractors take to ensure that payments for Part B drugs meet the appropriate coverage criteria
 - Identify challenges contractors face when making coverage decisions for drugs.
 - Premise: If Part B MACs do not have effective oversight mechanisms, Medicare and its beneficiaries may pay for drugs with little clinical evidence of the drugs' safety and effectiveness
 - Part B may also cover drugs when an "off-label" use of the drug is supported in major drug compendia or when an off-label use is supported by clinical evidence in authoritative medical literature

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Medicaid Home Health Services

- Home health services—provider and beneficiary eligibility
 - Review Medicaid HHA claims to determine whether the billing providers met applicable criteria to provide home health services to Medicaid beneficiaries
 - Minimum number of professional staff, proper licensing and certification, review of service plans of care, and proper authorization and documentation of provided services
 - Determine whether the beneficiaries met the criteria to receive such services

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Medicaid Adult Day Services

- Adult day health care services
 - Review Medicaid payments for adult day care services to determine whether the providers complied with Federal and State requirements
 - Beneficiaries enrolled must meet eligibility requirements
 - Services must be furnished in accordance with a plan of care

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Medicaid Home Health

- Home health services—Screenings of health care workers
 - Review health-screening records of Medicaid HHA health care workers to determine whether they were screened in accordance with Federal and State requirements
 - Health screenings for home health care workers include vaccinations such as those for hepatitis and influenza

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Medicaid Payments for Health-Care-Acquired Conditions

- Health-care-acquired conditions—Prohibition on Federal reimbursements
- Determine whether selected States made Medicaid payments for health-care-acquired conditions and provider-preventable conditions and quantify the amount of Medicaid payments for such conditions
 - As of July 1, 2011, Federal payments to States are prohibited for any amounts expended for providing medical assistance for health-care-acquired conditions. (Social Security Act, § 1903, and Affordable Care Act, § 2702.) Federal regulations prohibit Medicaid payments by States for services related to health-care-acquired conditions and for provider-preventable conditions

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OIG WP: Integrity Activities

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Integrity Contractors

- Medicare benefit integrity contractors' activities (new)
 - Review and report the level of benefit integrity activity performed by Medicare benefit integrity contractors in calendar years 2012 and 2013
 - Activities include analyzing data to identify aberrant billing patterns, conducting fraud investigations, responding to requests for information from law enforcement, and referring suspected cases of fraud to law enforcement for prosecution
 - Program Safeguard Contractors (PSCs) and Zone Program Integrity Contractors (ZPICs) carry out benefit integrity activities for Medicare Parts A and B, and a Medicare Drug Integrity Contractor (MEDIC) carries out benefit integrity activities for Medicare Parts C and D

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ZPICs & PSCs

- ZPICs and PSCs—Identification and collection status of Medicare overpayments (new)
 - Determine the total overpayments that ZPICs and PSCs identified and referred to claims processors in 2013 and the amount of these overpayments that claims processors collected
 - Review procedures for tracking collections on overpayments identified by ZPICs and PSCs
 - OIG has issued several reports critical of tracking and collection of overpayments
 - CMS has added reporting requirements that would improve overpayment tracking among the claims processors and ZPICs and PSCs
 - ZPICs and PSCs required to detect and deter fraud and abuse in Medicare Part A and/or Part B in their jurisdictions
 - Conduct investigations; refer cases to law enforcement; and take administrative actions, such as referring overpayments to claims processors for collection and return to the Medicare program

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Provider Eligibility

- Enhanced enrollment screening process for Medicare providers
 - Determine extent to which and the way in which CMS and its contractors have implemented enhanced screening procedures for providers pursuant to ACA § 6401
 - Collect data on and report number of initial enrollments and enrollment revalidations approved and denied by CMS before and after the implementation of the enhanced screening procedures
 - Automated screening
 - Finger printing
 - Background checks

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Provider Eligibility

- Idle Medicare provider records (new)
 - Identify active Medicare providers who have not billed Medicare for more than 1 year
 - Previous OIG work suggested many providers have active Medicare records but have not submitted any claims for more than 1 year
 - Providers enrolled solely to refer items and services for beneficiaries (ordering and referring providers) and certain provider specialty types are excluded from this deactivation process

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Provider Eligibility

- Payments to providers subject to debt collection
 - Review providers and suppliers that received Medicare payments after CMS referred them to the Department of the Treasury (Treasury) for failure to refund overpayments
 - Determine the extent to which they ceased billing under one Medicare provider number but billed Medicare under a different number after being referred to Treasury
 - The Debt Collection Improvement Act of 1996 (DCIA) requires Federal agencies to refer eligible delinquent debt to Treasury for appropriate action

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Medicaid Exclusions

- State terminations of providers terminated by Medicare or by other States
 - Review States' compliance with requirement that they terminate their Medicaid program providers that have been terminated under Medicare or by another State Medicaid program
 - Determine whether such providers are terminated by all State Medicaid programs in which they are enrolled
 - Assess the status of the supporting information-sharing system
 - Determine how CMS is ensuring that States share complete and accurate information
 - Identify obstacles States face in complying with the termination requirement
 - ACA § 6501

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Ownership Information

- State collection and verification of provider ownership information
 - Determine extent to which States and CMS collect and verify required ownership information for provider entities enrolled in Medicare and Medicaid
 - Review States' and CMS's practices for collecting and verifying provider ownership information and determine whether States and CMS had comparable provider ownership information for providers enrolled in both Medicaid and Medicare
 - Premise: Federal regulations require Medicaid and Medicare providers to disclose ownership information, such as the name, address, and date of birth of each person with an ownership or control interest in the provider entity

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Enhanced Provider Screening

- States' experiences with enhanced provider screening
 - Review States' progress toward rescreening or revalidating all Medicaid providers by 2016
 - Assess how States are complying with mandate to conduct enhanced screening; determine how many providers are enrolled in both Medicare and Medicaid; and determine whether States can use screenings from Medicare, other State Medicaid programs, and CHIP

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Medicaid Provider Payment Suspensions

- Provider payment suspensions during pending investigations of credible fraud allegations (new)
 - Review payments to providers with allegations of fraud deemed credible by States and States' suspension of payments processes
 - Review select Medicaid State agencies for compliance with new federal provisions:
 - Federal financial participation in the Medicaid program is not available for items or services furnished by an individual or entity when the State has failed to suspend payments during a period when there is a credible allegation of fraud
 - Upon determinations that allegations of fraud are credible, States must suspend all Medicaid payments to the providers, unless the States have good cause to not suspend payments or to suspend payment only in part
 - States are required to make fraud referrals to MFCUs or to appropriate law enforcement agencies in States with no certified MFCUs

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MCO Program Integrity

- Medicaid managed care entities' identification of fraud and abuse
 - Determine whether Medicaid MCOs identified and addressed potential fraud and abuse incidents
 - Describe how States oversee MCOs' efforts to identify and address fraud and abuse
 - Prior OIG report revealed that over a quarter of the MCOs surveyed did not report a single case of suspected fraud and abuse to their State Medicaid agencies in 2009
 - All MCOs are required to have processes to detect, correct, and prevent fraud, waste, and abuse. However, the Federal requirements surrounding these activities are general in nature (42 CFR § 438.608) and MCOs vary widely in how they deter fraud, waste, and abuse

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Legal Activities

- Exclusions
- CMPs
- False Claims Act cases and Corporate Integrity Agreements (CIAs)
- Provider compliance with CIAs
- Advisory opinions and other guidances
- Provider compliance trainings

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Legal Activities

- Provider self-disclosure
 - Protocol was updated in April 2013
 - Must admit fault
 - No guarantees

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Investigative Activities

- Medicare & Medicaid fraud & abuse
- Failure of care cases
- Medicare Fraud Strike Force Teams
- Collaboration with Federal Bureau of Investigation (FBI), the United States Postal Inspection Service, the Internal Revenue Service (IRS), and State Medicaid Fraud Control Units (MFCU)

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Investigative Activities

- Strike Force operations work to impose payment suspensions that immediately prevent losses from claims submitted by Strike Force targets
 - Quality-of-care and failure-of-care issues in nursing facilities, institutions, community-based settings, and other care settings and instances in which Federal programs may have been billed for services that were medically unnecessary, not rendered or not rendered as prescribed, or the care was so deficient that it constituted "worthless services"

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OIG WP: Focus on Protected Health Information (PHI)

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Security of Portable Devices

- Security of portable devices containing personal health information (PHI)
 - Review security controls implemented by Medicare and Medicaid contractors and at hospitals to prevent the loss of PHI stored on portable devices and media, such as laptops, jump drives, backup tapes, and equipment considered for disposal
 - Assess and test contractors' and hospitals' policies and procedures for electronic health information protections, access, storage, and transport

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Networked Medical Devices

- Controls over networked medical devices at hospitals (new)
 - Determine whether hospitals' security controls over networked medical devices are sufficient to effectively protect associated electronically protected health information (ePHI) and ensure beneficiary safety
 - Premise: Computerized medical devices, such as dialysis machines, radiology systems, and medication dispensing systems that are integrated with EMRs and the larger health network, pose a growing threat to the security and privacy of personal health information
 - Medical device manufacturers provide Manufacturer Disclosure Statement for Medical Device Security (MDS2) forms to assist health care providers in assessing the vulnerability and risks associated with ePHI that is transmitted or maintained by a medical devices

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OIG WP: Focus on Payment Issues

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Medicare Part C

- Risk adjustment data—Sufficiency of documentation supporting diagnoses
 - Review medical record documentation to ensure that it supports the diagnoses MA organizations submitted to CMS for use in CMS's risk-score calculations and determine whether the diagnoses submitted complied with Federal requirements
 - Prior OIG reviews have shown that medical record documentation does not always support the diagnoses submitted to CMS by the MA organizations)
 - Premise: Payments to MA organizations are adjusted on basis of the health status of each beneficiary, so inaccurate diagnoses may cause CMS to pay MA organizations improper amounts

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Provider Taxes

- State use of provider taxes to generate Federal funding
 - Review State health-care-related taxes imposed on various Medicaid providers to determine whether the taxes comply with applicable Federal requirements
 - Focus on the mechanism States use to raise revenue through provider taxes and determine the amount of Federal funding generated
 - Prior OIG work raised concerns about States' use of health-care-related taxes

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Certified Public Expenditures

- State compliance with Federal Certified Public Expenditures (CPE) regulations
 - Determine whether States are complying with Federal regulations for claiming CPEs, which are normally generated by local governments as part of their contribution to the coverage of Medicaid services
 - States may claim CPEs to provide the States' shares in claiming Federal reimbursement as long as the CPEs comply with Federal regulations and are being used for the required purposes

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Medicaid Credit Balances

- Recovering Medicaid overpayments—Credit balances in Medicaid patient accounts
 - Review providers' patient accounts to determine whether there are Medicaid overpayments in accounts with credit balances
 - Previous OIG work found Medicaid overpayments in patients' accounts with credit balances

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Medicaid MCOs

- Medicaid managed care reimbursement (new)
 - Review States' managed care plan reimbursements to determine whether MCOs are appropriately and correctly reimbursed for services provided
 - Ensure that the data used to set rates are reliable and include only costs for services covered under the State plan as required by or costs of services authorized by CMS
 - Verify that payments made under a risk-sharing mechanism and incentive payments made to MCOs are within the limits set forth in Federal regulations
 - Previous GAO work found that CMS's oversight of States' rate setting required improvement and that States may not audit or independently verify the MCO reported data used to set rates.

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Preparing for the Audits



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Resources

- HHS/DOJ Health Care Fraud and Abuse Control Program Report for Fiscal Year 2013:
<http://oig.hhs.gov/publications/docs/hcfac/FY2013-hcfac.pdf>
- OIG Outlook 2014:
<http://oig.hhs.gov/newsroom/outlook/index.asp>
- OIG Strategic Plan 2014-2018:
<http://oig.hhs.gov/reports-and-publications/strategic-plan/files/OIG-Strategic-Plan-2014-2018.pdf>
- OIG Work Plan for Fiscal Year 2014:
<http://oig.hhs.gov/reports-and-publications/archives/workplan/2014/Work-Plan-2014.pdf>

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Resources

- Selected recent OIG reports focused on post-acute providers:
 - Medicare Nursing Home Resident Hospitalization Rates Merit Additional Monitoring, OEI-06-0040, (Nov. 2013), <http://oig.hhs.gov/reports/oig-reports/oei-06-0040>
 - Frequency of Medicare Recertification Surveys for Hospitals Is Unimproved, OEI-06-13-00150, (Aug. 2013), <http://oig.hhs.gov/reports/oig-reports/oei-06-13-00150.pdf>
 - Some States Improperly Restrict Eligibility for Medicaid Mandatory Home Health Services, OEI-07-13-00065, (July 2013), <http://oig.hhs.gov/reports/oig-reports/oei-07-13-00065.pdf>
 - Medicare Hospital Use of General Inpatient Care, OEI-02-13-00440, (May 2013), <http://oig.hhs.gov/reports/oig-reports/oei-02-13-00440.pdf>
 - Medicare And State Medicaid By-the-Day Payment And Transfer Payment Policy For Early Discharge To Hospice Care, AAI-12-02607, (May 2013), <http://oig.hhs.gov/reports/oig-reports/aa-12-02607.pdf>
 - Skilled Nursing Facilities Often Fail To Meet Care Planning And Discharge Planning Requirements, OEI-02-09-00001, (Feb. 2013), <http://oig.hhs.gov/reports/oig-reports/oei-02-09-00001.pdf>
 - Personal Care Services: Trends, Vulnerabilities, and Recommendations for Improvement—A Portfolio, OIG-12-12-01, (Nov. 2013), <http://oig.hhs.gov/reports/oig-reports/oig-12-12-01.pdf>
 - Inappropriate Payments To Skilled Nursing Facilities Cost Medicare More Than A Billion Dollars In 2009, OEI-02-09-00020, (Nov. 2012), <http://oig.hhs.gov/reports/oig-reports/oei-02-09-00020.pdf>
 - Criminal Convictions for Nurse Aides With Substantiated Findings of Abuse, Neglect, and Misappropriation, OEI-07-10-00422, (Oct. 2012), <http://oig.hhs.gov/reports/oig-reports/oei-07-10-00422.pdf>
 - Medicare And State Medicaid By-the-Day Payment Policy For Residents Receiving Acylcyclostein Drugs, OEI-07-08-00151, (July 2012), <http://oig.hhs.gov/reports/oig-reports/oei-07-08-00151.pdf>
 - Guidelines To Exit In Response To Emergency Preparedness And Response During Disasters, 2007-2010, OEI-09-09-00270, (April 2012), <http://oig.hhs.gov/reports/oig-reports/oei-09-09-00270.pdf>
 - Home Health Agency And Skilled Nursing Facility Checks In Long-Term-Care Facilities: Results of Long-Term-Care Provider Administrator Survey, OEI-07-10-00421, (Jun. 2012), <http://oig.hhs.gov/reports/oig-reports/oei-07-10-00421.pdf>
 - Changes in Skilled Nursing Facility Billing in Fiscal Year 2011, OEI-02-09-00024, (Apr. 2011), <http://oig.hhs.gov/reports/oig-reports/oei-02-09-00024.pdf>
 - Medicare And State Medicaid By-the-Day Payment Policy For Non-Part A Nursing Home Stays in 2008, OEI-06-07-00580, (July 2011), <http://oig.hhs.gov/reports/oig-reports/oei-06-07-00580.pdf>
 - Medicaid Services Provided to An Adult Day Health Setting, OEI-09-07-00500, (July 2011), <http://oig.hhs.gov/reports/oig-reports/oei-09-07-00500.pdf>
 - Medicare Acylcyclostein Drug Claims For Elderly Nursing Home Residents, OEI-07-08-00150, (May 2011), <http://oig.hhs.gov/reports/oig-reports/oei-07-08-00150.pdf>
 - Questionable Billing By Skilled Nursing Facilities, OEI-02-09-00020, (Dec. 2010), <http://oig.hhs.gov/reports/oig-reports/oei-02-09-00020.pdf>

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HCCA 2014 Compliance Institute
San Diego, CA
April 2014

Top 10 Tips for Effectively Assessing Your Business Associates

Web Hull, Sr. Privacy & Compliance Specialist
Iron Mountain

1

Iron Mountain Data & Information Management

- Global
 - Over 30 countries & Growing
- Vendor to over 160,000 B2B Customers
 - Ranging from the world's largest to the smallest
- '000's of Vendors / Subcontractors / Business Associates
- 18,000 employees

2

Iron Mountain is a Business Associate to:

- Over 2,000 Covered Entities
- Thousands of Medical Practices, Clinics, Pharmacies, and the like
- An Unknown Number of Business Associates that are:
 - Banks
 - Law Firms
 - ...

3

Here's What We Do in Health Care

- Paper Records Storage
- Data Back-up & DR – Tapes, DVDs, CDs, ...
- Shredding
- Return of Information (“ROI”)
- Digital Scanning - Convert Paper to Image
- Store Medical Images – MRIs, CAT Scans, ...
- X-Ray on Demand
- Image on Demand
- Managed Data Centers
- Records Management Consulting

4

Why Worry About Your Business Associates?

- Ponemon Institute Studies
 - Almost 20% of data breaches were the result of “outsourcing data to a third party” - 2012
 - Identified “third party error” as the highest per capita contributor to the cost of a breach – 2013
- HHS 2014 Business Associate & Covered Entity Audits
- The Omnibus Rule

5

Where does it explicitly say that you have to assess your Business Associates?

- No where?
- At a minimum, you want to know and manage
 - Your risk of a breach
 - The confidentiality, integrity, and availability of your PHI & ePHI

6

But wait ... Here's Some Guidance!

- The Security Rule Says:

§ 164.308 (a)(1)(i)(ii)

(A) Risk analysis (Required).

Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity or business associate.

(B) Risk management (Required).

Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with § 164.306(a).

7

What about ... ?

- Paper?
 - The Privacy Rule
- Policies & Procedures – You Got to Have Them
 - The Security Rule Again – “Implement Policies and Procedures”
 - Think through what you need for your Business Associate assessment program

8

3 Pillars of Business Associate Management – Tip #1

1. Business Associate Agreement (“BAA”) & Contract – For your Legal Department
 - HHS Template / Model BAA
 - Stuff to go in a Master Services Agreement (“MSA”) or Addendum
 - OCC / FRB Guidance

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3 Pillars of the Business Associate Management – Tip #1

2. When to do a Risk Analysis / Assessment

- Request for Proposal (“RFP”)
- Pre-contract
- Periodically thereafter
- Contract Renewal
- Change in the Business Associate’s Business
- Change in Law or Regulation
- After an Incident

10

3 Pillars of the Business Associate Management – Tip #1

3. Monitor, Audit, Remediate

- Address / provide for in contract
- Have a plan

11

Top 10 Tips – Tip #2

- Make this a thoughtful & balanced process
- You will never have perfect information
- The perfect is the enemy of the good
- “Reasonable” – It’s My Favorite Word
- Judgment is a virtue – and
 - A Talent and
 - A Skill

12

Top 10 Tips – Tip #3

- Identify All Your Business Associates – You should have already updated your BAA with them
 - New
 - Legacy
- Who is responsible for generating the list of Business Associates & keeping it up to date?
 - Business Sponsors?
 - Procurement?
 - Others?

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Top 10 Tips – Tip #3

- PHI & ePHI – Know where your Business Associates are located, & what they
 - Have of yours
 - Do with it
 - Where They Send it
 - 4th Party
 - Cross Border – Safe Harbor, Model Contracts, BCRs

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Top 10 Tips – Tip #3

- Buy One – HIPAA
 - Get One Free - Massachusetts 201 CMR 17:00
 - And Another One for Free – State Breach Laws

15

Top 10 Tips – Tip #4

- Make Sure That ONE Person in Your Company Is Truly / Ultimately Responsible for Each Business Associate
 - This is the “Business Sponsor”

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Top 10 Tips – Tip #4

- The Business Sponsor is Responsible for:
 - Proposing the Business Associate
 - Knowing the details of the work that the Business Associate will do
 - Describing to the Assessment Team in a clear statement what the Business Associate will do and how it will do it
 - And a whole lot more ...

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Top 10 Tips – Tip #5

- Rank Your Risk & Manage It Accordingly
 - High, Medium, Low
 - 1 to 5
- It's up to you to decide the factors
 - Use 10 ± Qualifying Questions
- What might rank “High”?
 - Access to your Systems

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Top 10 Tips – Tip #5

- Risk Ranking Drives
 - The Detailed Assessment - Number of Questions, Depth of Interviews, On-site Audits, ...
 - On-going Oversight – Frequency of reassessment, On-site Audit, ...
- Answering these Questions is the responsibility of the Business Sponsor
 - Of course, you might have to help the Business Sponsor

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Top 10 Tips – Tip #6

- Have a Detailed Assessment Tool & Use It
 - Develop one – Usually a Questionnaire
 - Potential Sources of Specific Assessment Areas for a custom questionnaire
 - HIPAA Security Rule Standards
 - Massachusetts 201 CMR 17:00
 - PCI
 - Alternatively, use an existing tool
 - Shared Assessments: www.SharedAssessment.com
 - Others?

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Top 10 Tips – Tip #6

- Questionnaire Format – It's up to you
 - Yes / No Answers
 - Evidence – SOC 2, Code of Ethics, ...
 - Space for Comments

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Top 10 Tips – Tip #7

- Have a GRC System – or GRC Look Alike
 - There are lots of GRC vendors out there
 - SharePoint
 - Other?
- Uses
 - Push out Questionnaire
 - Score Returns
 - Repository of Historical Records –
Questionnaires, Certifications, emails, Audits, ...

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Top 10 Tips – Tip #8

- It Takes a Village
 - Business Sponsor
 - Procurement
 - Security – InfoSec & Physical Security
 - Privacy & Compliance
 - Legal
 - Accounts Payable
 - Others?

23

Top 10 Tips – Tip #9

- Have a program
 - Some one
 - Has to do the work
 - Have the authority to get things done
 - Have a place to sit
 - Report some where
 - Executive Sponsorship
 - Policy & Procedures

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Top 10 Tips - Tip #10

- There's No Such Thing as a Free Lunch
 - Staff
 - GRC
 - On-site Audits
- Who Pays?
 - Business Sponsor
 - Functions
 - Corporate
 - Other?

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But wait ...
There's more!

26

Top 10 Tips – Tip #11

- Have a Plan to Monitor, Reassess, & Audit (On-site & Desk Audits)
 - Make sure these rights are in your contract
 - Align with risk rating – “High” gets more attention than “Low”
- Tools – GRC Driven?
 - Certifications
 - Independent 3rd Party Attestations
 - Questionnaires
 - Audit Reports
 - Others?

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Top 10 Tips – Tip #12

- The “Cloud”
 - See OCC Guidance
 - Where’s the ePHI?
 - Can we reasonably assess the provider?
- Social Media
- BYOD

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Top 10 Tips – Tip #13

- There are always Vexing Issues
 - What Do You Do When They Can’t / Won’t Answer Your Questions?
 - What to Do When You Can’t Get Agreement / Items Need Remediation / Something Goes Wrong with Your Business Associate /?
 - Deal Breakers?
 - Encryption
 - Background Checks
 - Others?

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Thanks!
&
Questions?

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For More Information
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Guidance on Managing Outsourcing Risk

Division of Banking Supervision and Regulation
Division of Consumer and Community Affairs
Board of Governors of the Federal Reserve System

December 5, 2013

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I. Purpose

In addition to traditional core bank processing and information technology services, financial institutions¹ outsource operational activities such as accounting, appraisal management, internal audit, human resources, sales and marketing, loan review, asset and wealth management, procurement, and loan servicing. The Federal Reserve is issuing this guidance to financial institutions to highlight the potential risks arising from the use of service providers and to describe the elements of an appropriate service provider risk management program. This guidance supplements existing guidance on technology service provider (TSP) risk,² and applies to service provider relationships where business functions or activities are outsourced. For purposes of this guidance, “service providers” is broadly defined to include all entities³ that have entered into a contractual relationship with a financial institution to provide business functions or activities.

II. Risks from the Use of Service Providers

The use of service providers to perform operational functions presents various risks to financial institutions. Some risks are inherent to the outsourced activity itself, whereas others are introduced with the involvement of a service provider. If not managed effectively, the use of service providers may expose financial institutions to risks that can result in regulatory action, financial loss, litigation, and loss of reputation. Financial institutions should consider the following risks before entering into and while managing outsourcing arrangements.

- *Compliance risks* arise when the services, products, or activities of a service provider fail to comply with applicable U.S. laws and regulations.
- *Concentration risks* arise when outsourced services or products are provided by a limited number of service providers or are concentrated in limited geographic locations.
- *Reputational risks* arise when actions or poor performance of a service provider causes the public to form a negative opinion about a financial institution.

¹ For purposes of this guidance, a “financial institution” refers to state member banks, bank and savings and loan holding companies (including their nonbank subsidiaries), and U.S. operations of foreign banking organizations.

² Refer to the FFIEC *Outsourcing Technology Services Booklet* (June 2004) at <http://ithandbook.ffiec.gov/it-booklets/outsourcing-technology-services.aspx>.

³ Entities may be a bank or nonbank, affiliated or non-affiliated, regulated or non-regulated, or domestic or foreign.

- *Country risks* arise when a financial institution engages a foreign-based service provider, exposing the institution to possible economic, social, and political conditions and events from the country where the provider is located.
- *Operational risks* arise when a service provider exposes a financial institution to losses due to inadequate or failed internal processes or systems or from external events and human error.
- *Legal risks* arise when a service provider exposes a financial institution to legal expenses and possible lawsuits.

III. Board of Directors and Senior Management Responsibilities

The use of service providers does not relieve a financial institution's board of directors and senior management of their responsibility to ensure that outsourced activities are conducted in a safe-and-sound manner and in compliance with applicable laws and regulations. Policies governing the use of service providers should be established and approved by the board of directors, or an executive committee of the board. These policies should establish a service provider risk management program that addresses risk assessments and due diligence, standards for contract provisions and considerations, ongoing monitoring of service providers, and business continuity and contingency planning.

Senior management is responsible for ensuring that board-approved policies for the use of service providers are appropriately executed. This includes overseeing the development and implementation of an appropriate risk management and reporting framework that includes elements described in this guidance. Senior management is also responsible for regularly reporting to the board of directors on adherence to policies governing outsourcing arrangements.

IV. Service Provider Risk Management Programs

A financial institution's service provider risk management program should be risk-focused and provide oversight and controls commensurate with the level of risk presented by the outsourcing arrangements in which the financial institution is engaged. It should focus on outsourced activities that have a substantial impact on a financial institution's financial condition; are critical to the institution's ongoing operations; involve sensitive customer information or new bank products or services; or pose material compliance risk.

The depth and formality of the service provider risk management program will depend on the criticality, complexity, and number of material business activities being outsourced. A

community banking organization may have critical business activities being outsourced, but the number may be few and to highly reputable service providers. Therefore, the risk management program may be simpler and use less elements and considerations. For those financial institutions that may use hundreds or thousands of service providers for numerous business activities that have material risk, the financial institution may find that they need to use many more elements and considerations of a service provider risk management program to manage the higher level of risk and reliance on service providers.

While the activities necessary to implement an effective service provider risk management program can vary based on the scope and nature of a financial institution's outsourced activities, effective programs usually include the following core elements:

- A. Risk assessments;
- B. Due diligence and selection of service providers;
- C. Contract provisions and considerations;
- D. Incentive compensation review;
- E. Oversight and monitoring of service providers; and
- F. Business continuity and contingency plans.

A. Risk Assessments

Risk assessment of a business activity and the implications of performing the activity in-house or having the activity performed by a service provider are fundamental to the decision of whether or not to outsource. A financial institution should determine whether outsourcing an activity is consistent with the strategic direction and overall business strategy of the organization. After that determination is made, a financial institution should analyze the benefits and risks of outsourcing the proposed activity as well as the service provider risk, and determine cost implications for establishing the outsourcing arrangement. Consideration should also be given to the availability of qualified and experienced service providers to perform the service on an ongoing basis. Additionally, management should consider the financial institution's ability and expertise to provide appropriate oversight and management of the relationship with the service provider.

This risk assessment should be updated at appropriate intervals consistent with the financial institution's service provider risk management program. A financial institution should revise its risk mitigation plans, if appropriate, based on the results of the updated risk assessment.

B. Due Diligence and Selection of Service Providers

A financial institution should conduct an evaluation of and perform the necessary due diligence for a prospective service provider prior to engaging the service provider. The depth and formality of the due diligence performed will vary depending on the scope, complexity, and

importance of the planned outsourcing arrangement, the financial institution's familiarity with prospective service providers, and the reputation and industry standing of the service provider. Throughout the due diligence process, financial institution technical experts and key stakeholders should be engaged in the review and approval process as needed. The overall due diligence process includes a review of the service provider with regard to:

1. Business background, reputation, and strategy;
2. Financial performance and condition; and
3. Operations and internal controls.

1. Business Background, Reputation, and Strategy

Financial institutions should review a prospective service provider's status in the industry and corporate history and qualifications; review the background and reputation of the service provider and its principals; and ensure that the service provider has an appropriate background check program for its employees.

The service provider's experience in providing the proposed service should be evaluated in order to assess its qualifications and competencies to perform the service. The service provider's business model, including its business strategy and mission, service philosophy, quality initiatives, and organizational policies should be evaluated. Financial institutions should also consider the resiliency and adaptability of the service provider's business model as factors in assessing the future viability of the provider to perform services.

Financial institutions should check the service provider's references to ascertain its performance record, and verify any required licenses and certifications. Financial institutions should also verify whether there are any pending legal or regulatory compliance issues (for example, litigation, regulatory actions, or complaints) that are associated with the prospective service provider and its principals.

2. Financial Performance and Condition

Financial institutions should review the financial condition of the service provider and its closely-related affiliates. The financial review may include:

- The service provider's most recent financial statements and annual report with regard to outstanding commitments, capital strength, liquidity and operating results.
- The service provider's sustainability, including factors such as the length of time that the service provider has been in business and the service provider's growth of market share for a given service.
- The potential impact of the financial institution's business relationship on the service provider's financial condition.

- The service provider's commitment (both in terms of financial and staff resources) to provide the contracted services to the financial institution for the duration of the contract.
- The adequacy of the service provider's insurance coverage.
- The adequacy of the service provider's review of the financial condition of any subcontractors.
- Other current issues the service provider may be facing that could affect future financial performance.

3. Operations and Internal Controls

Financial institutions are responsible for ensuring that services provided by service providers comply with applicable laws and regulations and are consistent with safe-and-sound banking practices. Financial institutions should evaluate the adequacy of standards, policies, and procedures. Depending on the characteristics of the outsourced activity, some or all of the following may need to be reviewed:

- Internal controls;
- Facilities management (such as access requirements or sharing of facilities);
- Training, including compliance training for staff;
- Security of systems (for example, data and equipment);
- Privacy protection of the financial institution's confidential information;
- Maintenance and retention of records;
- Business resumption and contingency planning;
- Systems development and maintenance;
- Service support and delivery;
- Employee background checks; and
- Adherence to applicable laws, regulations, and supervisory guidance.

C. Contract Provisions and Considerations

Financial institutions should understand the service contract and legal issues associated with proposed outsourcing arrangements. The terms of service agreements should be defined in written contracts that have been reviewed by the financial institution's legal counsel prior to execution. The characteristics of the business activity being outsourced and the service

provider's strategy for providing those services will determine the terms of the contract. Elements of well-defined contracts and service agreements usually include:

- **Scope:** Contracts should clearly define the rights and responsibilities of each party, including:
 - Support, maintenance, and customer service;
 - Contract timeframes;
 - Compliance with applicable laws, regulations, and regulatory guidance;
 - Training of financial institution employees;
 - The ability to subcontract services;
 - The distribution of any required statements or disclosures to the financial institution's customers;
 - Insurance coverage requirements; and
 - Terms governing the use of the financial institution's property, equipment, and staff.
- **Cost and compensation:** Contracts should describe the compensation, variable charges, and any fees to be paid for non-recurring items and special requests. Agreements should also address which party is responsible for the payment of any legal, audit, and examination fees related to the activity being performed by the service provider. Where applicable, agreements should address the party responsible for the expense, purchasing, and maintenance of any equipment, hardware, software or any other item related to the activity being performed by the service provider. In addition, financial institutions should ensure that any incentives (for example, in the form of variable charges, such as fees and/or commissions) provided in contracts do not provide potential incentives to take imprudent risks on behalf of the institution.
- **Right to audit:** Agreements may provide for the right of the institution or its representatives to audit the service provider and/or to have access to audit reports. Agreements should define the types of audit reports the financial institution will receive and the frequency of the audits and reports.
- **Establishment and monitoring of performance standards:** Agreements should define measurable performance standards for the services or products being provided.
- **Confidentiality and security of information:** Consistent with applicable laws, regulations, and supervisory guidance, service providers should ensure the security and confidentiality of both the financial institution's confidential information and the financial institution's customer information. Information security measures for outsourced functions should be viewed as if the activity were being performed by the financial institution and afforded the same protections. Financial institutions have a responsibility to ensure service providers take appropriate measures designed to meet

the objectives of the information security guidelines within Federal Financial Institutions Examination Council (FFIEC) guidance⁴, as well as comply with section 501(b) of the Gramm-Leach-Bliley Act. These measures should be mapped directly to the security processes at financial institutions, as well as be included or referenced in agreements between financial institutions and service providers.

Service agreements should also address service provider use of financial institution information and its customer information. Information made available to the service provider should be limited to what is needed to provide the contracted services.

Service providers may reveal confidential supervisory information only to the extent authorized under applicable laws and regulations.⁵

If service providers handle any of the financial institution customer's Nonpublic Personal Information (NPPI), the service providers must comply with applicable privacy laws and regulations.⁶ Financial institutions should require notification from service providers of any breaches involving the disclosure of NPPI data. Generally, NPPI data is any nonpublic personally identifiable financial information; and any list, description, or other grouping of consumers (and publicly available information pertaining to them) derived using any personally identifiable financial information that is not publicly available.⁷ Financial institutions and their service providers who maintain, store, or process NPPI data are responsible for that information and any disclosure of it. The security of, retention of, and access to NPPI data should be addressed in any contracts with service providers.

When a breach or compromise of NPPI data occurs, financial institutions have legal requirements that vary by state and these requirements should be made part of the contracts between the financial institution and any service provider that provides storage, processing, or transmission of NPPI data. Misuse or unauthorized disclosure of confidential customer data by service providers may expose financial institutions to liability or action by a federal or state regulatory agency. Contracts should clearly authorize and disclose the roles and responsibilities of financial institutions and service providers regarding NPPI data.

- ***Ownership and license:*** Agreements should define the ability and circumstances under which service providers may use financial institution property inclusive of data, hardware, software, and intellectual property. Agreements should address the ownership and control of any information generated by service providers. If financial institutions purchase software from service providers, escrow agreements may be

⁴ For further guidance regarding vendor security practices, refer to the *FFIEC Information Security Booklet* (July 2006) at <http://ithandbook.ffiec.gov/it-booklets/information-security.aspx>.

⁵ See 12 CFR Part 261.

⁶ See 12 CFR Part 1016.

⁷ See 12 U.S.C. 6801(b).

needed to ensure that financial institutions have the ability to access the source code and programs under certain conditions.⁸

- ***Indemnification:*** Agreements should provide for service provider indemnification of financial institutions for any claims against financial institutions resulting from the service provider's negligence.
- ***Default and termination:*** Agreements should define events of a contractual default, list of acceptable remedies, and provide opportunities for curing default. Agreements should also define termination rights, including change in control, merger or acquisition, increase in fees, failure to meet performance standards, failure to fulfill the contractual obligations, failure to provide required notices, and failure to prevent violations of law, bankruptcy, closure, or insolvency. Contracts should include termination and notification requirements that provide financial institutions with sufficient time to transfer services to another service provider. Agreements should also address a service provider's preservation and timely return of financial institution data, records, and other resources.
- ***Dispute resolution:*** Agreements should include a dispute resolution process in order to expedite problem resolution and address the continuation of the arrangement between the parties during the dispute resolution period.
- ***Limits on liability:*** Service providers may want to contractually limit their liability. The board of directors and senior management of a financial institution should determine whether the proposed limitations are reasonable when compared to the risks to the institution if a service provider fails to perform.⁹
- ***Insurance:*** Service providers should have adequate insurance and provide financial institutions with proof of insurance. Further, service providers should notify financial institutions when there is a material change in their insurance coverage.
- ***Customer complaints:*** Agreements should specify the responsibilities of financial institutions and service providers related to responding to customer complaints. If service providers are responsible for customer complaint resolution, agreements should provide for summary reports to the financial institutions that track the status and resolution of complaints.
- ***Business resumption and contingency plan of the service provider:*** Agreements should address the continuation of services provided by service providers in the event of operational failures. Agreements should address service provider responsibility for

⁸ Escrow agreements are established with vendors when buying or leasing products that have underlying proprietary software. In such agreements, an organization can only access the source program code under specific conditions, such as discontinued product support or financial insolvency of the vendor.

⁹ Refer to SR letter 06-4, "Interagency Advisory on the Unsafe and Unsound Use of Limitations on Liability Provisions in External Audit Engagement Letters," regarding restrictions on the liability limitations for external audit engagements at <http://www.federalreserve.gov/boarddocs/srletters/2006/SR0604.htm>.

backing up information and maintaining disaster recovery and contingency plans. Agreements may include a service provider's responsibility for testing of plans and providing testing results to financial institutions.

- **Foreign-based service providers:** For agreements with foreign-based service providers, financial institutions should consider including express choice of law and jurisdictional provisions that would provide for the adjudication of all disputes between the two parties under the laws of a single, specific jurisdiction. Such agreements may be subject to the interpretation of foreign courts relying on local laws. Foreign law may differ from U.S. law in the enforcement of contracts. As a result, financial institutions should seek legal advice regarding the enforceability of all aspects of proposed contracts with foreign-based service providers and the other legal ramifications of such arrangements.
- **Subcontracting:** If agreements allow for subcontracting, the same contractual provisions should apply to the subcontractor. Contract provisions should clearly state that the primary service provider has overall accountability for all services that the service provider and its subcontractors provide. Agreements should define the services that may be subcontracted, the service provider's due diligence process for engaging and monitoring subcontractors, and the notification and approval requirements regarding changes to the service provider's subcontractors. Financial institutions should pay special attention to any foreign subcontractors, as information security and data privacy standards may be different in other jurisdictions. Additionally, agreements should include the service provider's process for assessing the subcontractor's financial condition to fulfill contractual obligations.

D. Incentive Compensation Review

Financial institutions should also ensure that an effective process is in place to review and approve any incentive compensation that may be embedded in service provider contracts, including a review of whether existing governance and controls are adequate in light of risks arising from incentive compensation arrangements. As the service provider represents the institution by selling products or services on its behalf, the institution should consider whether the incentives provided might encourage the service provider to take imprudent risks. Inappropriately structured incentives may result in reputational damage, increased litigation, or other risks to the financial institution. An example of an inappropriate incentive would be one where variable fees or commissions encourage the service provider to direct customers to products with higher profit margins without due consideration of whether such products are suitable for the customer.

E. Oversight and Monitoring of Service Providers

To effectively monitor contractual requirements, financial institutions should establish acceptable performance metrics that the business line or relationship management determines to be indicative of acceptable performance levels. Financial institutions should ensure that

personnel with oversight and management responsibilities for service providers have the appropriate level of expertise and stature to manage the outsourcing arrangement. The oversight process, including the level and frequency of management reporting, should be risk-focused. Higher risk service providers may require more frequent assessment and monitoring and may require financial institutions to designate individuals or a group as a point of contact for those service providers. Financial institutions should tailor and implement risk mitigation plans for higher risk service providers that may include processes such as additional reporting by the service provider or heightened monitoring by the financial institution. Further, more frequent and stringent monitoring is necessary for service providers that exhibit performance, financial, compliance, or control concerns. For lower risk service providers, the level of monitoring can be lessened.

Financial condition: Financial institutions should have established procedures to monitor the financial condition of service providers to evaluate their ongoing viability. In performing these assessments, financial institutions should review the most recent financial statements and annual report with regard to outstanding commitments, capital strength, liquidity and operating results. If a service provider relies significantly on subcontractors to provide services to financial institutions, then the service provider's controls and due diligence regarding the subcontractors should also be reviewed.

Internal controls: For significant service provider relationships, financial institutions should assess the adequacy of the provider's control environment. Assessments should include reviewing available audits or reports such as the American Institute of Certified Public Accountants' Service Organization Control 2 report.¹⁰ If the service provider delivers information technology services, the financial institution can request the FFIEC Technology Service Provider examination report from its primary federal regulator. Security incidents at the service provider may also necessitate the institution to elevate its monitoring of the service provider.

Escalation of oversight activities: Financial institutions should ensure that risk management processes include triggers to escalate oversight and monitoring when service providers are failing to meet performance, compliance, control, or viability expectations. These procedures should include more frequent and stringent monitoring and follow-up on identified issues, on-site control reviews, and when an institution should exercise its right to audit a service provider's adherence to the terms of the agreement. Financial institutions should develop criteria for engaging alternative outsourcing arrangements and terminating the service provider contract in the event that identified issues are not adequately addressed in a timely manner.

F. Business Continuity and Contingency Considerations

Various events may affect a service provider's ability to provide contracted services. For example, services could be disrupted by a provider's performance failure, operational disruption, financial difficulty, or failure of business continuity and contingency plans during operational

¹⁰ Refer to www.AICPA.org.

disruptions or natural disasters. Financial institution contingency plans should focus on critical services provided by service providers and consider alternative arrangements in the event that a service provider is unable to perform.¹¹ When preparing contingency plans, financial institutions should:

- Ensure that a disaster recovery and business continuity plan exists with regard to the contracted services and products;
- Assess the adequacy and effectiveness of a service provider's disaster recovery and business continuity plan and its alignment to their own plan;
- Document the roles and responsibilities for maintaining and testing the service provider's business continuity and contingency plans;
- Test the service provider's business continuity and contingency plans on a periodic basis to ensure adequacy and effectiveness; and
- Maintain an exit strategy, including a pool of comparable service providers, in the event that a contracted service provider is unable to perform.

G. Additional Risk Considerations

Suspicious Activity Report (SAR) reporting functions: The confidentiality of suspicious activity reporting makes the outsourcing of any SAR-related function more complex. Financial institutions need to identify and monitor the risks associated with using service providers to perform certain suspicious activity reporting functions in compliance with the Bank Secrecy Act (BSA). Financial institution management should ensure they understand the risks associated with such an arrangement and any BSA-specific guidance in this area.

Foreign-based service providers: Financial institutions should ensure that foreign-based service providers are in compliance with applicable U.S. laws, regulations, and regulatory guidance. Financial institutions may also want to consider laws and regulations of the foreign-based provider's country or regulatory authority regarding the financial institution's ability to perform on-site review of the service provider's operations. In addition, financial institutions should consider the authority or ability of home country supervisors to gain access to the financial institution's customer information while examining the foreign-based service provider.

Internal audit: Financial institutions should refer to existing guidance on the engagement of independent public accounting firms and other outside professionals to perform work that has been traditionally carried out by internal auditors.¹² The Sarbanes-Oxley Act of

¹¹ For further guidance regarding business continuity planning with service providers, refer to the FFIEC *Business Continuity Booklet* (March 2008) at <http://ithandbook.ffiec.gov/it-booklets/business-continuity-planning.aspx>.

¹² Refer to SR 13-1, "Supplemental Policy Statement on the Internal Audit Function and Its Outsourcing," specifically the section titled, "Depository Institutions Subject to the Annual Audit and Reporting Requirements of Section 36 of the FDI Act" at <http://www.federalreserve.gov/bankinforeg/srletters/sr1301.htm>. Refer also to SR 03-5, "Amended Interagency Guidance on the Internal Audit Function and its Outsourcing,"

2002 specifically prohibits a registered public accounting firm from performing certain non-audit services for a public company client for whom it performs financial statement audits.

Risk management activities: Financial institutions may outsource various risk management activities, such as aspects of interest rate risk and model risk management. Financial institutions should require service providers to provide information that demonstrates developmental evidence explaining the product components, design, and intended use, to determine whether the products and/or services are appropriate for the institution's exposures and risks.¹³ Financial institutions should also have standards and processes in place for ensuring that service providers offering model risk management services, such as validation, do so in a way that is consistent with existing model risk management guidance.

particularly the section titled, "Institutions Not Subject to Section 36 of the FDIA Act that are Neither Public Companies nor Subsidiaries of Public Companies" at
<http://www.federalreserve.gov/boarddocs/srletters/2003/sr0305.htm>.

¹³ Refer to SR 11-7, "Guidance on Model Risk Management" which informs financial institutions of the importance and risk to the use of models and the supervisory expectations that financial institutions should adhere to.
<http://www.federalreserve.gov/bankinforeg/srletters/sr1107.htm>



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Outsourced Cloud Computing

Summary

The Federal Financial Institution Examination Council Agencies consider *cloud computing* to be another form of outsourcing with the same basic risk characteristics and risk management requirements as traditional forms of outsourcing. This paper addresses the key risks of outsourced cloud computing identified in existing guidance.

Cloud computing is a relatively new term used to describe a variety of established business strategies, technologies, and processing methodologies. Although the term cloud computing is gaining in usage, there is no widely-accepted definition,¹ and numerous business strategies, technologies, and architectures are represented as cloud computing. In general, cloud computing is a migration from owned resources to shared resources in which client users receive information technology services, on demand, from third-party service providers via the Internet “cloud.”

Cloud computing has several service and deployment models. The service models include the provision of infrastructure, computing platforms, and software as a service. The deployment models relate to how the cloud service is provided. These models include: a private cloud, which is operated solely for an organization; a community cloud, which is shared by several organizations; a public cloud, which is available to any paying customer; and a hybrid cloud, which is a composition of two or more clouds (private, community, or public).

Financial institutions that contemplate or use a cloud computing model in which all or part of the service is outsourced (“*outsourced cloud computing*”) have to consider the fundamentals of risk and risk management defined in the *FFIEC Information Technology Examination Handbook* (IT Handbook), especially the Outsourcing Technology Services Booklet (“Outsourcing Booklet”).

¹ In December 2011, the National Institute for Standards and Technology (NIST) issued Special Publication 800-144, “Guidelines on Security and Privacy in Public Cloud Computing.” In this publication, NIST defines cloud computing “as a model for enabling convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or cloud provider interaction.”

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The following discussion addresses the key elements of outsourced cloud computing implementation and risk management as they relate to the Outsourcing Booklet.

Due Diligence

A financial institution's use of third parties to achieve its strategic plan does not diminish the responsibility of the board of directors and management to ensure that the third-party activity is conducted in a safe and sound manner and in compliance with applicable laws and regulations.

Outsourcing to a cloud service provider can be advantageous to financial institutions because of potential benefits such as cost reduction, flexibility, scalability, improved load balancing, and speed. Before approving any outsourcing of significant functions, it is important to ensure such actions are consistent with the institution's strategic plans and corporate objectives approved by the board of directors and senior management.

As detailed in the Outsourcing Booklet, a due diligence review is performed to ensure that the provider will meet the institution's requirements in terms of cost, quality of service, compliance with regulatory requirements, and risk management. The following are potential issues related to cloud computing:

- **Data classification:** How sensitive is the data that will be placed in the cloud (e.g., confidential, critical, public) and what controls should be in place to ensure it is properly protected? Does the cloud service provider appropriately encrypt or otherwise protect non-public personal information (NPPI) and other data whose disclosure could harm the institution or its customers?
- **Data segregation:** Will the financial institution's data share resources with data from other cloud clients? For example, will the data be transmitted over the same networks, and stored or processed on servers that are also used by other clients? If so, what controls does the service provider have to ensure the integrity and confidentiality of the financial institution's data?
- **Recoverability:** How will the service provider respond to disasters and ensure continued service? Do the financial institution's disaster recovery and business continuity plans include appropriate consideration of this form of outsourcing, the service provider's disaster recovery and business continuity plans, and the availability of essential communications links?

Vendor Management

Managing a cloud computing service provider may require additional controls if the servicer is unfamiliar with the financial industry and the financial institution's legal and regulatory requirements for safeguarding customer information and other sensitive data. Additionally, the use of such a servicer may present risks that the institution is unable or unwilling to mitigate. One example of such risks would be if the servicer is not

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implementing changes to meet regulatory requirements. Under such circumstances, management may determine that the institution cannot employ the servicer.

Disengagement of a service provider is another aspect of vendor management that can be complicated in cloud computing, particularly for smaller financial institutions. It is important that contracts and service level agreements are specific as to the ownership, location(s) and format(s) of data, and dispute resolution.

Audit

To effectively evaluate the risk and risk mitigation associated with the use of third-party servicers, a financial institution must determine the adequacy of a servicer's internal controls. Auditors assist in this evaluation by assessing whether those controls are functioning appropriately.

A financial institution's audit policies and practices may require adjustments to provide acceptable IT audit coverage of outsourced cloud computing. Also, it may be necessary to augment the internal audit staff with additional training and personnel with sufficient expertise in evaluating shared environments and virtualized technologies.

Information Security

As with other forms of outsourcing, information security implications are key considerations in the cloud computing model. Financial institutions may need to revise their information security policies, standards, and practices to incorporate the activities related to a cloud computing service provider. In high-risk situations, continuous monitoring may be necessary for financial institutions to have a sufficient level of assurance that the servicer is maintaining effective controls.

It is important that financial institutions maintain a comprehensive data inventory and a suitable data classification process, and that access to customer data is restricted appropriately through effective identity and access management. A multi-tenant cloud deployment, in which multiple clients share network resources, increases the need for data protection through encryption and additional assurance that proper controls are in place to restrict tenant access solely to their respective data. Verifying the data handling procedures, the adequacy and availability of backup data, and whether multiple service providers are sharing facilities are important considerations. If financial institutions are not sure that their data are satisfactorily protected and access to their data is appropriately controlled, entering into a third-party relationship with such servicer may be ill advised.

Storage of data in the cloud could increase the frequency and complexity of security incidents. Therefore, management processes of financial institutions should include effective monitoring of security-related threats, incidents, and events on both financial institutions' and servicers' networks; comprehensive incident response methodologies; and maintenance of appropriate forensic strategies for investigation and evidence collection.

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The potential that data are not completely removed or deleted from the servicer's storage media at the conclusion of a service contract may pose higher risk in a cloud computing environment than it does in more traditional forms of outsourcing. Before entering into a third-party relationship, it is prudent to ensure that the cloud-computing service provider can remove NPPI from all locations where it is stored.

Legal, Regulatory, and Reputational Considerations

Important considerations for financial institutions before deploying a public cloud computing model include clearly identifying and mitigating legal, regulatory, and reputational risks. The nature of cloud computing may increase the complexity of compliance with applicable laws and regulations because customer data may be stored or processed overseas. A financial institution's ability to assess compliance may be more complex and difficult in an environment where the cloud computing service provider processes and stores data overseas or comingles the financial institution's data with data from other customers that operate under diverse legal and regulatory jurisdictions. A financial institution should understand the applicability of laws and regulations within the hosting countries and the financial institution's ability to control access to its data. Contracts with the cloud-computing service providers should specify the servicers' obligations with respect to the financial institutions' responsibilities for compliance with privacy laws, for responding to and reporting about security incidents, and for fulfilling regulatory requirements to notify customers and regulators of any breaches.

Business Continuity Planning

The business continuity planning process in a financial institution involves the recovery, resumption, and maintenance of the entire business, including outsourced activities. When considering outsourcing to a cloud-computing service provider, financial institutions need to determine whether the servicer and the network carriers have adequate plans and resources to ensure the financial institution's continuity of operations, as well as its ability to recover and resume operations if an unexpected disruption occurs.²

Conclusion

The fundamentals of risk and risk management defined in the IT Handbook apply to cloud computing as they do to other forms of outsourcing. Cloud computing may require more robust controls due to the nature of the service. When evaluating the feasibility of outsourcing to a cloud-computing service provider, it is important to look beyond potential benefits and to perform a thorough due diligence and risk assessment of elements specific to that service. Vendor management, information security, audits, legal and regulatory compliance, and business continuity planning are key elements of sound risk management and risk mitigation controls for cloud computing. As with other service provider offerings, cloud computing may not be appropriate for all financial institutions.

² For further information, refer to the "Business Continuity Planning" section in the Outsourcing Booklet.

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§ 164.308(a)(4)(ii)(A) and § 164.504(g), as applicable.

(c)(1) *Standard: Documentation.* A covered entity must maintain a written or electronic record of a designation as required by paragraphs (a) or (b) of this section.

(2) *Implementation specification: Retention period.* A covered entity must retain the documentation as required by paragraph (c)(1) of this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later.

[68 FR 8375, Feb. 20, 2003, as amended at 78 FR 5692, Jan. 25, 2013]

§ 164.106 Relationship to other parts.

In complying with the requirements of this part, covered entities and, where provided, business associates, are required to comply with the applicable provisions of parts 160 and 162 of this subchapter.

[78 FR 5693, Jan. 25, 2013]

Subpart B [Reserved]**Subpart C—Security Standards for the Protection of Electronic Protected Health Information**

AUTHORITY: 42 U.S.C. 1320d-2 and 1320d-4; sec. 13401, Pub. L. 111-5, 123 Stat. 260.

SOURCE: 68 FR 8376, Feb. 20, 2003, unless otherwise noted.

§ 164.302 Applicability.

A covered entity or business associate must comply with the applicable standards, implementation specifications, and requirements of this subpart with respect to electronic protected health information of a covered entity.

[78 FR 5693, Jan. 25, 2013]

§ 164.304 Definitions.

As used in this subpart, the following terms have the following meanings:

Access means the ability or the means necessary to read, write, modify, or communicate data/information or otherwise use any system resource. (This definition applies to “access” as used in this subpart, not as used in subparts D or E of this part.)

Administrative safeguards are administrative actions, and policies and procedures, to manage the selection, development, implementation, and maintenance of security measures to protect electronic protected health information and to manage the conduct of the covered entity's or business associate's workforce in relation to the protection of that information.

Authentication means the corroboration that a person is the one claimed.

Availability means the property that data or information is accessible and useable upon demand by an authorized person.

Confidentiality means the property that data or information is not made available or disclosed to unauthorized persons or processes.

Encryption means the use of an algorithmic process to transform data into a form in which there is a low probability of assigning meaning without use of a confidential process or key.

Facility means the physical premises and the interior and exterior of a building(s).

Information system means an interconnected set of information resources under the same direct management control that shares common functionality. A system normally includes hardware, software, information, data, applications, communications, and people.

Integrity means the property that data or information have not been altered or destroyed in an unauthorized manner.

Malicious software means software, for example, a virus, designed to damage or disrupt a system.

Password means confidential authentication information composed of a string of characters.

Physical safeguards are physical measures, policies, and procedures to protect a covered entity's or business associate's electronic information systems and related buildings and equipment, from natural and environmental hazards, and unauthorized intrusion.

Security or Security measures encompass all of the administrative, physical, and technical safeguards in an information system.

Security incident means the attempted or successful unauthorized access, use,

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disclosure, modification, or destruction of information or interference with system operations in an information system.

Technical safeguards means the technology and the policy and procedures for its use that protect electronic protected health information and control access to it.

User means a person or entity with authorized access.

Workstation means an electronic computing device, for example, a laptop or desktop computer, or any other device that performs similar functions, and electronic media stored in its immediate environment.

[68 FR 8376, Feb. 20, 2003, as amended at 74 FR 42767, Aug. 24, 2009; 78 FR 5693, Jan. 25, 2013]

§ 164.306 Security standards: General rules.

(a) *General requirements.* Covered entities and business associates must do the following:

(1) Ensure the confidentiality, integrity, and availability of all electronic protected health information the covered entity or business associate creates, receives, maintains, or transmits.

(2) Protect against any reasonably anticipated threats or hazards to the security or integrity of such information.

(3) Protect against any reasonably anticipated uses or disclosures of such information that are not permitted or required under subpart E of this part.

(4) Ensure compliance with this subpart by its workforce.

(b) *Flexibility of approach.* (1) Covered entities and business associates may use any security measures that allow the covered entity or business associate to reasonably and appropriately implement the standards and implementation specifications as specified in this subpart.

(2) In deciding which security measures to use, a covered entity or business associate must take into account the following factors:

(i) The size, complexity, and capabilities of the covered entity or business associate.

(ii) The covered entity's or the business associate's technical infrastruc-

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ture, hardware, and software security capabilities.

(iii) The costs of security measures.

(iv) The probability and criticality of potential risks to electronic protected health information.

(c) *Standards.* A covered entity or business associate must comply with the applicable standards as provided in this section and in §164.308, §164.310, §164.312, §164.314 and §164.316 with respect to all electronic protected health information.

(d) *Implementation specifications.* In this subpart:

(1) Implementation specifications are required or addressable. If an implementation specification is required, the word "Required" appears in parentheses after the title of the implementation specification. If an implementation specification is addressable, the word "Addressable" appears in parentheses after the title of the implementation specification.

(2) When a standard adopted in §164.308, §164.310, §164.312, §164.314, or §164.316 includes required implementation specifications, a covered entity or business associate must implement the implementation specifications.

(3) When a standard adopted in §164.308, §164.310, §164.312, §164.314, or §164.316 includes addressable implementation specifications, a covered entity or business associate must—

(i) Assess whether each implementation specification is a reasonable and appropriate safeguard in its environment, when analyzed with reference to the likely contribution to protecting electronic protected health information; and

(ii) As applicable to the covered entity or business associate—

(A) Implement the implementation specification if reasonable and appropriate; or

(B) If implementing the implementation specification is not reasonable and appropriate—

\$(1) Document why it would not be reasonable and appropriate to implement the implementation specification; and

\$(2) Implement an equivalent alternative measure if reasonable and appropriate.

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(e) *Maintenance.* A covered entity or business associate must review and modify the security measures implemented under this subpart as needed to continue provision of reasonable and appropriate protection of electronic protected health information, and update documentation of such security measures in accordance with § 164.316(b)(2)(iii).

[68 FR 8376, Feb. 20, 2003; 68 FR 17153, Apr. 8, 2003; 78 FR 5693, Jan. 25, 2013]

§ 164.308 Administrative safeguards.

(a) A covered entity or business associate must, in accordance with § 164.306:

(1)(i) *Standard: Security management process.* Implement policies and procedures to prevent, detect, contain, and correct security violations.

(ii) *Implementation specifications:*

(A) *Risk analysis (Required).* Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information held by the covered entity or business associate.

(B) *Risk management (Required).* Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with § 164.306(a).

(C) *Sanction policy (Required).* Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of the covered entity or business associate.

(D) *Information system activity review (Required).* Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.

(2) *Standard: Assigned security responsibility.* Identify the security official who is responsible for the development and implementation of the policies and procedures required by this subpart for the covered entity or business associate.

(3)(1) *Standard: Workforce security.* Implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic protected health information, as provided under paragraph (a)(4) of this sec-

tion, and to prevent those workforce members who do not have access under paragraph (a)(4) of this section from obtaining access to electronic protected health information.

(ii) *Implementation specifications:*

(A) *Authorization and/or supervision (Addressable).* Implement procedures for the authorization and/or supervision of workforce members who work with electronic protected health information or in locations where it might be accessed.

(B) *Workforce clearance procedure (Addressable).* Implement procedures to determine that the access of a workforce member to electronic protected health information is appropriate.

(C) *Termination procedures (Addressable).* Implement procedures for terminating access to electronic protected health information when the employment of, or other arrangement with, a workforce member ends or as required by determinations made as specified in paragraph (a)(3)(ii)(B) of this section.

(4)(i) *Standard: Information access management.* Implement policies and procedures for authorizing access to electronic protected health information that are consistent with the applicable requirements of subpart E of this part.

(ii) *Implementation specifications:*

(A) *Isolating health care clearinghouse functions (Required).* If a health care clearinghouse is part of a larger organization, the clearinghouse must implement policies and procedures that protect the electronic protected health information of the clearinghouse from unauthorized access by the larger organization.

(B) *Access authorization (Addressable).* Implement policies and procedures for granting access to electronic protected health information, for example, through access to a workstation, transaction, program, process, or other mechanism.

(C) *Access establishment and modification (Addressable).* Implement policies and procedures that, based upon the covered entity's or the business associate's access authorization policies, establish, document, review, and modify a user's right of access to a workstation, transaction, program, or process.

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(5)(i) *Standard: Security awareness and training.* Implement a security awareness and training program for all members of its workforce (including management).

(ii) *Implementation specifications.* Implement:

(A) *Security reminders (Addressable).* Periodic security updates.

(B) *Protection from malicious software (Addressable).* Procedures for guarding against, detecting, and reporting malicious software.

(C) *Log-in monitoring (Addressable).* Procedures for monitoring log-in attempts and reporting discrepancies.

(D) *Password management (Addressable).* Procedures for creating, changing, and safeguarding passwords.

(6)(i) *Standard: Security incident procedures.* Implement policies and procedures to address security incidents.

(ii) *Implementation specification: Response and reporting (Required).* Identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents that are known to the covered entity or business associate; and document security incidents and their outcomes.

(7)(i) *Standard: Contingency plan.* Establish (and implement as needed) policies and procedures for responding to an emergency or other occurrence (for example, fire, vandalism, system failure, and natural disaster) that damages systems that contain electronic protected health information.

(ii) *Implementation specifications:*

(A) *Data backup plan (Required).* Establish and implement procedures to create and maintain retrievable exact copies of electronic protected health information.

(B) *Disaster recovery plan (Required).* Establish (and implement as needed) procedures to restore any loss of data.

(C) *Emergency mode operation plan (Required).* Establish (and implement as needed) procedures to enable continuation of critical business processes for protection of the security of electronic protected health information while operating in emergency mode.

(D) *Testing and revision procedures (Addressable).* Implement procedures for periodic testing and revision of contingency plans.

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(E) *Applications and data criticality analysis (Addressable).* Assess the relative criticality of specific applications and data in support of other contingency plan components.

(8) *Standard: Evaluation.* Perform a periodic technical and nontechnical evaluation, based initially upon the standards implemented under this rule and, subsequently, in response to environmental or operational changes affecting the security of electronic protected health information, that establishes the extent to which a covered entity's or business associate's security policies and procedures meet the requirements of this subpart.

(b)(1) *Business associate contracts and other arrangements.* A covered entity may permit a business associate to create, receive, maintain, or transmit electronic protected health information on the covered entity's behalf only if the covered entity obtains satisfactory assurances, in accordance with § 164.314(a), that the business associate will appropriately safeguard the information. A covered entity is not required to obtain such satisfactory assurances from a business associate that is a subcontractor.

(2) A business associate may permit a business associate that is a subcontractor to create, receive, maintain, or transmit electronic protected health information on its behalf only if the business associate obtains satisfactory assurances, in accordance with § 164.314(a), that the subcontractor will appropriately safeguard the information.

(3) *Implementation specifications: Written contract or other arrangement (Required).* Document the satisfactory assurances required by paragraph (b)(1) or (b)(2) of this section through a written contract or other arrangement with the business associate that meets the applicable requirements of § 164.314(a).

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013]

§ 164.310 Physical safeguards.

A covered entity or business associate must, in accordance with § 164.306:

(a)(1) *Standard: Facility access controls.* Implement policies and procedures to limit physical access to its

electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed.

(2) *Implementation specifications:*

(i) *Contingency operations (Addressable).* Establish (and implement as needed) procedures that allow facility access in support of restoration of lost data under the disaster recovery plan and emergency mode operations plan in the event of an emergency.

(ii) *Facility security plan (Addressable).* Implement policies and procedures to safeguard the facility and the equipment therein from unauthorized physical access, tampering, and theft.

(iii) *Access control and validation procedures (Addressable).* Implement procedures to control and validate a person's access to facilities based on their role or function, including visitor control, and control of access to software programs for testing and revision.

(iv) *Maintenance records (Addressable).* Implement policies and procedures to document repairs and modifications to the physical components of a facility which are related to security (for example, hardware, walls, doors, and locks).

(b) *Standard: Workstation use.* Implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic protected health information.

(c) *Standard: Workstation security.* Implement physical safeguards for all workstations that access electronic protected health information, to restrict access to authorized users.

(d)(1) *Standard: Device and media controls.* Implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic protected health information into and out of a facility, and the movement of these items within the facility.

(2) *Implementation specifications:*

(i) *Disposal (Required).* Implement policies and procedures to address the final disposition of electronic protected health information, and/or the hard-

ware or electronic media on which it is stored.

(ii) *Media re-use (Required).* Implement procedures for removal of electronic protected health information from electronic media before the media are made available for re-use.

(iii) *Accountability (Addressable).* Maintain a record of the movements of hardware and electronic media and any person responsible therefore.

(iv) *Data backup and storage (Addressable).* Create a retrievable, exact copy of electronic protected health information, when needed, before movement of equipment.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013]

§ 164.312 Technical safeguards.

A covered entity or business associate must, in accordance with § 164.306:

(a)(1) *Standard: Access control.* Implement technical policies and procedures for electronic information systems that maintain electronic protected health information to allow access only to those persons or software programs that have been granted access rights as specified in § 164.308(a)(4).

(2) *Implementation specifications:*

(i) *Unique user identification (Required).* Assign a unique name and/or number for identifying and tracking user identity.

(ii) *Emergency access procedure (Required).* Establish (and implement as needed) procedures for obtaining necessary electronic protected health information during an emergency.

(iii) *Automatic logoff (Addressable).* Implement electronic procedures that terminate an electronic session after a predetermined time of inactivity.

(iv) *Encryption and decryption (Addressable).* Implement a mechanism to encrypt and decrypt electronic protected health information.

(b) *Standard: Audit controls.* Implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic protected health information.

(c)(1) *Standard: Integrity.* Implement policies and procedures to protect electronic protected health information from improper alteration or destruction.

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(2) *Implementation specification: Mechanism to authenticate electronic protected health information (Addressable).* Implement electronic mechanisms to corroborate that electronic protected health information has not been altered or destroyed in an unauthorized manner.

(d) *Standard: Person or entity authentication.* Implement procedures to verify that a person or entity seeking access to electronic protected health information is the one claimed.

(e)(1) *Standard: Transmission security.* Implement technical security measures to guard against unauthorized access to electronic protected health information that is being transmitted over an electronic communications network.

(2) *Implementation specifications:*

(i) *Integrity controls (Addressable).* Implement security measures to ensure that electronically transmitted electronic protected health information is not improperly modified without detection until disposed of.

(ii) *Encryption (Addressable).* Implement a mechanism to encrypt electronic protected health information whenever deemed appropriate.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013]

§ 164.314 Organizational requirements.

(a)(1) *Standard: Business associate contracts or other arrangements.* The contract or other arrangement required by § 164.308(b)(3) must meet the requirements of paragraph (a)(2)(i), (a)(2)(ii), or (a)(2)(iii) of this section, as applicable.

(2) *Implementation specifications (Required).*

(1) *Business associate contracts.* The contract must provide that the business associate will—

(A) Comply with the applicable requirements of this subpart;

(B) In accordance with § 164.308(b)(2), ensure that any subcontractors that create, receive, maintain, or transmit electronic protected health information on behalf of the business associate agree to comply with the applicable requirements of this subpart by entering into a contract or other arrangement that complies with this section; and

(C) Report to the covered entity any security incident of which it becomes

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aware, including breaches of unsecured protected health information as required by § 164.410.

(ii) *Other arrangements.* The covered entity is in compliance with paragraph (a)(1) of this section if it has another arrangement in place that meets the requirements of § 164.504(e)(3).

(iii) *Business associate contracts with subcontractors.* The requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section apply to the contract or other arrangement between a business associate and a subcontractor required by § 164.308(b)(4) in the same manner as such requirements apply to contracts or other arrangements between a covered entity and business associate.

(b)(1) *Standard: Requirements for group health plans.* Except when the only electronic protected health information disclosed to a plan sponsor is disclosed pursuant to § 164.504(f)(1)(ii) or (iii), or as authorized under § 164.508, a group health plan must ensure that its plan documents provide that the plan sponsor will reasonably and appropriately safeguard electronic protected health information created, received, maintained, or transmitted to or by the plan sponsor on behalf of the group health plan.

(2) *Implementation specifications (Required).* The plan documents of the group health plan must be amended to incorporate provisions to require the plan sponsor to—

(i) Implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits on behalf of the group health plan;

(ii) Ensure that the adequate separation required by § 164.504(f)(2)(iii) is supported by reasonable and appropriate security measures;

(iii) Ensure that any agent to whom it provides this information agrees to implement reasonable and appropriate security measures to protect the information; and

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(iv) Report to the group health plan any security incident of which it becomes aware.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5694, Jan. 25, 2013; 78 FR 34266, June 7, 2013]

§ 164.316 Policies and procedures and documentation requirements.

A covered entity or business associate must, in accordance with § 164.306:

(a) *Standard: Policies and procedures.* Implement reasonable and appropriate policies and procedures to comply with the standards, implementation specifications, or other requirements of this subpart, taking into account those factors specified in § 164.306(b)(2)(i), (ii), (iii), and (iv). This standard is not to be construed to permit or excuse an action that violates any other standard, implementation specification, or other requirements of this subpart. A covered entity or business associate may change its policies and procedures at any time, provided that the changes are documented and are implemented in accordance with this subpart.

(b)(1) *Standard: Documentation.* (1) Maintain the policies and procedures implemented to comply with this subpart in written (which may be electronic) form; and

(ii) If an action, activity or assessment is required by this subpart to be documented, maintain a written (which may be electronic) record of the action, activity, or assessment.

(2) *Implementation specifications:*

(i) *Time limit (Required).* Retain the documentation required by paragraph (b)(1) of this section for 6 years from the date of its creation or the date when it last was in effect, whichever is later.

(ii) *Availability (Required).* Make documentation available to those persons responsible for implementing the procedures to which the documentation pertains.

(iii) *Updates (Required).* Review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the electronic protected health information.

[68 FR 8376, Feb. 20, 2003, as amended at 78 FR 5695, Jan. 25, 2013]

§ 164.318 Compliance dates for the initial implementation of the security standards.

(a) *Health plan.* (1) A health plan that is not a small health plan must comply with the applicable requirements of this subpart no later than April 20, 2005.

(2) A small health plan must comply with the applicable requirements of this subpart no later than April 20, 2006.

(b) *Health care clearinghouse.* A health care clearinghouse must comply with the applicable requirements of this subpart no later than April 20, 2005.

(c) *Health care provider.* A covered health care provider must comply with the applicable requirements of this subpart no later than April 20, 2005.

APPENDIX A TO SUBPART C OF PART 164—SECURITY STANDARDS: MATRIX

Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
Administrative Safeguards		
Security Management Process	164.308(a)(1)	Risk Analysis (R) Risk Management (R) Sanction Policy (R) Information System Activity Review (R) (R) Authorization and/or Supervision (A) Workforce Clearance Procedure Termination Procedures (A) Isolating Health care Clearinghouse Function (R) Access Authorization (A) Access Establishment and Modification (A) Security Reminders (A) Protection from Malicious Software (A) Log-in Monitoring (A) Password Management (A)
Assigned Security Responsibility	164.308(a)(2)	
Workforce Security	164.308(a)(3)	
Information Access Management	164.308(a)(4)	
Security Awareness and Training	164.308(a)(5)	

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Standards	Sections	Implementation Specifications (R)=Required, (A)=Addressable
Security Incident Procedures	164.308(a)(6)	Response and Reporting (R)
Contingency Plan	164.308(a)(7)	Data Backup Plan (R) Disaster Recovery Plan (R) Emergency Mode Operation Plan (R) Testing and Revision Procedure (A) Applications and Data Criticality Analysis (A)
Evaluation	164.308(a)(8)	(R)
Business Associate Contracts and Other Arrangement.	164.308(b)(1)	Written Contract or Other Arrangement (R)
Physical Safeguards		
Facility Access Controls	164.310(a)(1)	Contingency Operations (A) Facility Security Plan (A) Access Control and Validation Procedures (A) Maintenance Records (A)
Workstation Use	164.310(b)	(R)
Workstation Security	164.310(c)	(R)
Device and Media Controls	164.310(d)(1)	Disposal (R) Media Re-use (R) Accountability (A) Data Backup and Storage (A)
Technical Safeguards (see § 164.312)		
Access Control	164.312(a)(1)	Unique User Identification (R) Emergency Access Procedure (R) Automatic Logoff (A) Encryption and Decryption (A)
Audit Controls	164.312(b)	(R)
Integrity	164.312(c)(1)	Mechanism to Authenticate Electronic Protected Health Information (A)
Person or Entity Authentication	164.312(d)	(R)
Transmission Security	164.312(e)(1)	Integrity Controls (A) Encryption (A)

Subpart D—Notification in the Case of Breach of Unsecured Protected Health Information

SOURCE: 74 FR 42767, Aug. 24, 2009, unless otherwise noted.

§ 164.400 Applicability.

The requirements of this subpart shall apply with respect to breaches of protected health information occurring on or after September 23, 2009.

§ 164.402 Definitions.

As used in this subpart, the following terms have the following meanings:

Breach means the acquisition, access, use, or disclosure of protected health information in a manner not permitted under subpart E of this part which compromises the security or privacy of the protected health information.

(1) Breach excludes:

(i) Any unintentional acquisition, access, or use of protected health information by a workforce member or per-

son acting under the authority of a covered entity or a business associate, if such acquisition, access, or use was made in good faith and within the scope of authority and does not result in further use or disclosure in a manner not permitted under subpart E of this part.

(ii) Any inadvertent disclosure by a person who is authorized to access protected health information at a covered entity or business associate to another person authorized to access protected health information at the same covered entity or business associate, or organized health care arrangement in which the covered entity participates, and the information received as a result of such disclosure is not further used or disclosed in a manner not permitted under subpart E of this part.

(iii) A disclosure of protected health information where a covered entity or business associate has a good faith belief that an unauthorized person to whom the disclosure was made would

201 CMR 17.00: STANDARDS FOR THE PROTECTION OF PERSONAL INFORMATION OF RESIDENTS OF THE COMMONWEALTH

Section:

17.01: Purpose and Scope

17.02: Definitions

17.03: Duty to Protect and Standards for Protecting Personal Information

17.04: Computer System Security Requirements

17.05: Compliance Deadline

17.01 Purpose and Scope

(1) Purpose

This regulation implements the provisions of M.G.L. c. 93H relative to the standards to be met by persons who own or license personal information about a resident of the Commonwealth of Massachusetts. This regulation establishes minimum standards to be met in connection with the safeguarding of personal information contained in both paper and electronic records. The objectives of this regulation are to insure the security and confidentiality of customer information in a manner fully consistent with industry standards; protect against anticipated threats or hazards to the security or integrity of such information; and protect against unauthorized access to or use of such information that may result in substantial harm or inconvenience to any consumer.

(2) Scope

The provisions of this regulation apply to all persons that own or license personal information about a resident of the Commonwealth.

17.02: Definitions

The following words as used herein shall, unless the context requires otherwise, have the following meanings:

Breach of security, the unauthorized acquisition or unauthorized use of unencrypted data or, encrypted electronic data and the confidential process or key that is capable of compromising the security, confidentiality, or integrity of personal information, maintained by a person or agency that creates a substantial risk of identity theft or fraud against a resident of the commonwealth. A good faith but unauthorized acquisition of personal information by a person or agency, or employee or agent thereof, for the lawful purposes of such person or agency, is not a breach of security unless the personal information is used in an unauthorized manner or subject to further unauthorized disclosure.

Electronic, relating to technology having electrical, digital, magnetic, wireless, optical, electromagnetic or similar capabilities.

Encrypted, the transformation of data into a form in which meaning cannot be assigned without the use of a confidential process or key.

Owns or licenses, receives, stores, maintains, processes, or otherwise has access to personal information in connection with the provision of goods or services or in connection with employment.

Person, a natural person, corporation, association, partnership or other legal entity, other than an agency, executive office, department, board, commission, bureau, division or authority of the Commonwealth, or any of its branches, or any political subdivision thereof.

Personal information, a Massachusetts resident's first name and last name or first initial and last name in combination with any one or more of the following data elements that relate to such resident: (a) Social Security number; (b) driver's license number or state-issued identification card number; or (c) financial account number, or credit or debit card number, with or without any required security code, access code, personal identification number or password, that would permit access to a resident's financial account; provided, however, that "Personal information" shall not include information that is lawfully obtained from publicly available information, or from federal, state or local government records lawfully made available to the general public.

Record or Records, any material upon which written, drawn, spoken, visual, or electromagnetic information or images are recorded or preserved, regardless of physical form or characteristics.

Service provider, any person that receives, stores, maintains, processes, or otherwise is permitted access to personal information through its provision of services directly to a person that is subject to this regulation.

17.03: Duty to Protect and Standards for Protecting Personal Information

(1) Every person that owns or licenses personal information about a resident of the Commonwealth shall develop, implement, and maintain a comprehensive information security program that is written in one or more readily accessible parts and contains administrative, technical, and physical safeguards that are appropriate to (a) the size, scope and type of business of the person obligated to safeguard the personal information under such comprehensive information security program; (b) the amount of resources available to such person; (c) the amount of stored data; and (d) the need for security and confidentiality of both consumer and employee information. The safeguards contained in such program must be consistent with the safeguards for protection of personal information and information of a similar character set forth in any state or federal regulations by which the person who owns or licenses such information may be regulated.

- (2) Without limiting the generality of the foregoing, every comprehensive information security program shall include, but shall not be limited to:
- (a) Designating one or more employees to maintain the comprehensive information security program;
 - (b) Identifying and assessing reasonably foreseeable internal and external risks to the security, confidentiality, and/or integrity of any electronic, paper or other records containing personal information, and evaluating and improving, where necessary, the effectiveness of the current safeguards for limiting such risks, including but not limited to:
 1. ongoing employee (including temporary and contract employee) training;
 2. employee compliance with policies and procedures; and
 3. means for detecting and preventing security system failures.
 - (c) Developing security policies for employees relating to the storage, access and transportation of records containing personal information outside of business premises.
 - (d) Imposing disciplinary measures for violations of the comprehensive information security program rules.
 - (e) Preventing terminated employees from accessing records containing personal information.
 - (f) Oversee service providers, by:
 1. Taking reasonable steps to select and retain third-party service providers that are capable of maintaining appropriate security measures to protect such personal information consistent with these regulations and any applicable federal regulations; and
 2. Requiring such third-party service providers by contract to implement and maintain such appropriate security measures for personal information; provided, however, that until March 1, 2012, a contract a person has entered into with a third party service provider to perform services for said person or functions on said person's behalf satisfies the provisions of 17.03(2)(f)(2) even if the contract does not include a requirement that the third party service provider maintain such appropriate safeguards, as long as said person entered into the contract no later than March 1, 2010.
 - (g) Reasonable restrictions upon physical access to records containing personal information,, and storage of such records and data in locked facilities, storage areas or containers.
 - (h) Regular monitoring to ensure that the comprehensive information security program is operating in a manner reasonably calculated to prevent unauthorized access to or unauthorized use of personal information; and upgrading information safeguards as necessary to limit risks.
 - (i) Reviewing the scope of the security measures at least annually or whenever there is a material change in business practices that may reasonably implicate the security or integrity of records containing personal information.
 - (j) Documenting responsive actions taken in connection with any incident involving a breach of security, and mandatory post-incident review of events and actions taken, if any, to make changes in business practices relating to protection of personal information.

17.04: Computer System Security Requirements

Every person that owns or licenses personal information about a resident of the Commonwealth and electronically stores or transmits such information shall include in its written, comprehensive information security program the establishment and maintenance of a

security system covering its computers, including any wireless system, that, at a minimum, and to the extent technically feasible, shall have the following elements:

- (1) Secure user authentication protocols including:
 - (a) control of user IDs and other identifiers;
 - (b) a reasonably secure method of assigning and selecting passwords, or use of unique identifier technologies, such as biometrics or token devices;
 - (c) control of data security passwords to ensure that such passwords are kept in a location and/or format that does not compromise the security of the data they protect;
 - (d) restricting access to active users and active user accounts only; and
 - (e) blocking access to user identification after multiple unsuccessful attempts to gain access or the limitation placed on access for the particular system;
- (2) Secure access control measures that:
 - (a) restrict access to records and files containing personal information to those who need such information to perform their job duties; and
 - (b) assign unique identifications plus passwords, which are not vendor supplied default passwords, to each person with computer access, that are reasonably designed to maintain the integrity of the security of the access controls;
- (3) Encryption of all transmitted records and files containing personal information that will travel across public networks, and encryption of all data containing personal information to be transmitted wirelessly.
- (4) Reasonable monitoring of systems, for unauthorized use of or access to personal information;
- (5) Encryption of all personal information stored on laptops or other portable devices;
- (6) For files containing personal information on a system that is connected to the Internet, there must be reasonably up-to-date firewall protection and operating system security patches, reasonably designed to maintain the integrity of the personal information.
- (7) Reasonably up-to-date versions of system security agent software which must include malware protection and reasonably up-to-date patches and virus definitions, or a version of such software that can still be supported with up-to-date patches and virus definitions, and is set to receive the most current security updates on a regular basis.
- (8) Education and training of employees on the proper use of the computer security system and the importance of personal information security.

17.05: Compliance Deadline

- (1) Every person who owns or licenses personal information about a resident of the Commonwealth shall be in full compliance with 201 CMR 17.00 on or before March 1, 2010.

REGULATORY AUTHORITY

201 CMR 17.00: M.G.L. c. 93H

OCC BULLETIN 2013-29

Subject: Third-Party Relationships
Date: October 30, 2013

To: Chief Executive Officers and Chief Risk Officers of All National Banks and Federal Savings Associations, Technology Service Providers, Department and Division Heads, All Examining Personnel, and Other Interested Parties

Description: Risk Management Guidance

Summary

This bulletin provides guidance to national banks and federal savings associations (collectively, banks) for assessing and managing risks associated with third-party relationships. A third-party relationship is any business arrangement between a bank and another entity, by contract or otherwise.¹

The Office of the Comptroller of the Currency (OCC) expects a bank to practice effective risk management regardless of whether the bank performs the activity internally or through a third party. A bank's use of third parties does not diminish the responsibility of its board of directors and senior management to ensure that the activity is performed in a safe and sound manner and in compliance with applicable laws.²

This bulletin rescinds OCC Bulletin 2001-47, "Third-Party Relationships: Risk Management Principles," and OCC Advisory Letter 2000-9, "Third-Party Risk." This bulletin supplements and should be used in conjunction with other OCC and interagency issuances on third-party relationships and risk management listed in appendix B. In connection with the issuance of this bulletin, the OCC is applying to federal savings associations (FSA) certain guidance applicable to national banks, as indicated in appendix B.

Highlights

- A bank should adopt risk management processes commensurate with the level of risk and complexity of its third-party relationships.
- A bank should ensure comprehensive risk management and oversight of third-party relationships involving critical activities.
- An effective risk management process throughout the life cycle of the relationship includes
 - plans that outline the bank's strategy, identify the inherent risks of the activity, and detail how the bank selects, assesses, and oversees the third party.
 - proper due diligence in selecting a third party.
 - written contracts that outline the rights and responsibilities of all parties.
 - ongoing monitoring of the third party's activities and performance.
 - contingency plans for terminating the relationship in an effective manner.
 - clear roles and responsibilities for overseeing and managing the relationship and risk management process.
 - Documentation and reporting that facilitates oversight, accountability, monitoring, and risk management.
 - Independent reviews that allow bank management to determine that the bank's process aligns with its strategy and effectively manages risks.

Note for Community Banks

This guidance applies to all banks with third-party relationships. A community bank should adopt risk management practices commensurate with the level of risk and complexity of its third-party relationships. A community bank's board and management should identify those third-party relationships that involve critical activities and ensure the bank has risk management practices in place to assess, monitor, and manage the risks.

Background

Banks continue to increase the number and complexity of relationships with both foreign and domestic third parties, such as

- outsourcing entire bank functions to third parties, such as tax, legal, audit, or information technology operations.
- outsourcing lines of business or products.
- relying on a single third party to perform multiple activities, often to such an extent that the third party becomes an integral component of the bank's operations.
- working with third parties that engage directly with customers.³
- contracting with third parties that subcontract activities to other foreign and domestic providers.
- contracting with third parties whose employees, facilities, and subcontractors may be geographically concentrated.
- working with a third party to address deficiencies in bank operations or compliance with laws or regulations.

The OCC is concerned that the quality of risk management over third-party relationships may not be keeping pace with the level of risk and complexity of these relationships. The OCC has identified instances in which bank management has

- failed to properly assess and understand the risks and direct and indirect costs involved in third-party relationships.
- failed to perform adequate due diligence and ongoing monitoring of third-party relationships.
- entered into contracts without assessing the adequacy of a third party's risk management practices.
- entered into contracts that incentivize a third party to take risks that are detrimental to the bank or its customers, in order to maximize the third party's revenues.
- engaged in informal third-party relationships without contracts in place.

These examples represent trends whose associated risks reinforce the need for banks to maintain effective risk management practices over third-party relationships.

Risk Management Life Cycle

The OCC expects a bank to have risk management processes that are commensurate with the level of risk and complexity of its third-party relationships and the bank's organizational structures. Therefore, the OCC expects more comprehensive and rigorous oversight and management of third-party relationships that involve ***critical activities***—significant bank functions (e.g., payments, clearing, settlements, custody) or significant shared services (e.g., information technology), or other activities that

- could cause a bank to face significant risk⁴ if the third party fails to meet expectations.
- could have significant customer impacts.
- require significant investment in resources to implement the third-party relationship and manage the risk.
- could have a major impact on bank operations if the bank has to find an alternate third party or if the outsourced activity has to be brought in-house.

An effective third-party risk management process follows a continuous life cycle for all relationships and incorporates the following phases:

Planning: Developing a plan to manage the relationship is often the first step in the third-party risk management process. This step is helpful for many situations but is necessary when a bank is considering contracts with third parties that involve critical activities.

Due diligence and third-party selection: Conducting a review of a potential third party before signing a contract⁵ helps ensure that the bank selects an appropriate third party and understands and controls the risks posed by the relationship, consistent with the bank's risk appetite.

Contract negotiation: Developing a contract that clearly defines expectations and responsibilities of the third party helps to ensure the contract's enforceability, limit the bank's liability, and mitigate disputes about performance.

Ongoing monitoring: Performing ongoing monitoring of the third-party relationship once the contract is in place is essential to the bank's ability to manage risk of the third-party relationship.

Termination: Developing a contingency plan to ensure that the bank can transition the activities to another third party, bring the activities in-house, or discontinue the activities when a contract expires, the terms of the contract have been satisfied, in response to contract default, or in response to changes to the bank's or third party's business strategy.

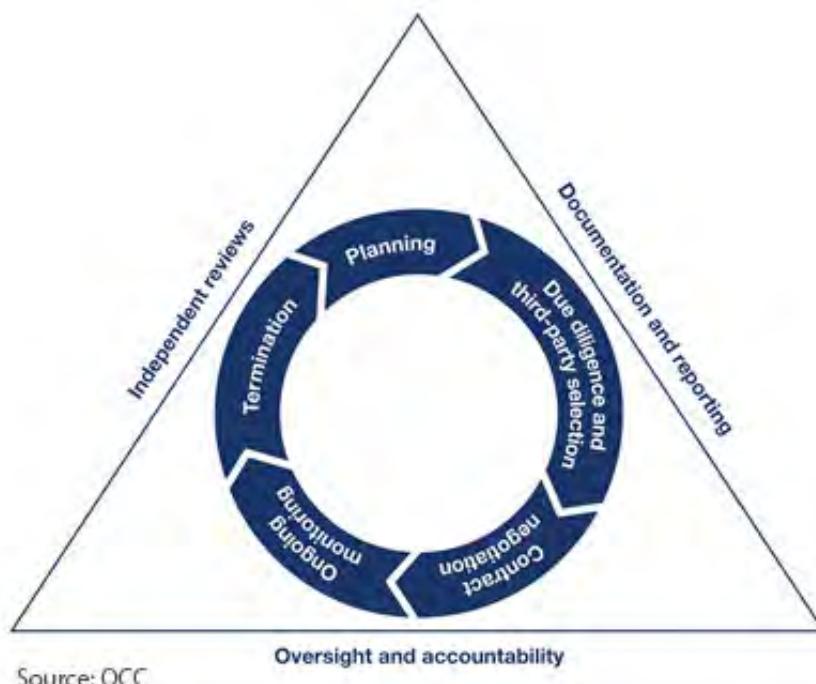
In addition, a bank should perform the following throughout the life cycle of the relationship as part of its risk management process:

Oversight and accountability: Assigning clear roles and responsibilities for managing third-party relationships and integrating the bank's third-party risk management process with its enterprise risk management framework enables continuous oversight and accountability.

Documentation and reporting: Proper documentation and reporting facilitates oversight, accountability, monitoring, and risk management associated with third-party relationships.

Independent reviews: Conducting periodic independent reviews of the risk management process enables management to assess whether the process aligns with the bank's strategy and effectively manages risk posed by third-party relationships.

Figure 1: Risk Management Life Cycle



Planning

Before entering into a third-party relationship, senior management should develop a plan to manage the relationship. The management plan should be commensurate with the level of risk and complexity of the third-party relationship and should

- discuss the risks inherent in the activity.
- outline the strategic purposes (e.g., reduce costs, leverage specialized expertise or technology, augment resources, expand or enhance operations), legal and compliance aspects, and inherent risks associated with using third parties, and discuss how the arrangement aligns with the bank's overall strategic goals, objectives, and risk appetite.
- assess the complexity of the arrangement, such as the volume of activity, potential for subcontractors, the technology needed, and the likely degree of foreign-based third-party support.
- determine whether the potential financial benefits outweigh the estimated costs to control the risks (including estimated direct contractual costs and indirect costs to augment or alter bank processes, systems, or staffing to properly manage the third-party relationship or adjust or terminate existing contracts).
- consider how the third-party relationship could affect other strategic bank initiatives, such as large technology projects, organizational changes, mergers, acquisitions, or divestitures.
- consider how the third-party relationship could affect bank and dual employees⁶ and what transition steps are needed to manage the impacts when the activities currently conducted internally are outsourced.
- assess the nature of customer interaction with the third party and potential impact the relationship will have on the bank's customers—including access to or use of those customers' confidential information, joint marketing or franchising arrangements, and handling of customer complaints—and outline plans to manage these impacts.
- assess potential information security implications including access to the bank's systems and to its confidential information.
- consider the bank's contingency plans in the event the bank needs to transition the activity to another third party or bring it in-house.
- assess the extent to which the activities are subject to specific laws and regulations (e.g., privacy, information security, Bank Secrecy Act/Anti-Money Laundering (BSA/AML), fiduciary requirements).
- consider whether the selection of the third party is consistent with the bank's broader corporate policies and practices including its diversity policies and practices.
- detail how the bank will select, assess, and oversee the third party, including monitoring the third party's compliance with the contract.
- be presented to and approved by the bank's board of directors when critical activities are involved.

Due Diligence and Third-Party Selection

A bank should conduct due diligence on all potential third parties before selecting and entering into contracts or relationships. A bank should not rely solely on experience with or prior knowledge of the third party as a proxy for an objective, in-depth assessment of the third party's ability to perform the activity in compliance with all applicable laws and regulations and in a safe and sound manner.

The degree of due diligence should be commensurate with the level of risk and complexity of the third-party relationship. More extensive due diligence is necessary when a third-party relationship involves critical activities. On-site visits may be useful to understand fully the third party's operations and capacity. If the bank uncovers information that warrants additional scrutiny, it should broaden the scope or assessment methods of the due diligence as needed.

The bank should consider the following during due diligence:

Strategies and Goals

Review the third party's overall business strategy and goals to ensure they do not conflict with

those of the bank. Consider how the third party's current and proposed strategic business arrangements (such as mergers, acquisitions, divestitures, joint ventures, or joint marketing initiatives) may affect the activity. Also consider reviewing the third party's service philosophies, quality initiatives, efficiency improvements, and employment policies and practices.

Legal and Regulatory Compliance

Evaluate the third party's legal and regulatory compliance program to determine whether the third party has the necessary licenses to operate and the expertise, processes, and controls to enable the bank to remain compliant with domestic and international laws and regulations. Check compliance status with regulators and self-regulatory organizations as appropriate.

Financial Condition

Assess the third party's financial condition, including reviews of the third party's audited financial statements. Evaluate growth, earnings, pending litigation, unfunded liabilities, and other factors that may affect the third party's overall financial stability. Depending on the significance of the third-party relationship, the bank's analysis may be as comprehensive as if extending credit to the third party.

Business Experience and Reputation

Evaluate the third party's depth of resources and previous experience providing the specific activity. Assess the third party's reputation, including history of customer complaints or litigation. Determine how long the third party has been in business, its market share for the activities, and whether there have been significant changes in the activities offered or in its business model. Conduct reference checks with external organizations and agencies such as the industry associations, Better Business Bureau, Federal Trade Commission, state attorneys general offices, state consumer affairs offices, and similar foreign authorities. Check U.S. Securities and Exchange Commission or other regulatory filings. Review the third party's Web sites and other marketing materials to ensure that statements and assertions are in-line with the bank's expectations and do not overstate or misrepresent activities and capabilities. Determine whether and how the third party plans to use the bank's name and reputation in marketing efforts.

Fee Structure and Incentives

Evaluate the third party's normal fee structure and incentives for similar business arrangements to determine if the fee structure and incentives would create burdensome upfront fees or result in inappropriate risk taking by the third party or the bank.

Qualifications, Backgrounds, and Reputations of Company Principals

Ensure the third party periodically conducts thorough background checks on its senior management and employees as well as on subcontractors who may have access to critical systems or confidential information. Ensure that third parties have policies and procedures in place for removing employees who do not meet minimum background check requirements.

Risk Management

Evaluate the effectiveness of the third party's risk management program, including policies, processes, and internal controls. Where applicable, determine whether the third party's internal audit function independently and effectively tests and reports on the third party's internal controls. Evaluate processes for escalating, remediating, and holding management accountable for concerns identified during audits or other independent tests. If available, review Service Organization Control (SOC) reports, prepared in accordance with the American Institute of Certified Public Accountants Statement on Standards for Attestation Engagements No. 16 (SSAE 16). Consider whether these reports contain sufficient information to assess the third party's risk or whether additional scrutiny is required through an audit by the bank or other third party at the bank's request. Consider any certification by independent third parties for compliance with domestic or international internal control standards (e.g., the National Institute of

Standards and Technology and the International Standards Organization).

Information Security

Assess the third party's information security program. Determine whether the third party has sufficient experience in identifying, assessing, and mitigating known and emerging threats and vulnerabilities. When technology is necessary to support service delivery, assess the third party's infrastructure and application security programs, including the software development life cycle and results of vulnerability and penetration tests. Evaluate the third party's ability to implement effective and sustainable corrective actions to address deficiencies discovered during testing.

Management of Information Systems

Gain a clear understanding of the third party's business processes and technology that will be used to support the activity. When technology is a major component of the third-party relationship, review both the bank's and the third party's information systems to identify gaps in service-level expectations, technology, business process and management, or interoperability issues. Review the third party's processes for maintaining accurate inventories of its technology and its subcontractors. Assess the third party's change management processes to ensure that clear roles, responsibilities, and segregation of duties are in place. Understand the third party's performance metrics for its information systems and ensure they meet the bank's expectations.

Resilience

Assess the third party's ability to respond to service disruptions or degradations resulting from natural disasters, human error, or intentional physical or cyber attacks. Determine whether the third party maintains disaster recovery and business continuity plans that specify the time frame to resume activities and recover data. Review the third party's telecommunications redundancy and resilience plans and preparations for known and emerging threats and vulnerabilities, such as wide-scale natural disasters, distributed denial of service attacks, or other intentional or unintentional events. Review the results of business continuity testing and performance during actual disruptions.

Incident-Reporting and Management Programs

Review the third party's incident reporting and management programs to ensure there are clearly documented processes and accountability for identifying, reporting, investigating, and escalating incidents. Ensure that the third party's escalation and notification processes meet the bank's expectations and regulatory requirements.

Physical Security

Evaluate whether the third party has sufficient physical and environmental controls to ensure the safety and security of its facilities, technology systems, and employees.

Human Resource Management

Review the third party's program to train and hold employees accountable for compliance with policies and procedures. Review the third party's succession and redundancy planning for key management and support personnel. Review training programs to ensure that the third party's staff is knowledgeable about changes in laws, regulations, technology, risk, and other factors that may affect the quality of the activities provided.

Reliance on Subcontractors

Evaluate the volume and types of subcontracted activities and the subcontractors' geographic locations. Evaluate the third party's ability to assess, monitor, and mitigate risks from its use of subcontractors and to ensure that the same level of quality and controls exists no matter where the subcontractors' operations reside. Evaluate whether additional concentration-related risks

may arise from the third party's reliance on subcontractors and, if necessary, conduct similar due diligence on the third party's critical subcontractors.

Insurance Coverage

Verify that the third party has fidelity bond coverage to insure against losses attributable to dishonest acts, liability coverage for losses attributable to negligent acts, and hazard insurance covering fire, loss of data, and protection of documents. Determine whether the third party has insurance coverage for its intellectual property rights, as such coverage may not be available under a general commercial policy. The amounts of such coverage should be commensurate with the level of risk involved with the third party's operations and the type of activities to be provided.

Conflicting Contractual Arrangements With Other Parties

Obtain information regarding legally binding arrangements with subcontractors or other parties in cases where the third party has indemnified itself, as such arrangements may transfer risks to the bank. Evaluate the potential legal and financial implications to the bank of these contracts between the third party and its subcontractors or other parties.

Senior management should review the results of the due diligence to determine whether the third party is able to meet the bank's expectations and whether the bank should proceed with the third-party relationship. If the results do not meet expectations, management should recommend that the third party make appropriate changes, find an alternate third party, conduct the activity in-house, or discontinue the activity. As part of any recommended changes, the bank may need to supplement the third party's resources or increase or implement new controls to manage the risks. Management should present results of due diligence to the board when making recommendations for third-party relationships that involve critical activities.

Contract Negotiation

Once the bank selects a third party, management should negotiate a contract that clearly specifies the rights and responsibilities of each party to the contract. Additionally, senior management should obtain board approval of the contract before its execution when a third-party relationship will involve critical activities. A bank should review existing contracts periodically, particularly those involving critical activities, to ensure they continue to address pertinent risk controls and legal protections. Where problems are identified, the bank should seek to renegotiate at the earliest opportunity.

Contracts should generally address the following:

Nature and Scope of Arrangement

Ensure that the contract specifies the nature and scope of the arrangement. For example, a third-party contract should specifically identify the frequency, content, and format of the service, product, or function provided. Include in the contract, as applicable, such ancillary services as software or other technology support and maintenance, employee training, and customer service. Specify which activities the third party is to conduct, whether on or off the bank's premises, and describe the terms governing the use of the bank's information, facilities, personnel, systems, and equipment, as well as access to and use of the bank's or customers' information. When dual employees will be used, clearly articulate their responsibilities and reporting lines.⁷

Performance Measures or Benchmarks

Specify performance measures that define the expectations and responsibilities for both parties including conformance with regulatory standards or rules. Such measures can be used to motivate the third party's performance, penalize poor performance, or reward outstanding performance. Performance measures should not incentivize undesirable performance, such as encouraging processing volume or speed without regard for accuracy, compliance requirements, or adverse effects on customers. Industry standards for service-level agreements may provide a reference point for standardized services, such as payroll processing. For more customized

activities, there may be no standard measures. Instead, the bank and third party should agree on appropriate measures.

Responsibilities for Providing, Receiving, and Retaining Information

Ensure that the contract requires the third party to provide and retain timely, accurate, and comprehensive information such as records and reports that allow bank management to monitor performance, service levels, and risks. Stipulate the frequency and type of reports required, for example: performance reports, control audits, financial statements, security reports, BSA/AML and Office of Foreign Asset Control (OFAC) compliance responsibilities and reports for monitoring potential suspicious activity, reports for monitoring customer complaint activity, and business resumption testing reports.

Ensure that the contract sufficiently addresses

- the responsibilities and methods to address failures to adhere to the agreement including the ability of both parties to the agreement to exit the relationship.
- the prompt notification of financial difficulty, catastrophic events, and significant incidents such as information breaches, data loss, service or system interruptions, compliance lapses, enforcement actions, or other regulatory actions.
- the bank's materiality thresholds and procedures for notifying the bank in writing whenever service disruptions, security breaches, or other events pose a significant risk to the bank.
- notification to the bank before making significant changes to the contracted activities, including acquisition, subcontracting, off-shoring, management or key personnel changes, or implementing new or revised policies, processes, and information technology.
- notification to the bank of significant strategic business changes, such as mergers, acquisitions, joint ventures, divestitures, or other business activities that could affect the activities involved.
- the ability of the third party to resell, assign, or permit access to the bank's data and systems to other entities.
- the bank's obligations to notify the third party if the bank implements strategic or operational changes or experiences significant incidents that may affect the third party.

The Right to Audit and Require Remediation

Ensure that the contract establishes the bank's right to audit, monitor performance, and require remediation when issues are identified. Generally, a third-party contract should include provisions for periodic independent internal or external audits of the third party, and relevant subcontractors, at intervals and scopes consistent with the bank's in-house functions to monitor performance with the contract. A bank should include in the contract the types and frequency of audit reports the bank is entitled to receive from the third party (e.g., financial, SSAE 16, SOC 1, SOC 2, and SOC 3 reports, and security reviews). Consider whether to accept audits conducted by the third party's internal or external auditors. Reserve the bank's right to conduct its own audits of the third party's activities or to engage an independent party to perform such audits. Audit reports should include a review of the third party's risk management and internal control environment as it relates to the activities involved and of the third party's information security program and disaster recovery and business continuity plans.

Responsibility for Compliance With Applicable Laws and Regulations

Ensure the contract addresses compliance with the specific laws, regulations, guidance, and self-regulatory standards applicable to the activities involved, including provisions that outline compliance with certain provisions of the Gramm-Leach-Bliley Act (GLBA) (including privacy and safeguarding of customer information); BSA/AML; OFAC; and Fair Lending and other consumer protection laws and regulations. Ensure that the contract requires the third party to maintain policies and procedures which address the bank's right to conduct periodic reviews so as to verify the third party's compliance with the bank's policies and expectations. Ensure that the contract states the bank has the right to monitor on an ongoing basis the third party's compliance with applicable laws, regulations, and policies and requires remediation if issues

arise.

Cost and Compensation

Fully describe compensation, fees, and calculations for base services, as well as any fees based on volume of activity and for special requests. Ensure the contracts do not include burdensome upfront fees or incentives that could result in inappropriate risk taking by the bank or third party. Indicate which party is responsible for payment of legal, audit, and examination fees associated with the activities involved. Consider outlining cost and responsibility for purchasing and maintaining hardware and software. Specify the conditions under which the cost structure may be changed, including limits on any cost increases.

Ownership and License

State whether and how the third party has the right to use the bank's information, technology, and intellectual property, such as the bank's name, logo, trademark, and copyrighted material. Indicate whether any records generated by the third party become the bank's property. Include appropriate warranties on the part of the third party related to its acquisition of licenses for use of any intellectual property developed by other third parties. If the bank purchases software, establish escrow agreements to provide for the bank's access to source code and programs under certain conditions (e.g., insolvency of the third party).

Confidentiality and Integrity

Prohibit the third party and its subcontractors from using or disclosing the bank's information, except as necessary to provide the contracted activities or comply with legal requirements. If the third party receives bank customers' personally identifiable information, the contract should ensure that the third party implements and maintains appropriate security measures to comply with privacy regulations and regulatory guidelines. Specify when and how the third party will disclose, in a timely manner, information security breaches that have resulted in unauthorized intrusions or access that may materially affect the bank or its customers. Stipulate that intrusion notifications include estimates of the effects on the bank and specify corrective action to be taken by the third party. Address the powers of each party to change security and risk management procedures and requirements, and resolve any confidentiality and integrity issues arising out of shared use of facilities owned by the third party. Stipulate whether and how often the bank and the third party will jointly practice incident management plans involving unauthorized intrusions or other breaches in confidentiality and integrity.

Business Resumption and Contingency Plans

Ensure the contract provides for continuation of the business function in the event of problems affecting the third party's operations, including degradations or interruptions resulting from natural disasters, human error, or intentional attacks. Stipulate the third party's responsibility for backing up and otherwise protecting programs, data, and equipment, and for maintaining current and sound business resumption and contingency plans. Include provisions—in the event of the third party's bankruptcy, business failure, or business interruption—for transferring the bank's accounts or activities to another third party without penalty.

Ensure that the contract requires the third party to provide the bank with operating procedures to be carried out in the event business resumption and disaster recovery plans are implemented. Include specific time frames for business resumption and recovery that meet the bank's requirements, and when appropriate, regulatory requirements. Stipulate whether and how often the bank and the third party will jointly practice business resumption and disaster recovery plans.

Indemnification

Consider including indemnification clauses that specify the extent to which the bank will be held liable for claims that cite failure of the third party to perform, including failure of the third party to obtain any necessary intellectual property licenses. Carefully assess indemnification clauses that require the bank to hold the third party harmless from liability.

Insurance

Stipulate that the third party is required to maintain adequate insurance, notify the bank of material changes to coverage, and provide evidence of coverage where appropriate. Types of insurance coverage may include fidelity bond coverage, liability coverage, hazard insurance, and intellectual property insurance.

Dispute Resolution

Consider whether the contract should establish a dispute resolution process (arbitration, mediation, or other means) to resolve problems between the bank and the third party in an expeditious manner, and whether the third party should continue to provide activities to the bank during the dispute resolution period.

Limits on Liability

Determine whether the contract limits the third party's liability and whether the proposed limit is in proportion to the amount of loss the bank might experience because of the third party's failure to perform or to comply with applicable laws. Consider whether a contract would subject the bank to undue risk of litigation, particularly if the third party violates or is accused of violating intellectual property rights.

Default and Termination

Ensure that the contract stipulates what constitutes default, identifies remedies and allows opportunities to cure defaults, and stipulates the circumstances and responsibilities for termination. Determine whether it includes a provision that enables the bank to terminate the contract, upon reasonable notice and without penalty, in the event that the OCC formally directs the bank to terminate the relationship. Ensure the contract permits the bank to terminate the relationship in a timely manner without prohibitive expense. Include termination and notification requirements with time frames to allow for the orderly conversion to another third party. Provide for the timely return or destruction of the bank's data and other resources and ensure the contract provides for ongoing monitoring of the third party after the contract terms are satisfied as necessary. Clearly assign all costs and obligations associated with transition and termination.

Customer Complaints

Specify whether the bank or third party is responsible for responding to customer complaints. If it is the third party's responsibility, specify provisions that ensure that the third party receives and responds timely to customer complaints and forwards a copy of each complaint and response to the bank. The third party should submit sufficient, timely, and usable information to enable the bank to analyze customer complaint activity and trends for risk management purposes.

Subcontracting

Stipulate when and how the third party should notify the bank of its intent to use a subcontractor. Specify the activities that cannot be subcontracted or whether the bank prohibits the third party from subcontracting activities to certain locations or specific subcontractors. Detail the contractual obligations—such as reporting on the subcontractor's conformance with performance measures, periodic audit results, compliance with laws and regulations, and other contractual obligations. State the third party's liability for activities or actions by its subcontractors and which party is responsible for the costs and resources required for any additional monitoring and management of the subcontractors. Reserve the right to terminate the contract without penalty if the third party's subcontracting arrangements do not comply with the terms of the contract.

Foreign-Based Third Parties

Include in contracts with foreign-based third parties choice-of-law covenants and jurisdictional covenants that provide for adjudication of all disputes between the parties under the laws of a

single, specific jurisdiction. Understand that such contracts and covenants may be subject, however, to the interpretation of foreign courts relying on local laws. Foreign courts and laws may differ substantially from U.S. courts and laws in the application and enforcement of choice-of-law covenants, requirements on banks, protection of privacy of customer information, and the types of information that the third party or foreign governmental entities will provide upon request. Therefore, seek legal advice to ensure the enforceability of all aspects of a proposed contract with a foreign-based third party and other legal ramifications of each such arrangement.

OCC Supervision

In contracts with service providers, stipulate that the performance of activities by external parties for the bank is subject to OCC examination oversight, including access to all work papers, drafts, and other materials. The OCC treats as subject to 12 USC 1867(c) and 12 USC 1464(d)(7), situations in which a bank arranges, by contract or otherwise, for the performance of any applicable functions of its operations. Therefore, the OCC generally has the authority to examine and to regulate the functions or operations performed or provided by third parties to the same extent as if they were performed by the bank itself on its own premises.⁸

Ongoing Monitoring

Ongoing monitoring for the duration of the third-party relationship is an essential component of the bank's risk management process. More comprehensive monitoring is necessary when the third-party relationship involves critical activities. Senior management should periodically assess existing third-party relationships to determine whether the nature of the activity performed now constitutes a critical activity.

After entering into a contract with a third party, bank management should dedicate sufficient staff with the necessary expertise, authority, and accountability to oversee and monitor the third party commensurate with the level of risk and complexity of the relationship. Regular on site visits may be useful to understand fully the third party's operations and ongoing ability to meet contract requirements. Management should ensure that bank employees that directly manage third-party relationships monitor the third party's activities and performance. A bank should pay particular attention to the quality and sustainability of the third party's controls, and its ability to meet service-level agreements, performance metrics and other contractual terms, and to comply with legal and regulatory requirements.

The OCC expects the bank's ongoing monitoring of third-party relationships to cover the due diligence activities discussed earlier. Because both the level and types of risks may change over the lifetime of third-party relationships, a bank should ensure that its ongoing monitoring adapts accordingly. This monitoring may result in changes to the frequency and types of required reports from the third party, including service-level agreement performance reports, audit reports, and control testing results. In addition to ongoing review of third-party reports, some key areas of consideration for ongoing monitoring may include assessing changes to the third party's

- business strategy (including acquisitions, divestitures, joint ventures) and reputation (including litigation) that may pose conflicting interests and impact its ability to meet contractual obligations and service-level agreements.
- compliance with legal and regulatory requirements.
- financial condition.
- insurance coverage.
- key personnel and ability to retain essential knowledge in support of the activities.
- ability to effectively manage risk by identifying and addressing issues before they are cited in audit reports.
- process for adjusting policies, procedures, and controls in response to changing threats and new vulnerabilities and material breaches or other serious incidents.
- information technology used or the management of information systems.
- ability to respond to and recover from service disruptions or degradations and meet business resilience expectations.
- reliance on, exposure to, or performance of subcontractors; location of subcontractors; and the

- ongoing monitoring and control testing of subcontractors.
- agreements with other entities that may pose a conflict of interest or introduce reputation, operational, or other risks to the bank.
- ability to maintain the confidentiality and integrity of the bank's information and systems.
- volume, nature, and trends of consumer complaints, in particular those that indicate compliance or risk management problems.
- ability to appropriately remediate customer complaints.

Bank employees who directly manage third-party relationships should escalate to senior management significant issues or concerns arising from ongoing monitoring, such as an increase in risk, material weaknesses and repeat audit findings, deterioration in financial condition, security breaches, data loss, service or system interruptions, or compliance lapses. Additionally, management should ensure that the bank's controls to manage risks from third-party relationships are tested regularly, particularly where critical activities are involved. Based on the results of the ongoing monitoring and internal control testing, management should respond to issues when identified including escalating significant issues to the board.

Termination

A bank may terminate third-party relationships for various reasons, including

- expiration or satisfaction of the contract.
- desire to seek an alternate third party.
- desire to bring the activity in-house or discontinue the activity.
- breach of contract.

Management should ensure that relationships terminate in an efficient manner, whether the activities are transitioned to another third party or in-house, or discontinued. In the event of contract default or termination, the bank should have a plan to bring the service in-house if there are no alternate third parties. This plan should cover

- capabilities, resources, and the time frame required to transition the activity while still managing legal, regulatory, customer, and other impacts that might arise.
- risks associated with data retention and destruction, information system connections and access control issues, or other control concerns that require additional risk management and monitoring during and after the end of the third-party relationship.
- handling of joint intellectual property developed during the course of the arrangement.
- reputation risks to the bank if the termination happens as a result of the third party's inability to meet expectations.

The extent and flexibility of termination rights may vary with the type of activity.

Oversight and Accountability

The bank's board of directors (or a board committee) and senior management are responsible for overseeing the bank's overall risk management processes. The board, senior management, and employees within the lines of businesses who manage the third-party relationships have distinct but interrelated responsibilities to ensure that the relationships and activities are managed effectively and commensurate with their level of risk and complexity, particularly for relationships that involve critical activities:⁹

Board of Directors

- Ensure an effective process is in place to manage risks related to third-party relationships in a manner consistent with the bank's strategic goals, organizational objectives, and risk appetite.
- Approve the bank's risk-based policies that govern the third-party risk management process and identify critical activities.
- Review and approve management plans for using third parties that involve critical activities.

- Review summary of due diligence results and management's recommendations to use third parties that involve critical activities.
- Approve contracts with third parties that involve critical activities.
- Review the results of management's ongoing monitoring of third-party relationships involving critical activities.
- Ensure management takes appropriate actions to remedy significant deterioration in performance or address changing risks or material issues identified through ongoing monitoring.
- Review results of periodic independent reviews of the bank's third-party risk management process.

Senior Bank Management

- Develop and implement the bank's third-party risk management process.
- Establish the bank's risk-based policies to govern the third-party risk management process.
- Develop plans for engaging third parties, identify those that involve critical activities, and present plans to the board when critical activities are involved.
- Ensure appropriate due diligence is conducted on potential third parties and present results to the board when making recommendations to use third parties that involve critical activities.
- Review and approve contracts with third parties. Board approval should be obtained for contracts that involve critical activities.
- Ensure ongoing monitoring of third parties, respond to issues when identified, and escalate significant issues to the board.
- Ensure appropriate documentation and reporting throughout the life cycle for all third-party relationships.
- Ensure periodic independent reviews of third-party relationships that involve critical activities and of the bank's third-party risk management process. Analyze the results, take appropriate actions, and report results to the board.
- Hold accountable the bank employees within business lines or functions who manage direct relationships with third parties.
- Terminate arrangements with third parties that do not meet expectations or no longer align with the bank's strategic goals, objectives, or risk appetite.
- Oversee enterprise-wide risk management and reporting of third-party relationships.

Bank Employees Who Directly Manage Third-Party Relationships

- Conduct due diligence of third parties and report results to senior management.
- Ensure that third parties comply with the bank's policies and reporting requirements.
- Perform ongoing monitoring of third parties and ensure compliance with contract terms and service-level agreements.
- Ensure the bank or the third party addresses any issues identified.
- Escalate significant issues to senior management.
- Notify the third party of significant operational issues at the bank that may affect the third party.
- Ensure that the bank has regularly tested controls in place to manage risks associated with third-party relationships.
- Ensure that third parties regularly test and implement agreed-upon remediation when issues arise.
- Maintain appropriate documentation throughout the life cycle.
- Respond to material weaknesses identified by independent reviews.
- Recommend termination of arrangements with third parties that do not meet expectations or no longer align with the bank's strategic goals, objectives, or risk appetite.

Documentation and Reporting

A bank should properly document and report on its third-party risk management process and specific arrangements throughout their life cycle. Proper documentation and reporting facilitates the accountability, monitoring, and risk management associated with third parties and typically includes

- a current inventory of all third-party relationships, which should clearly identify those relationships

that involve critical activities and delineate the risks posed by those relationships across the bank.¹⁰

- approved plans for the use of third-party relationships.
- due diligence results, findings, and recommendations.
- analysis of costs associated with each activity or third-party relationship, including any indirect costs assumed by the bank.
- executed contracts.
- regular risk management and performance reports required and received from the third party (e.g., audit reports, security reviews, and reports indicating compliance with service-level agreements).
- regular reports to the board and senior management on the results of internal control testing and ongoing monitoring of third parties involved in critical activities.
- regular reports to the board and senior management on the results of independent reviews of the bank's overall risk management process.

Independent Reviews

Senior management should ensure that periodic independent reviews are conducted on the third-party risk management process, particularly when a bank involves third parties in critical activities. The bank's internal auditor or an independent third party may perform the reviews, and senior management should ensure the results are reported to the board. Reviews may include assessing the adequacy of the bank's process for

- ensuring third-party relationships align with the bank's business strategy.
- identifying, assessing, managing, and reporting on risks of third-party relationships.
- responding to material breaches, service disruptions, or other material issues.
- identifying and managing risks associated with complex third-party relationships, including foreign-based third parties and subcontractors.
- involving multiple disciplines across the bank as appropriate during each phase of the third-party risk management life cycle.¹¹
- ensuring appropriate staffing and expertise to perform due diligence and ongoing monitoring and management of third parties.
- ensuring oversight and accountability for managing third-party relationships (e.g., whether roles and responsibilities are clearly defined and assigned and whether the individuals possess the requisite expertise, resources, and authority).
- ensuring that conflicts of interest or appearances of conflicts of interest do not exist when selecting or overseeing third parties.
- identifying and managing concentration risks that may arise from relying on a single third party for multiple activities, or from geographic concentration of business due to either direct contracting or subcontracting agreements to the same locations.

Senior management should analyze the results of independent reviews to determine whether and how to adjust the bank's third-party risk management process, including policy, reporting, resources, expertise, and controls. Additionally, the results may assist senior management's understanding of the effectiveness of the bank's third-party risk management process so that they can make informed decisions about commencing new or continuing existing third-party relationships, bringing activities in-house, or discontinuing activities. Management should respond promptly and thoroughly to significant issues or concerns identified and escalate to the board if the risk posed is approaching the bank's risk appetite limits.

Supervisory Reviews of Third-Party Relationships

The OCC expects bank management to engage in a robust analytical process to identify, measure, monitor, and control the risks associated with third-party relationships and to avoid excessive risk taking that may threaten a bank's safety and soundness. A bank's failure to have an effective third-party risk management process that is commensurate with the level of risk, complexity of third-party relationships, and organizational structure of the bank may be an *unsafe and unsound banking practice*.

When reviewing third-party relationships, examiners should

- assess the bank's ability to oversee and manage its relationships.
- highlight and discuss material risks and any deficiencies in the bank's risk management process with the board of directors and senior management.
- carefully review the bank's plans for appropriate and sustainable remediation of such deficiencies, particularly those associated with the oversight of third parties that involve critical activities.
- follow existing guidance for citing deficiencies in supervisory findings and reports of examination, and recommend appropriate supervisory actions. These actions may range from citing the deficiencies in Matters Requiring Attention to recommending formal enforcement action.
- consider the findings when assigning the management component of the Federal Financial Institutions Examination Council's (FFIEC) Uniform Financial Institutions Rating System (CAMELS ratings).¹² Serious deficiencies may result in management being deemed less than satisfactory.
- reflect the associated risks in their overall assessment of the bank's risk profile.

When circumstances warrant, the OCC may use its authority to examine the functions or operations performed by a third party on the bank's behalf. Such examinations may evaluate safety and soundness risks, the financial and operational viability of the third party to fulfill its contractual obligations, compliance with applicable laws and regulations, including consumer protection, fair lending, BSA/AML and OFAC laws, and whether the third party engages in unfair or deceptive acts or practices in violation of federal or applicable state law. The OCC will pursue appropriate corrective measures, including enforcement actions, to address violations of law and regulations or unsafe or unsound banking practices by the bank or its third party. The OCC has the authority to assess a bank a special examination or investigation fee when the OCC examines or investigates the activities of a third party for the bank.

Further Information

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[Appendix A: Risks Associated With Third-Party Relationships](#)

[Appendix B: References](#)

APPENDIX A: Risks Associated With Third-Party Relationships

Use of third parties reduces management's direct control of activities and may introduce new or increase existing risks, specifically, operational, compliance, reputation, strategic, and credit risks and the interrelationship of these risks. Increased risk most often arises from greater complexity, ineffective risk management by the bank, and inferior performance by the third party. Refer to the "Bank Supervision Process" booklet of the *Comptroller's Handbook* for an expanded discussion of banking risks and their definitions.

Operational Risk

Operational risk is present in all products, services, functions, delivery channels, and processes. Third-party relationships may increase a bank's exposure to operational risk because the bank may not have direct control of the activity performed by the third party.

Operational risk can increase significantly when third-party relationships result in concentrations.

Concentrations may arise when a bank relies on a single third party for multiple activities, particularly when several of the activities are critical to bank operations. Additionally, geographic concentrations can arise when a bank's own operations and that of its third parties and subcontractors are located in the same region or are dependent on the same critical power and telecommunications infrastructures.

Compliance Risk

Compliance risk exists when products, services, or systems associated with third-party relationships are not properly reviewed for compliance or when the third party's operations are not consistent with laws, regulations, ethical standards, or the bank's policies and procedures. Such risks also arise when a third party implements or manages a product or service in a manner that is unfair, deceptive, or abusive to the recipient of the product or service. Compliance risk may arise when a bank licenses or uses technology from a third party that violates a third party's intellectual property rights. Compliance risk may also arise when the third party does not adequately monitor and report transactions for suspicious activities to the bank under the BSA or OFAC. The potential for serious or frequent violations or noncompliance exists when a bank's oversight program does not include appropriate audit and control features, particularly when the third party is implementing new bank activities or expanding existing ones, when activities are further subcontracted, when activities are conducted in foreign countries, or when customer and employee data is transmitted to foreign countries.

Compliance risk increases when conflicts of interest between a bank and a third party are not appropriately managed, when transactions are not adequately monitored for compliance with all necessary laws and regulations, and when a bank or its third parties have not implemented appropriate controls to protect consumer privacy and customer and bank records. Compliance failures by the third party could result in litigation or loss of business to the bank and damage to the bank's reputation.

Reputation Risk

Third-party relationships that do not meet the expectations of the bank's customers expose the bank to reputation risk. Poor service, frequent or prolonged service disruptions, significant or repetitive security lapses, inappropriate sales recommendations, and violations of consumer law and other law can result in litigation, loss of business to the bank, or negative perceptions in the marketplace. Publicity about adverse events surrounding the third parties also may increase the bank's reputation risk. In addition, many of the products and services involved in franchising arrangements expose banks to higher reputation risks. Franchising the bank's attributes often includes direct or subtle reference to the bank's name. Thus, the bank is permitting its attributes to be used in connection with the products and services of a third party. In some cases, however, it is not until something goes wrong with the third party's products, services, or client relationships, that it becomes apparent to the third party's clients that the bank is involved or plays a role in the transactions. When a bank is offering products and services actually originated by third parties as its own, the bank can be exposed to substantial financial loss and damage to its reputation if it fails to maintain adequate quality control over those products and services and adequate oversight over the third party's activities.

Strategic Risk

A bank is exposed to strategic risk if it uses third parties to conduct banking functions or offer products and services that are not compatible with the bank's strategic goals, cannot be effectively monitored and managed by the bank, or do not provide an adequate return on investment. Strategic risk exists in a bank that uses third parties in an effort to remain competitive, increase earnings, or control expense without fully performing due diligence reviews or implementing the appropriate risk management infrastructure to oversee the activity. Strategic risk also arises if management does not possess adequate expertise and experience to oversee properly the third-party relationship.

Conversely, strategic risk can arise if a bank does not use third parties when it is prudent to do so. For example, a bank may introduce strategic risk when it does not leverage third parties that possess greater expertise than the bank does internally, when the third party can more cost effectively supplement internal expertise, or when the third party is more efficient at providing a service with better

risk management than the bank can provide internally.

Credit Risk

Credit risk may arise when management has exercised ineffective due diligence and oversight of third parties that market or originate certain types of loans on the bank's behalf, resulting in low-quality receivables and loans. Ineffective oversight of third parties can also result in poor account management, customer service, or collection activities. Likewise, where third parties solicit and refer customers, conduct underwriting analysis, or set up product programs on behalf of the bank, substantial credit risk may be transferred to the bank if the third party is unwilling or unable to fulfill its obligations.

Credit risk also may arise from country or sovereign exposure. To the extent that a bank engages a foreign-based third party, either directly or through subcontractors, the bank may expose itself to country risk.

APPENDIX B: References

Additional guidance about third-party relationships and risk management practices can be found in the following documents.¹³

OCC Guidance

Issuance	Date	Subject	Description/Applicability to FSAs
<i>Comptroller's Handbook</i>	Various	Asset Management series	Each of the booklets in the Comptroller's Handbook Asset Management series provides guidance on oversight of third-party providers. Applies to FSAs.
<i>Comptroller's Handbook</i>	September 2013	Other Real Estate Owned	Provides guidance on managing foreclosed properties, including risk management of third-party relationships. Applies to FSAs.
<i>Comptroller's Handbook</i>	April 2012	SAFE Act	Provides procedures for examining mortgage loan originator (MLO) activities for compliance with the Secure & Fair Enforcement & Licensing Act of 2008, which mandates a nationwide licensing and registration system for residential MLOs. MLOs may be employees of a bank or third-party vendors. Applies to FSAs.
<i>Comptroller's Handbook</i>	May 2011	Servicemembers Civil Relief Act of 2003 (SCRA)	Provides guidance on SCRA requirements applicable to banks and servicers, as a large number of banks outsource loan-servicing functions such as credit administration to third-party servicers.
<i>Comptroller's Handbook</i>	December 2010	Truth in Lending Act	Provides guidance to banks and servicers on the content and timing of disclosures; interest rate calculations; and prohibited activities.
<i>Comptroller's Handbook</i>	September 2010	Real Estate Settlement Procedures	Provides guidance to banks and servicers on the content and timing of pre-settlement and settlement disclosures to borrowers and on prohibited practices.

<i>Comptroller's Handbook</i>	January 2010	Fair Lending	Provides guidance on indicators of potential disparate treatment in loan servicing and loss mitigation; use of vendor-designed credit scorecards; and guidance on evaluating third parties.
<i>Comptroller's Handbook</i>	April 2003	Internal and External Audits	Provides guidelines for banks that outsource internal audit.
<i>Comptroller's Handbook</i>	December 2001	Merchant Processing	Provides guidance on risk management of third-party processors.
<i>Comptroller's Handbook</i>	February 1994	Retail Nondeposit Investment Sales	Provides guidance on risk management and board oversight of third-party vendors selling nondeposit investment products. (See OCC Bulletin 1994-13)
Alert 2012-16	December 21, 2012	Information Security: Distributed Denial of Service Attacks and Customer Account Fraud	Highlights the risks related to these attacks; raises awareness for banks to be prepared to mitigate associated risks. Preparation may include ensuring sufficient resources in conjunction with pre-contracted third-party servicers that can assist in managing the internet-based traffic flow. Applies to FSAs.
Alert 2001-4	April 24, 2001	Network Securities Vulnerabilities	Alerts banks to review contracts with service providers to ensure that security maintenance and reporting responsibilities are clearly described.
News Release 2013-116	July 17, 2013	OCC Statement Regarding Oversight of Debt Collection and Debt Sales	Appendix provides guidance on the due diligence and ongoing monitoring of third parties to which banks sell consumer debt. Applies to FSAs.
News Release 2012-93	June 21, 2012	Regulators Issue Joint Guidance to Address Mortgage Servicer Practices that Affect Servicemembers	Provides guidance to banks and mortgage servicers, including ensuring that their employees are adequately trained about the options available for homeowners with permanent change of station orders. Applies to FSAs.
Bulletin 2013-10	March 29, 2013	Flood Disaster Protection Act: Interagency Statement on Effective Dates of Certain Provisions of the Biggert-Waters Act and Impact on Proposed Interagency Questions and Answers	Provides guidance to lenders or their servicers regarding the contents of notifications to borrowers about flood insurance renewals, force placement to ensure continuity of coverage, use of private flood insurance policies, related insurance fees, and escrow accounts. Provides summaries of new requirements for disclosure contents and timing. Applies to FSAs.
Bulletin 2011-39	September 22, 2011	Fair Credit Reporting and Equal Credit Opportunity Acts—Risk-Based Pricing Notices: Final Rules	Provides guidance on notification requirements (timing, content) when adverse credit decision relies on a credit score, including those generated by third-party vendors (i.e., consumer reporting

			agencies). Applies to FSAs.
Bulletin 2011-30	July 6, 2011	Counterparty Credit Risk Management: Interagency Supervisory Guidance	Addresses some of the weaknesses highlighted by the recent financial crisis and reinforces sound governance of counterparty credit risk (CCR) management practices through prudent board and senior management oversight and an effective CCR management framework. Applies to FSAs with the issuance of this bulletin.
Bulletin 2011-29	June 30, 2011	Foreclosure Management: Supervisory Guidance	Discusses third-party vendor management and reaffirms expectations that management should properly structure, carefully conduct, and prudently manage relationships with third-party vendors, including outside law firms assisting in the foreclosure process. Applies to FSAs.
Bulletin 2011-27	June 28, 2011	Prepaid Access Programs: Risk Management Guidance and Sound Practices	Highlights the risks and provides risk management guidance concerning prepaid access programs. Applies to FSAs.
Bulletin 2011-26	June 28, 2011	Authentication in an Internet Banking Environment: Supplement	Reinforces the guidance's risk management framework and updates expectations regarding banks' authentication systems and practices whether they are provided internally or by a technology service provider. Applies to FSAs.
Bulletin 2011-12	April 4, 2011	Sound Practices for Model Risk Management: Supervisory Guidance	Includes guidance on the use of third-party models. Applies to FSAs.
Bulletin 2011-11	March 29, 2011	Risk Management Elements: Collective Investment Funds and Outsourcing Arrangements	Expands upon long-standing guidance on sound risk management and beneficiary/participant protections for bank-offered collective investment funds (CIF). The focus is on supervisory concerns that arise if a bank delegates responsibility for a bank CIF to a third-party service provider, such as a registered investment adviser. Applies to FSAs with the issuance of this bulletin.
Bulletin 2010-42	December 10, 2010	Sound Practices for Appraisals and Evaluations: Interagency Appraisal and Evaluation Guidelines	Provides guidance regarding a bank's responsibility for selecting appraisers and people performing evaluations based on their competence, experience, and knowledge of the market and type of property being valued. Applies to FSAs.
Bulletin 2010-30	August 16, 2010	Reverse Mortgages: Interagency Guidance	Provides guidance on managing the compliance and reputation risks when

			making, purchasing, or servicing reverse mortgages through a third party, such as a mortgage broker or correspondent. Applies to FSAs.
Bulletin 2010-7	February 18, 2010	Tax Refund Anticipation Loans: Guidance on Consumer Protection and Safety and Soundness	Provides guidance to enhance, clarify, and increase awareness regarding the measures the OCC expects to see in place for tax refund-related products offered by banks, including issues related to reliance on third-party tax return preparers who interact with consumers.
Bulletin 2010-1	January 8, 2010	Interest Rate Risk: Interagency Advisory on Interest Rate Risk Management	Includes guidance on selection, control frameworks, and validation of third-party asset liability management models. Applies to FSAs.
Bulletin 2009-15	May 22, 2009	Investment Securities: Risk Management and Lessons Learned	Provides guidance for banks that use the services of third parties who compile and provide investment analytics for bank management.
Bulletin 2008-12	April 24, 2008	Payment Processors: Risk Management Guidance	Provides guidance to banks regarding relationships with third-party processors and requirements for effective due diligence, underwriting, and monitoring. Applies to FSAs with the issuance of this bulletin.
Bulletin 2008-5	March 6, 2008	Conflicts of Interest: Risk Management Guidance—Divestiture of Certain Asset Management Businesses	Provides guidance for banks that contemplate divestiture of affiliated funds and associated advisers, whether directly, or through their broader corporate organizations.
Bulletin 2008-4	February 2, 2008	Flood Disaster Protection Act: Flood Hazard Determination Practices	Provides guidance to banks that outsource flood hazard determinations to third-party servicers to ensure that appropriate information is used when performing flood determinations and that revision dates be included in the determination form. Applies to FSAs with the issuance of this bulletin.
Bulletin 2006-47	December 13, 2006	Allowance for Loan and Lease Losses (ALLL): Guidance and Frequently Asked Questions (FAQs) on the ALLL	Includes guidance for when some or the entire loan review function and the validation of the ALLL methodology is outsourced to a qualified external party, and identifies the minimum objectives of a loan review program. Applies to FSAs.
Bulletin 2006-39	September 1, 2006	Automated Clearing House Activities: Risk Management Guidance	Provides guidance for banks and examiners on managing the risks of automated clearing house (ACH) activity, which can include new and evolving types of ACH transactions as well as new participants in the ACH network, including

			certain merchants and third parties known as third-party senders. Applies to FSAs with the issuance of this bulletin.
Bulletin 2005-35	October 12, 2005	Authentication in an Internet Banking Environment: Interagency Guidance	Highlights requirements for banks to use this guidance when evaluating and implementing authentication systems and practices whether they are provided internally or by a technology service provider. Applies to FSAs.
Bulletin 2005-27	August 4, 2005	Real Estate Settlement Procedures Act (RESPA): Sham Controlled Business Arrangements	Provides guidance on determining if a RESPA settlement service provider (often a third-party servicer or vendor) is a "controlled business arrangement" and therefore entitled to certain exemptions. Applies to FSAs with the issuance of this bulletin.
Bulletin 2005-22	May 16, 2005	Home Equity Lending: Credit Risk Management Guidance	Sets forth regulatory expectations for enhanced risk management practices, including management of third-party originations. Applies to FSAs.
Bulletin 2005-13	April 14, 2005	Response Programs for Unauthorized Access to Customer Information and Customer Notice: Final Guidance: Interagency Guidance	Provides guidance on banks implementing a response program to address unauthorized access to customer information maintained by the institution or its service providers. Applies to FSAs.
Bulletin 2005-1	January 12, 2005	Proper Disposal of Consumer Information: Final Rule	Sets standards for information security. Requires agreements with service providers on disposal. Describes duties of users of consumer reports regarding identity theft. Applies to FSAs with the issuance of this bulletin.
Bulletin 2004-47	October 27, 2004	FFIEC Guidance: Risk Management for the Use of Free and Open Source Software (FOSS)	Provides guidance for institutions considering using or deploying FOSS regardless of whether it will be provided internally or by a third-party service provider. Applies to FSAs.
Bulletin 2004-20	May 10, 2004	Risk Management of New, Expanded, or Modified Bank Products and Services: Risk Management Process	Reminds banks of the risk management process they should follow to prudently manage the risks associated with new, expanded, or modified bank products and services, including those provided by third parties.
Bulletin 2003-15	April 23, 2003	Weblinking: Interagency Guidance on Weblinking Activity	Provides guidance to institutions that develop and maintain their own Web sites, as well as institutions that use third-party service providers for this function. Applies to FSAs.
Bulletin 2003-12	March 17, 2003	Interagency Policy Statement on Internal	Reflects developments within the financial, audit, and regulatory industries, particularly

		Audit and Internal Audit Outsourcing: Revised Guidance on Internal Audit and Its Outsourcing	the Sarbanes–Oxley Act of 2002 that established numerous independence parameters for audit firms that provide external audit, outsourced internal audit, and other non-audit services for financial institutions. Applies to FSAs.
Bulletin 2002-16	May 15, 2002	Bank Use of Foreign-Based Third-Party Service Providers: Risk Management Guidance	Provides guidance on managing the risks that may arise from outsourcing relationships with foreign-based third-party service providers, and addresses the need for banks to establish relationships with foreign-based third-party service providers in a way that does not diminish the ability of the OCC to timely access data or information needed for supervisory activities. Applies to FSAs with the issuance of this bulletin.
Bulletin 2002-03	January 15, 2002	Real Estate Settlement Procedures Act: Examiner Guidance—Mark-ups of Settlement Service Fees	Provides guidance on determining if a RESPA settlement service provider (often a third-party servicer or vendor) is charging more for a settlement service provided by a third party than is actually paid to the third party and the third party is not involved in the mark-up, which is prohibited by RESPA Section 8(b) (implemented by Regulation X) in most but not all states. Applies to FSAs with the issuance of this bulletin.
Bulletin 2001-51	December 12, 2001	Privacy of Consumer Financial Information: Small Bank Compliance Guide	Includes guidance for banks to evaluate agreements with nonaffiliated third parties that involve the disclosure of consumer information. Applies to FSAs.
Bulletin 2001-12	February 28, 2001	Bank-Provided Account Aggregation Services: Guidance to Banks	Includes guidance for banks that offer aggregation services through third-party service providers.
Bulletin 2001-8	February 15, 2001	Guidelines Establishing Standards for Safeguarding Customer Information: Final Guidelines	Alerts banks that oversight program of service providers should include confirmation that the providers have implemented appropriate measures designed to meet the objectives of the guidelines. Applies to FSAs with the issuance of this bulletin.
Bulletin 2000-25	September 8, 2000	Privacy Laws and Regulations: Summary of Requirements	Includes guidance for banks to evaluate agreements with third parties that involve the disclosure of consumer information. Applies to FSAs with the issuance of this bulletin.
Bulletin 2000-14	May 15, 2000	Infrastructure Threats —Intrusion Risks: Message to Bankers and Examiners	Provides guidance on how to prevent, detect, and respond to intrusions into bank computer systems, including outsourced systems.

Bulletin 1999-14	March 29, 1999	Real Estate Settlement Procedures Act: Statement of Policy—Lender Payments to Mortgage Brokers	Provides guidance on services normally performed in loan origination, including those often performed by a third-party servicer or vendor. Applies to FSAs with the issuance of this bulletin.
Bulletin 1998-3	March 17, 1998	Technology Risk Management: Guidance for Bankers and Examiners	Includes a short description of a bank's responsibility with regard to outsourcing its technology products and services. Applies to FSAs with the issuance of this bulletin.
Bulletin 1996-48	September 3, 1996	Stored Value Card Systems: Information for Bankers and Examiners	Provides basic information to assist banks in identifying and managing risks involved in stored value systems. Applies to FSAs with the issuance of this bulletin.
Advisory Letter 2004-6	May 6, 2004	Payroll Card Systems	Advises banks engaged in payroll cards systems involving nonbank third parties to fully comply with OCC guidance on third-party relationships.
Advisory Letter 2002-3	March 22, 2002	Guidance on Unfair or Deceptive Acts or Practices	Describes legal standards and provides guidance on unfair or deceptive acts and practices. Cross references other OCC guidance on: selecting a third-party vendor; monitoring vendor performance; maintaining proper documentation about vendor management; review of contractual arrangements; compensation concerns; monitoring consumer complaints; payment procedures; and loan collection activities.
Advisory Letter 2000-11	November 27, 2000	Title Loan Programs	Alerts banks to OCC concerns over title loan programs, including the involvement of third-party vendors.
Advisory Letter 2000-10	November 27, 2000	Payday Lending	Alerts banks to OCC concerns over payday lending programs, including the involvement of third-party vendors. Applies to FSAs.
Banking Circular 181	August 2, 1984	Purchases of Loans in Whole or in Part-Participations	Describes prudent purchases of loans from and loan participations with third parties. Applies to FSAs with the issuance of this bulletin.

FFIEC Handbooks

Issuance	Date	Subject	Description
FFIEC Bank Secrecy Act/ Anti-Money Laundering Examination Manual	April 29, 2010	Bank Secrecy Act and Anti-Money Laundering	Provides guidance on identifying and controlling risks associated with money laundering and terrorist financing, including third-party payment processors and professional service providers.
FFIEC Information Technology	Various	“Outsourcing Technology Services”	Provides guidance on managing risks associated with the outsourcing of IT

Examination
Handbook

and “Supervision of
Technology Service
Providers”

services. Several other booklets of the FFIEC IT Examination Handbook also provide guidance addressing third-party relationships.

¹ Third-party relationships include activities that involve outsourced products and services, use of independent consultants, networking arrangements, merchant payment processing services, services provided by affiliates and subsidiaries, joint ventures, and other business arrangements where the bank has an ongoing relationship or may have responsibility for the associated records. Affiliate relationships are also subject to sections 23A and 23B of the Federal Reserve Act (12 USC 371c and 12 USC 371c-1) as implemented in Regulation W (12 CFR 223). Third-party relationships generally do not include customer relationships.

² An OCC-supervised bank that provides services to another OCC-supervised bank is held to the same standards of due diligence, controls, and oversight as is a non-bank entity.

³ For example, in franchising arrangements, the bank lends its name or regulated entity status to activities originated or predominantly conducted by others. Thus, the bank is permitting its attributes to be used in connection with the products and services of a third party. The risks to the bank from these franchising arrangements vary based on the terms of the agreement between the bank and the third party and the nature of the services offered. When a bank is offering products and services originated by third parties as its own, the bank can be exposed to substantial financial loss and damage to its reputation if it fails to maintain adequate quality control over those products and services and adequate oversight over the third-party activities. Risk may also increase when the third party relies on the bank's regulated entity status and offers services or products through the bank with fees, interest rates, or other terms that cannot be offered by the third party directly.

⁴ Refer to appendix A for a discussion of risks associated with third-party relationships.

⁵ Except for nondisclosure agreements that may be required in order for the bank to conduct due diligence.

⁶ Dual employees are employed by both the bank and the third party.

⁷ If the bank enters into a written arrangement under which a broker registered under the securities laws offers brokerage services on or off the premises of the bank, the bank should ensure that the arrangement qualifies for the exception in the Securities and Exchange Act of 1934, 15 USC 78c(a)(4)(B)(i), and Regulation R, 12 CFR 218.700-701 and 17 CFR 247.700-701, for third-party brokerage arrangements. Otherwise, the bank may be required to register as a securities broker under the federal securities laws. The bank also should ensure compliance with regulatory requirements if bank employees receive fees for referrals to the third-party broker.

⁸ Before conducting an examination of a third party that is a functionally regulated affiliate (FRA), the OCC is required to give notice to and consult with the FRA's primary regulator and, to the fullest extent possible, avoid duplication of examination activities, reporting requirements, and requests for information. See 12 USC 1831v.

⁹ When a third-party relationship involves critical activities, a bank may need to consider appointing a senior officer to provide oversight of that relationship.

¹⁰ Under 12 USC 1867(c)(2), national banks are required to notify the OCC of the existence of a servicing relationship. FSAs are subject to similar requirements set forth in 12 USC 1464(d)(7)(D)(ii) and 12 USC 1867(c)(2). The OCC implements this notification requirement by requiring banks to maintain a current inventory of all third-party relationships and make it available to examiners upon request.

¹¹ In addition to the functional business units, this may include information technology, identity and access management, physical security, information security, business continuity, compliance, legal, risk management, and human resources.

¹² The CAMELS rating is an overall assessment of a bank based on six individual ratings; the word CAMELS is an acronym for these individual elements of regulatory assessment (capital adequacy, asset quality, management, earnings, liquidity, and

sensitivity to market risk).

¹³ All guidance applies to national banks. Guidance not currently applicable to FSAs (as noted in this appendix) is undergoing review through the OCC's policy integration efforts.

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Business Associate Contracts

SAMPLE BUSINESS ASSOCIATE AGREEMENT PROVISIONS

(Published January 25, 2013)

Introduction

A "business associate" is a person or entity, other than a member of the workforce of a covered entity, who performs functions or activities on behalf of, or provides certain services to, a covered entity that involve access by the business associate to protected health information. A "business associate" also is a subcontractor that creates, receives, maintains, or transmits protected health information on behalf of another business associate. The HIPAA Rules generally require that covered entities and business associates enter into contracts with their business associates to ensure that the business associates will appropriately safeguard protected health information. The business associate contract also serves to clarify and limit, as appropriate, the permissible uses and disclosures of protected health information by the business associate, based on the relationship between the parties and the activities or services being performed by the business associate. A business associate may use or disclose protected health information only as permitted or required by its business associate contract or as required by law. A business associate is directly liable under the HIPAA Rules and subject to civil and, in some cases, criminal penalties for making uses and disclosures of protected health information that are not authorized by its contract or required by law. A business associate also is directly liable and subject to civil penalties for failing to safeguard electronic protected health information in accordance with the HIPAA Security Rule.

A written contract between a covered entity and a business associate must: (1) establish the permitted and required uses and disclosures of protected health information by the business associate; (2) provide that the business associate will not use or further disclose the information other than as permitted or required by the contract or as required by law; (3) require the business associate to implement appropriate safeguards to prevent unauthorized use or disclosure of the information, including implementing requirements of the HIPAA Security Rule with regard to electronic protected health information; (4) require the business associate to report to the covered entity any use or disclosure of the information not provided for by its contract, including incidents that constitute breaches of unsecured protected health information; (5) require the business associate to disclose protected health information as specified in its contract to satisfy a covered entity's obligation with respect to individuals' requests for copies of their protected health information, as well as make available protected health information for amendments (and incorporate any amendments, if required) and accountings; (6) to the extent the business associate is to carry out a covered entity's obligation under the Privacy Rule, require the business associate to comply with the requirements applicable to the obligation; (7) require the business associate to make available to HHS its internal practices, books, and records relating to the use and disclosure of protected health information received from, or created or received by the business associate on behalf of, the covered entity for purposes of HHS determining the covered entity's compliance with the HIPAA Privacy Rule; (8) at termination of the contract, if feasible, require the business associate to return or destroy all protected health information received from, or created or received by the business associate on behalf of, the covered entity; (9) require the business associate to ensure that any subcontractors it may engage on its behalf that will have access to protected health information agree to the same restrictions and conditions that apply to the business associate with respect to such information; and (10) authorize termination of the contract by the covered entity if the business associate violates a material term of the contract. Contracts between business associates and business associates that are subcontractors are subject to these same requirements.

This document includes sample business associate agreement provisions to help covered entities and business associates more easily comply with the business associate contract requirements. While these sample provisions are written for the purposes of the contract between a covered entity and its business associate, the language may be adapted for purposes of the contract between a

Guidance Materials for Covered Entities
» Summary of the Privacy Rule
» Guidance on Significant Aspects of the Privacy Rule
» Fast Facts for Covered Entities
» Provider Guide: Communicating With a Patient's Family, Friends, or Other Persons Identified by the Patient
» Guidance on the Application of FERPA and HIPAA to Student Health Records
» Sample Business Associate Contract
» Misleading Marketing Claims
» Sign Up for the OCR Privacy Listserv

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business associate and subcontractor.

This is only sample language and use of these sample provisions is not required for compliance with the HIPAA Rules. The language may be changed to more accurately reflect business arrangements between a covered entity and business associate or business associate and subcontractor. In addition, these or similar provisions may be incorporated into an agreement for the provision of services between a covered entity and business associate or business associate and subcontractor, or they may be incorporated into a separate business associate agreement. These provisions address only concepts and requirements set forth in the HIPAA Privacy, Security, Breach Notification, and Enforcement Rules, and alone may not be sufficient to result in a binding contract under State law. They do not include many formalities and substantive provisions that may be required or typically included in a valid contract. Reliance on this sample may not be sufficient for compliance with State law, and does not replace consultation with a lawyer or negotiations between the parties to the contract.

Sample Business Associate Agreement Provisions

Words or phrases contained in brackets are intended as either optional language or as instructions to the users of these sample provisions.

Definitions

Catch-all definition:

The following terms used in this Agreement shall have the same meaning as those terms in the HIPAA Rules: Breach, Data Aggregation, Designated Record Set, Disclosure, Health Care Operations, Individual, Minimum Necessary, Notice of Privacy Practices, Protected Health Information, Required By Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

Specific definitions:

- (a) Business Associate. "Business Associate" shall generally have the same meaning as the term "business associate" at 45 CFR 160.103, and in reference to the party to this agreement, shall mean [Insert Name of Business Associate].
- (b) Covered Entity. "Covered Entity" shall generally have the same meaning as the term "covered entity" at 45 CFR 160.103, and in reference to the party to this agreement, shall mean [Insert Name of Covered Entity].
- (c) HIPAA Rules. "HIPAA Rules" shall mean the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and Part 164.

Obligations and Activities of Business Associate

Business Associate agrees to:

- (a) Not use or disclose protected health information other than as permitted or required by the Agreement or as required by law;
- (b) Use appropriate safeguards, and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information, to prevent use or disclosure of protected health information other than as provided for by the Agreement;
- (c) Report to covered entity any use or disclosure of protected health information not provided for by the Agreement of which it becomes aware, including breaches of unsecured protected health information as required at 45 CFR 164.410, and any security incident of which it becomes aware;

[The parties may wish to add additional specificity regarding the breach notification obligations of

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the business associate, such as a stricter timeframe for the business associate to report a potential breach to the covered entity and/or whether the business associate will handle breach notifications to individuals, the HHS Office for Civil Rights (OCR), and potentially the media, on behalf of the covered entity.]

(d) In accordance with 45 CFR 164.502(e)(1)(ii) and 164.308(b)(2), if applicable, ensure that any subcontractors that create, receive, maintain, or transmit protected health information on behalf of the business associate agree to the same restrictions, conditions, and requirements that apply to the business associate with respect to such information;

(e) Make available protected health information in a designated record set to the [Choose either "covered entity" or "individual or the individual's designee"] as necessary to satisfy covered entity's obligations under 45 CFR 164.524;

[The parties may wish to add additional specificity regarding how the business associate will respond to a request for access that the business associate receives directly from the individual (such as whether and in what time and manner a business associate is to provide the requested access or whether the business associate will forward the individual's request to the covered entity to fulfill) and the timeframe for the business associate to provide the information to the covered entity.]

(f) Make any amendment(s) to protected health information in a designated record set as directed or agreed to by the covered entity pursuant to 45 CFR 164.526, or take other measures as necessary to satisfy covered entity's obligations under 45 CFR 164.526;

[The parties may wish to add additional specificity regarding how the business associate will respond to a request for amendment that the business associate receives directly from the individual (such as whether and in what time and manner a business associate is to act on the request for amendment or whether the business associate will forward the individual's request to the covered entity) and the timeframe for the business associate to incorporate any amendments to the information in the designated record set.]

(g) Maintain and make available the information required to provide an accounting of disclosures to the [Choose either "covered entity" or "individual"] as necessary to satisfy covered entity's obligations under 45 CFR 164.528;

[The parties may wish to add additional specificity regarding how the business associate will respond to a request for an accounting of disclosures that the business associate receives directly from the individual (such as whether and in what time and manner the business associate is to provide the accounting of disclosures to the individual or whether the business associate will forward the request to the covered entity) and the timeframe for the business associate to provide information to the covered entity.]

(h) To the extent the business associate is to carry out one or more of covered entity's obligation(s) under Subpart E of 45 CFR Part 164, comply with the requirements of Subpart E that apply to the covered entity in the performance of such obligation(s); and

(i) Make its internal practices, books, and records available to the Secretary for purposes of determining compliance with the HIPAA Rules.

Permitted Uses and Disclosures by Business Associate

(a) Business associate may only use or disclose protected health information

[Option 1 – Provide a specific list of permissible purposes.]

[Option 2 – Reference an underlying service agreement, such as "as necessary to perform the services set forth in Service Agreement."]

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[In addition to other permissible purposes, the parties should specify whether the business associate is authorized to use protected health information to de-identify the information in accordance with 45 CFR 164.514(a)-(c). The parties also may wish to specify the manner in which the business associate will de-identify the information and the permitted uses and disclosures by the business associate of the de-identified information.]

(b) Business associate may use or disclose protected health information as required by law.

(c) Business associate agrees to make uses and disclosures and requests for protected health information

[Option 1] consistent with covered entity's minimum necessary policies and procedures.

[Option 2] subject to the following minimum necessary requirements: [Include specific minimum necessary provisions that are consistent with the covered entity's minimum necessary policies and procedures.]

(d) Business associate may not use or disclose protected health information in a manner that would violate Subpart E of 45 CFR Part 164 if done by covered entity [if the Agreement permits the business associate to use or disclose protected health information for its own management and administration and legal responsibilities or for data aggregation services as set forth in optional provisions (e), (f), or (g) below, then add ", except for the specific uses and disclosures set forth below."]

(e) [Optional] Business associate may use protected health information for the proper management and administration of the business associate or to carry out the legal responsibilities of the business associate.

(f) [Optional] Business associate may disclose protected health information for the proper management and administration of business associate or to carry out the legal responsibilities of the business associate, provided the disclosures are required by law, or business associate obtains reasonable assurances from the person to whom the information is disclosed that the information will remain confidential and used or further disclosed only as required by law or for the purposes for which it was disclosed to the person, and the person notifies business associate of any instances of which it is aware in which the confidentiality of the information has been breached.

(g) [Optional] Business associate may provide data aggregation services relating to the health care operations of the covered entity.

Provisions for Covered Entity to Inform Business Associate of Privacy Practices and Restrictions

(a) [Optional] Covered entity shall notify business associate of any limitation(s) in the notice of privacy practices of covered entity under 45 CFR 164.520, to the extent that such limitation may affect business associate's use or disclosure of protected health information.

(b) [Optional] Covered entity shall notify business associate of any changes in, or revocation of, the permission by an individual to use or disclose his or her protected health information, to the extent that such changes may affect business associate's use or disclosure of protected health information.

(c) [Optional] Covered entity shall notify business associate of any restriction on the use or disclosure of protected health information that covered entity has agreed to or is required to abide by under 45 CFR 164.522, to the extent that such restriction may affect business associate's use or disclosure of protected health information.

Permissible Requests by Covered Entity

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[Optional] Covered entity shall not request business associate to use or disclose protected health information in any manner that would not be permissible under Subpart E of 45 CFR Part 164 if done by covered entity. [Include an exception if the business associate will use or disclose protected health information for, and the agreement includes provisions for, data aggregation or management and administration and legal responsibilities of the business associate.]

Term and Termination

(a) Term. The Term of this Agreement shall be effective as of [Insert effective date], and shall terminate on [Insert termination date or event] or on the date covered entity terminates for cause as authorized in paragraph (b) of this Section, whichever is sooner.

(b) Termination for Cause. Business associate authorizes termination of this Agreement by covered entity, if covered entity determines business associate has violated a material term of the Agreement [and business associate has not cured the breach or ended the violation within the time specified by covered entity]. [Bracketed language may be added if the covered entity wishes to provide the business associate with an opportunity to cure a violation or breach of the contract before termination for cause.]

(c) Obligations of Business Associate Upon Termination.

[Option 1 – if the business associate is to return or destroy all protected health information upon termination of the agreement]

Upon termination of this Agreement for any reason, business associate shall return to covered entity [or, if agreed to by covered entity, destroy] all protected health information received from covered entity, or created, maintained, or received by business associate on behalf of covered entity, that the business associate still maintains in any form. Business associate shall retain no copies of the protected health information.

[Option 2—if the agreement authorizes the business associate to use or disclose protected health information for its own management and administration or to carry out its legal responsibilities and the business associate needs to retain protected health information for such purposes after termination of the agreement]

Upon termination of this Agreement for any reason, business associate, with respect to protected health information received from covered entity, or created, maintained, or received by business associate on behalf of covered entity, shall:

1. Retain only that protected health information which is necessary for business associate to continue its proper management and administration or to carry out its legal responsibilities;
2. Return to covered entity [or, if agreed to by covered entity, destroy] the remaining protected health information that the business associate still maintains in any form;
3. Continue to use appropriate safeguards and comply with Subpart C of 45 CFR Part 164 with respect to electronic protected health information to prevent use or disclosure of the protected health information, other than as provided for in this Section, for as long as business associate retains the protected health information;
4. Not use or disclose the protected health information retained by business associate other than for the purposes for which such protected health information was retained and subject to the same conditions set out at [Insert section number related to paragraphs (e) and (f) above under "Permitted Uses and Disclosures By Business Associate"] which applied prior to termination; and
5. Return to covered entity [or, if agreed to by covered entity, destroy] the protected health information retained by business associate when it is no longer needed by business associate for its proper management and administration or to carry out its legal responsibilities.

U.S. Department of Health & Human Services

Improving the health, safety, and well-being of America

Health Information Privacy

[The agreement also could provide that the business associate will transmit the protected health information to another business associate of the covered entity at termination, and/or could add terms regarding a business associate's obligations to obtain or ensure the destruction of protected health information created, received, or maintained by subcontractors.]

(d) Survival. The obligations of business associate under this Section shall survive the termination of this Agreement.

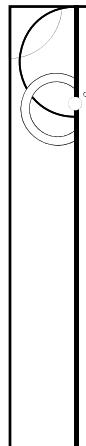
Miscellaneous [Optional]

(a) [Optional] Regulatory References. A reference in this Agreement to a section in the HIPAA Rules means the section as in effect or as amended.

(b) [Optional] Amendment. The Parties agree to take such action as is necessary to amend this Agreement from time to time as is necessary for compliance with the requirements of the HIPAA Rules and any other applicable law.

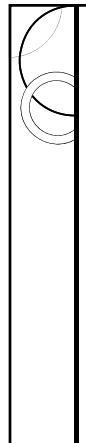
(c) [Optional] Interpretation. Any ambiguity in this Agreement shall be interpreted to permit compliance with the HIPAA Rules.

[Back to Top](#)



Coaching Compliance: Connecting the Dots When Problems Arise

Jacqueline Nash Bloink MBA, CHC, CPC-I, CMRS
Director of Compliance – Arizona Community Physicians
HCCA Compliance Institute **March 30 – April 2, 2014**



Coaching- Role Models

- Recognize any of these scenes?

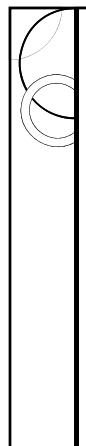
 50 inspirational speeches in 5 Minutes.mp4

<http://www.youtube.com/watch?v=havdo8-k6Fo>

Ref I

2/20/2014

2



Is there a Difference between Consulting and Coaching?

- External vs Internal
- Influence Level
- Perceptions
- Building Loyalty
- Learning Styles with each approach
- Longevity with goals and outcomes
- Interaction / Engagement of staff
- Financial Implications
- **Effect on Moral Courage and Speaking the Truth**

2/20/2014

3



External vs Internal

- **Consultants** are hired from an **external source**.
- **Coaches** can either be found internally **or externally -many consultants are now taking on the role of coach.**

2/20/2014

4



Influence and Perceptions

- Do organizations / employees look at (**perceive**) **external** sources as “experts?”
- Or ... do employees **value and trust** existing **internal** relationships?

2/20/2014

5



Loyalty Issues

- Will employees **feel safer** if they discuss **sensitive compliance issues** with an **external consultant**?

Versus

- Employees that discuss compliance issues with an **internal member of management** that has been a coach / role model for the employee for a period of time.

2/20/2014

6



Longevity of Outcomes

- If the **consultant** delivers the information – is it more likely to be easily forgotten?

Versus

- Internal coaching** – which... should be a constant (gentle) reminder if done correctly!

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Level of Interaction with Staff

- Trust Issues???** Do I trust this person enough (with my job) ...that they will try to protect me if I tell them the truth / give them information of alleged wrong doing???

Could work either way

- Some employees might trust external sources in lieu of internal sources - depending on relationships.

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Financial Implications

- Internal Coaching** – mentoring by the internal Compliance Professional – Cost is salary, benefits, etc.
- Consultants** are a fixed amount (*usually*) and budgeted on an *annual* basis.

Both have Advantages!!!!

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Moral Courage to Speak the Truth!!!!

This is the BIG question!

Consultant or Coach??? Which one lends courage to the employee to speak the truth concerning Compliance Issues???

Both!!!

Some employees feel safer with someone that they know (internally)... **Others** feel safer with an outside source.

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Connecting the Dots When Problems Arise....

- This is a dilemma regardless - of if you are an “internal” - or an “external” resource that is brought in.
- **Questions to Consider:**
 - To whom does the Internal Compliance Professional report?
 - To whom does the External Compliance Consultant report?
 - Ideal Situation is where the Compliance Professional has a dual reporting obligation to both the Board and the CEO.

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Questions to Consider....

** What happens if a Compliance Concern goes first to Human Resources (HR?)

** Does your organization have a policy that Compliance Issues are to be given directly to the Compliance Professional? Or ... can the CEO / COO / CFO control HR and suppress Compliance Concerns from reaching the Compliance Professional or the Board?

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Possible Solution...

*** **Develop Policies and Procedures** to ensure that **ALL** Compliance concerns **go to the Compliance Professional – regardless** of where the Compliance Concern originates.

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From HCCA's recent survey...

... ” while many other aspects of the **(Federal) Guidelines** have grown well established, the relationship with the board of directors **is still far from mature**. Many compliance officers report concerns about whether the relationship is as strong as it should be, **or even if** it is serving its intended role of enabling the board to exercise sufficient oversight.” **Jan. 2014, HCCA**

Ref 2

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HCCA's Code of Ethics for Healthcare Compliance Professionals

“R1.4: If, in the course of their work, HCCPs become aware of any decision by their employing organization which, if implemented, would constitute misconduct, adversely affect the health of patients, residents, or clients, **or defraud the system**, the professional shall: (a) refuse to consent to the decision;

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HCCA's Code of Ethics –

Cont...

(b) escalate to the highest governing authority, as appropriate; **(c)** if serious issues remain unresolved after exercising “a” and “b”, consider resignation; and **(d) report the decision to public officials when required by law.“**

Ref 3

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Connecting the Dots....

- What would an **Internal** Compliance Professional Do???
- What would an **External Consultant / Coach** do???

Hopefully – the Healthcare Compliance Professional **would do the same whether Internal or External!!!!**

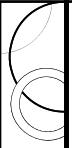
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But what are the realities when Push comes to Shove???

- Is it more difficult for an **internal professional** to report the organization to authorities if that job is their “**bread and butter ???**”
- **Ethics?** Depends on the **internal moral values of that professional!!!**
- The **external professional** has dilemmas too... **What if** the firm the consultant is employed by...wants to keep the entity as a client – **regardless of wrong doing?**

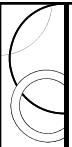
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An Interesting Slant From the Government...Their Attempt at Connecting the Dots...

Using financial words such as **Return on Investment (ROI)** ... some states (and the federal government) are trying to get constituents to rally the **fight on fraud** by seeing that *fighting fraud can be lucrative!*

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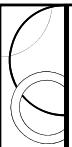


Fighting Medicare Fraud- ROI

“According to **Attorney General Eric Holder**, efforts to fight Medicare fraud have yielded an impressive “**return on investment**” for the American taxpayer. **For every dollar spent fighting fraud, approximately \$7 has been recovered and returned.**”

Other similar examples include **Utah and New York.** **Ref 4**

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Consultants – Connecting the Dots and Fighting Fraud:

A New Breed of Whistleblower? Consulting Company Turns in its Own Health Care Client for Alleged False Claims”.... (September 2013)

“the allegations in the complaint in this particular case are striking, as the **whistleblower who brought these allegations to the government’s attention** and who stands to be awarded millions for his part in uncovering the alleged fraud was the **president of a consulting company** “

2/20/2014 Ref 5 21



Compliance Professionals – Connecting the Dots and Fighting Fraud:

“When Compliance Has to Consider Blowing the Whistle— Some Pros and Cons “ (July 2013)

“You are appalled by what you have witnessed and may even be concerned with being held accountable if and when the misconduct gets exposed and turns into a civil or criminal action. You understandably are worried about your reputation, both professionally and personally. You’re near the end of your rope.”

Ref 6

2020014

27



Attorneys – Connecting the Dots and Fighting Fraud:

“Often the SEC (Securities Exchange Commission) rules allow disclosure where state rules do not.”

Arizona Disclosure Permitted*

- ARPC 1.6(b)(2) Disclosure Permitted*
 - ARPC 1.6(d)(1) Δ Disclosure Required
 - ARPC 1.6(d)(2) Δ Disclosure Required
 - ARPC 3.3(a)(3) and (b)** Disclosure Required+
 - ARPC 1.2(d) and 4.1(b) Δ Disclosure Permitted
 - ARPC 1.13(c)

Ref 7

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How Do You Connect the Dots....

- In your Organization?
 - As a Compliance Professional?
 - As a Consultant?
 - As a Board Member?
 - In your Community?
 - As a beneficiary of **valuable/ scarce** tax dollars?

What We Permit ... We Promote

What is your solution to connecting the dots....?

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References

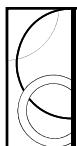
Reference 1 (slide 2) 50 Inspirational Speeches in 5 Minutes
<http://www.youtube.com/watch?v=havdo8-k6Fo>

Reference 2 (slide 14) Relationship Between the Board of Directors and the Compliance and Ethics Officer ([January 2014](http://www.hcca.info.org/Resources/ResourceOverview/Surveys.aspx))
<http://www.hcca.info.org/Resources/ResourceOverview/Surveys.aspx>

Reference 3 (slide 15 and 16) HCCA Code of Ethics (pg 3),
<http://www.hcca-info.org/Portals/0/PDFs/Resources/HCCACodeOfEthics.pdf>

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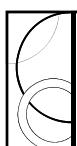
References

Reference 4 (slide 20) Investing in Investigations: Examining the ROI When Fighting Fraud (July 2013)
<http://www.propertycasualty360.com/2013/07/03/investing-in-investigations-examining-the-roi-when>

**Reference 5 (slide 21) A New Breed of Whistleblowers...
(September 2013) <http://www.bricker.com/publications-and-resources/publications-and-resources-details.aspx?publicationid=2706>**

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References

Reference 6 (slide 22) _When Compliance Has To Consider Blowing the Whistle ... (July 2013)
<http://www.corporatecomplianceinsights.com/when-compliance-has-to-consider-blowing-the-whistle-some-pros-and-cons/>

Reference 7 (slide 23) Attorneys as SEC Whistleblowers (May 2013)

www.lw.com/thoughtLeadership/SEC-whistleblowers AND
Reference 8 (slide 23) Harvard Law School Forum on
Corporate Governance and Financial Regulation : Can
Attorneys be Award Seeking SEC Whistleblowers? (June

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MEDICAID ENFORCEMENT UPDATE

Judith Fox, JD, MPA
Strategic Management

Jack Wenik, Esq.
Sills Cummis & Gross P.C.



Sills Cummis & Gross P.C.

GENERAL TOPICS

- Medicaid Enforcement Initiatives (MIPs, MFCUs, OIG, RACs)
- Data Mining, Risk Mitigation & Audit Challenges
- Medicaid Enforcement Update
- Compliance Tips

1

MEDICAID ENFORCEMENT INITIATIVES

- Increased coordination between state and federal authorities resulting in record breaking recoveries
- Increased enforcement Medicaid Integrity Program ("MIP") instituted
- ACA mandates for Medicaid Audit Contractors ("RACs")
- Medicaid Fraud Control Units ("MFCUs") granted authority to engage in data mining

2

MEDICAID INTEGRITY PROGRAM

- MIP is comprehensive federal strategy designed to prevent fraud, waste & abuse in the \$300 billion/year Medicaid program.
- Comprehensive Medicaid Integrity Plan (CMIP) outlines strategy
- Significant funding for MIP enforcement (*\$75m*)
- Medicaid Integrity Contractors (MICs) address reviews, education and audit
- MICs identify overpayments (automated review, data mining; and sampling of records)

3

RECOVERY AUDIT CONTRACTORS

- Under ACA states must establish a RAC
- Paid on a contingency fee basis
- Identify for the State over & under payments
- Coordinates with other contractors/entities performing audits (e.g. DOJ, FBI, OIG, MFCU)

4

MEDICAID FRAUD CONTROL UNITS

- Certified HHS–OIG to investigate & prosecute health care fraud
- Charged with investigating fraud
- Collects and/or referring collection of identified overpayments to the single state agency

5

MFCU DATA MINING

- State MFCU could not use Federal funds for "data mining"
- Now rules have reversed that and permit data mining.
- MFCUs must satisfy certain conditions
 - Identifying methods for coordination with State Medicaid agencies and designating individuals to serve as primary contact;
 - Ensuring MFCU staff are properly trained in data mining technology;
 - provide OIG annual report (associated costs, # of cases generated, monetary recoveries resulting)
 - Requires OIG approval; good for three years

6

MFCU DATA MINING

OIG State Policy Transmittal No. 2013

- **Elements** for a complete data mining application
 - Methods of coordination with State Medicaid Agency (SMA)
 - Staffing and training
 - Reporting
 - Budget Implications
- **Process** for submitting application
 - Electronic submission: Medicaid Fraud & Policy Oversight Division
 - OIG has 90 days from receipt to review, consult with CMS and approve or deny unless additional info is requested; additional 90 days*
 - Failure to respond by OIG constitutes approval

7

MFCU DATA MINING

"We believe that allowing MFCUs to receive funding for data mining will enable them to marshal their resources more effectively and take full advantage of their expertise in detecting and investigating Medicaid fraud vulnerabilities"

Federal Register, May 17, 2013

8

MFCU DATA MINING

(Cont'd)

- ▶ Florida– July 2010 waiver of 42 CFR § 1007.19
- ▶ Waiver terms; Memorandum of Understanding
 - 3 years
 - Limited staff time utilized in data mining
 - Detailed plan how MFCU would coordinate data mining efforts with AHCA's MIP to avoid duplicating efforts.
- ▶ FL MFCU –Has 74 data mining projects for review; 13 cases and 3 complaints opened from these projects
 - Billing for phantom patients, Billing for services and/or equipment not medically necessary, Overcharging, Double billing, Misuse of Medicaid provider and recipient numbers

9

MFCU DATA MINING

(cont'd)

Results can lead to enforcement action:

- Withhold of payments pending investigation outcome
- Patients interviewed
- Employees subpoenaed
- Facilities checked
- MFCU agents can enter facility, review records with minimal notice
- MFCU agents can investigate any suspected criminal activity, not just Medicaid fraud
- Repayments can be extrapolated i.e. without a complete audit, using legislatively authorized and court sanctioned statistical estimating formulas

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DATA MINING & EXTRAPOLATION

- ▶ Automated Review—identify inappropriate and large payment amounts by analyzing large sets of claims to detect “systematic errors”
- ▶ Complex Review—requires sampling; medical chart and billing records analysis
- ▶ Extrapolation from a small sample (e.g. 30 claims) to a large universe to find inappropriate payments leading to huge recovery demands

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DATA MINING & EXTRAPOLATION

- ▶ Risk Mitigation
 - Provider's own analysis to detect unusual patterns or high risk profiles
 - Billing training and verification protocols
 - Prepare for government audit (e.g. clerical mistakes, sloppy record keeping, attention to detail)
- ▶ Extrapolation Challenges
 - Medical, clinical and coverage criteria
 - Statistical calculations
- ▶ Statistical sampling basics to challenge

12

DATA MINING & EXTRAPOLATION

- ▶ Preconditions/limitation for extrapolating (e.g. CMS Medicare Program Integrity Manual (PIM))
 - Before extrapolating, must establish sustained or high level of payment error required , or
 - Educational intervention failed to correct payment error
- ▶ Technical Grounds
 - Guidance for Medicaid contractors/state agencies conducting audits and using overpayment extrapolations are less detailed and consistent than PIM
- ▶ Obtain guidance & Medicaid audit manuals for your state

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DATA MINING & EXTRAPOLATION

- State must use a statistically valid random sample (SVRS) that is fair, replicable and allows verification by an independent auditor
- Response to Demand Letter, Recovery Amount Determination, or Damage Assessment
 - **Statistical Expertise** in sampling and statistical formula e.g. OIG RAT-STATS, SAS, R software, etc.
 - **Clinical and Health Information Management expertise** (to assess medical necessity, clinical standards, and coding & billing accuracy)
 - **Regulatory and Legal expertise** (to assess coverage criteria, payer rules, & applicable federal and state law)

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DATA MINING & EXTRAPOLATION

- Government Auditing Standards ("GAGAS")
 - General Guidelines that must be followed by government auditors and may be used when challenging overpayment assessments
 - Objectivity and independence are key; adherence to clear criteria that conform to inter-rater reliability – findings must be prepared to allow for validation and verification of assumptions, methods, and results in a challenge

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MEDICIAID ENFORCEMENT UPDATE

- MFCUs in all states and the District of Columbia
- Most MFCUs are part of Attorney General Office
- Most program integrity functions are part of the state Medicaid agency
- New trend: Offices of Medicaid Inspector General (OMIG) independent of the state Medicaid agency
- OMIGs conduct audits, refer criminal cases to MFCUs

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STATES WITH AN OMIG

- | | | |
|------------|---------------|-----------------|
| • Arizona* | • Kentucky | • New York* |
| • Arkansas | • Maryland | • Tennessee |
| * | • Michigan | • Texas* |
| • Florida | • Minnesota | • Utah |
| • Georgia* | • New Jersey* | • West Virginia |
| • Illinois | • New Mexico | • Wisconsin |
| • Kansas | | |

*Self Disclosure Policy

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NJ OFFICE STATE COMPTROLLER Medicaid Fraud Division Work Plan

- **Primary Care Physicians:** Medical necessity reviews of records for non-Medicaid referring providers to identify outliers (excessive ordering) and send letters to alert them to their rank relative to other physicians with possible follow-up audits
- **Home Health Agencies:** Will audit to ensure that charts contain proper documentation and plans of care
- **Hospice:** Will use Data Mining Unit to analyze claims to see who has been on hospice for more than 6 months
- **Labs:** Will review claims from independent clinical labs to see if tests were already included in facility rate, or if services were improperly un-bundled

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NY OMIG WORK PLAN

- **Primary Care Physicians:** Has list of outliers of those ordering controlled substances that exceed that of their peers and review for medical necessity
- **Home Health Agencies:** Will analyze claims to determine services were actually provided and staff was properly trained; focus on dual-eligible patients to ensure Medicaid is not paying an excessive amount
- **Pharmacies:** Will audit to verify prescriptions were ordered by a qualified provider and pharmacists are not taking part in drug diversion

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HHS-OIG WORK PLAN

- **Home Health Agencies:** Will focus on provider & beneficiary eligibility and review health screening records (i.e., vaccinations for hepatitis/influenza) for workers as required
- **Adult Day Care:** OIG will review Medicaid payments by States to determine whether the providers complied with Federal and State requirements
- **Transportation Services:** OIG will focus on compliance with Federal and State requirements

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HARSHER STATUTORY/REGULATORY MANDATES

- “Federal Financial Participation” to be withheld from states failing to suspend provider payments as required
- Payment suspension required when credible allegation of fraud is under investigation
- No time limit for Medicaid suspensions
- No uniform guidance on verification of fraud
- “Pending investigation” not necessarily by a law enforcement agency
- Allegation can be from a hotline, data mining, audits, etc.
- Each state has “flexibility” to define “credible allegation of fraud” pursuant to individual state law
- Can be an allegation from employee of a physician

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HARSHER STATUTORY/REGULATORY MANDATES GOOD CAUSE EXEMPTION

- Recipient access to care would be jeopardized
- Sole community doctor or specialist
- Provider serves recipients in medically underserved area
- Suspension is not in “best interests of Medicaid”
- New Mexico Experience: 15 largest mental health providers suspended, due to “credible allegation of fraud” in audit report with 30,000 beneficiaries affected. Audit report basis for suspension sealed pending completion of investigation and months later some “cleared,” others forced out of business

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EXCLUSION REQUIREMENTS

- Mandatory 5 year exclusion for health care fraud convictions. 42 U.S.C. § 1320a-7(a); 42 C.F.R. § 1001.101
- Misdemeanor fraud convictions can result in 3 year exclusion or more 42 C.F.R. § 1001.201
- Periods can be adjusted by aggravating or mitigating factors
- *Friedman v. Sebelius*, 646 F.3d 813, (D.C. Cir. (2012)) - “responsible corporate officer” doctrine can lead to exclusion
- *Bee Homes, Inc.* case from Maryland – executive’s exclusion can endanger all Medicaid funds
- CVS case from New York – CVS paid \$900,000 for employing excluded pharmacist who admitted conviction on job application

23

^[2]

TIPS TO MITIGATE SANCTION RISKS

- Many states now impose monthly sanction screening
- OIG recommends monthly checks¹
- State and Federal sanction lists should be checked
- Screen all Employees/Officers/Vendors/Contractors
- Multiple variation of names should be checked
- Establish sanction screening policies
- New hires and current employees should be checked

¹ OIG, Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs, May 8, 2013

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TIPS TO MITIGATE SANCTION RISKS

- Do not hire sanctioned parties, even if services not separately billed for, e.g. nurses
- Enrollment in Medicaid can be denied/terminated if a 5% or more owner was convicted in last 10 years for Medicare/Medicaid related crime
- Screen providers in managed care network

25

HOME HEALTH UNDER INCREASED SCRUTINY

- 40% of MFCU criminal cases are home health
- Leading number of cases by DOJ Medicare Strike Force
- Services billed, but not performed
- Billing for services to deceased/hospitalized clients
- Improperly trained staff
- Provision of services to family members
- Falsification of information used for submitting claims
- Services provided by excluded individuals
- Phony personal care assistant: a relative or family friend
- Kickbacks to physicians to qualify beneficiaries
- Kickback to individuals to pose as beneficiaries
- Personal assistants/beneficiaries in collusion splitting benefits
- Patient recruiter kickbacks recruit beneficiaries

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Slide 25

jf2 add attachment of federal and state websites
jfox, 2/10/2014

TIPS TO MITIGATE HOME HEALTH COMPLIANCE RISKS

- Audit client and CHHA information for “red flags”
 - Multiple clients at same address
 - Multiple clients with same treating physicians
 - CHHAs working at same address
 - CHHAs residing in same apartment building/address as clients
 - Excessive number of client transfers
- Conduct monthly sanction screening checks
- Determine if CHHAs working for multiple agencies
- Check handwriting/information on CMS form 485 against client/CHHA records
- Check driver license/auto ownership info for CHHAs

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TIPS TO MITIGATE HOME HEALTH COMPLIANCE RISKS(*Cont'd*)

- Check for supervisory visit forms signed in blank
- Audit supervisory visit forms for “red flags”
 - Multiple forms for nurse on same date
 - Misspelled names of patient/CHHA
 - Excessive number of daily/weekly visits by nurse
 - Majority of forms dated at 60 day deadline
- Audit CHHA training materials
 - CHHA names missing from attendance lists
 - CHHAs signing in different inks
 - CHHA names misspelled on attendance lists
 - Instructor’s name missing/misspelled
 - Undated attendance lists

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ADULT DAY CARE ISSUES UNDER SCRUTINY

- Verify client attendance, check sign-in sheets with transportation logs
- Proper staffing at centers
 - Number of RNs, LPNs on duty
 - Administrator on duty, qualifications of same
 - Staff present for activities being provided
- Verifying centers are open & providing services for all days claimed
- Verify capacity of center has not been exceeded
- Look at any instances of abuse/crimes, proper reporting of same

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Adult Day Care: Compliance Tips to Mitigate Risk

- ▶ Audit transportation logs and client sign-in sheets
- ▶ Maintain detailed attendance records for all staff, including administrators
- ▶ Train all staff regarding capacity restrictions
- ▶ Report all instances of suspected abuse/crimes

30

COMPLIANCE TIPS

- *Lippman v. Ethicon, Inc.*, No. A-4318-10T2, New Jersey Appellate Division (September 4, 2013)
 - Extended protection of CEPA to "watchdog employees"
 - Implies compliance officers can be protected "whistleblowers"
- Medicaid providers should have compliance officers
- Document proper action to any and all issues raised by compliance officers
- Document evidence of proper compliance oversight

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RECENT MEDICAID ENFORCEMENT ACTIONS

- ▶ DME – Owner of Kim's Medical Supplies ("KMS") in Los Angeles, pled guilty to fraud against Medicare/Medi-Cal of more than \$650,000 for un-needed power wheelchairs (PWCs) and using fraudulent prescriptions forged by her co-conspirators.
- ▶ Home Health Care – Owner of Home Care Solutions in NJ was arrested for billing Medicaid for services not rendered and some beneficiaries at time of service were hospitalized or on vacation. Owner of Ultimate Care Home Health Services in Texas was sentenced to 10 years in prison and ordered to pay \$25.5 million for a scheme where he recruited beneficiaries to sign up for home health care services for which they did not qualify.

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RECENT MEDICAID ENFORCEMENT ACTIONS

(cont'd)

- Adult Day Care- Owners of Garden Adult Medical Day Care in NJ fined \$1.6 million for billing for services never provided. Adult Daycare Villas in Missouri fined \$70,000 for billing for services never provided; Owner excluded from Medicaid.
 - Mental Health Center- Supervisor at Health Care Solutions Network in Florida sentenced to 10 years in prison and fined \$15 million for alteration, fabrication, and forgery of thousands of documents that purported to support the fraudulent claims.
 - Behavioral Health- Owner of three behavioral health facilities in NJ fined \$2.7 million for billing for patients for which no documentation could be found; and billing for patients treated elsewhere. Even submitted claims on days they were closed.

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RECENT MEDICAID ENFORCEMENT ACTIONS

(cont'd)

- ▶ **Ambulance Fraud**—A Tennessee couple was convicted for submitting fraudulent claims totaling more than \$1.6. They misrepresented patient transfers on stretchers, when in reality; patients were riding in the front seat or jump seat of the ambulance.
 - ▶ **Pharmacy Fraud**—A Maryland pharmacy owner and two employees in Maryland convicted for health care fraud and identity theft in connection in a \$3.6 million fraud by submitting false claims for prescription refills. A pharmacist in Florida pleaded guilty to fraud of \$351,358.14. Their pharmacy submitted claims for prescriptions, not filled or provided to beneficiaries and recipients.
 - ▶ **Medical Practice**—A medical practice in Tennessee pleaded guilty to health care fraud for billing for more infant hearing exams than medically necessary and for urinalysis not performed. He was excluded for 20 years and ordered to pay \$1.6 million.

Questions?

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Continuous Auditing Programs

Allen Still & Ryan Merryman
March 31, 2014

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Agenda

- Presentation Objectives
- Defining Continuous Auditing Programs
- The Benefits of Continuous Auditing
- Developing Your Own Program in 10 Easy Steps
- Demonstration

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Presentation Objectives

- To understand what continuous auditing is
- To realize the benefits of continuous auditing in a cost effective manner
- To gain knowledge to be able to start, or enhance, your own program
- To demonstrate techniques internal audit may use in a continuous auditing program to increase its value proposition to the organization

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Defining Continuous Audit Programs

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Defining continuous Auditing Programs

"An auditing process that examines accounting practices throughout the year. Continuous audits are usually technology driven and designed to automate error checking and data verification in real time. A continuous audit driven system generates alarm triggers that program advance notice about anomalies and errors detected by the system"

(Source: Investopedia).

The IIA continuous auditing is "any methods used to perform audit-related activities on a more continuous or continual basis."

- Continuous auditing can be a manual process – it is more about the frequency of testing and not the tools
- Real time auditing versus historical data sampling
- Data mining versus alerts
- Continuous auditing versus continuous monitoring

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Defining Continuous Auditing

Continuous Auditing vs. Monitoring

There are many definitions but here is how we understand it:

Continuous auditing is a method used by auditors to perform audit-related activities on a continuous basis. Activities range from continuous control assessment to continuous risk assessment. Technology plays a key role in making it a viable option through automation.

Continuous auditing requires you to test data, reports controls financial, etc. It is as the name suggests – auditing.

Continuous monitoring of controls is a process that management puts in place to ensure that its policies and procedures are operating effectively.

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The Benefits of Continuous Auditing

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The Benefits of Continuous Auditing

The pressure on audit to do more with less is increasing. Some of the most difficult challenges are for audit to:

- Provide timely assurance on the effectiveness of internal controls
- Better identify and assess levels of risk
- Quickly identify noncompliance with regulations and policies

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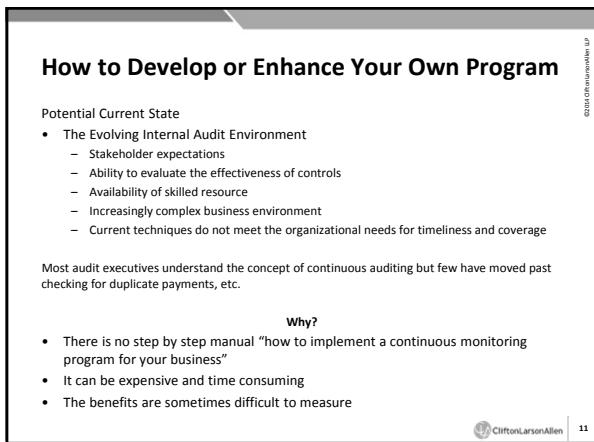
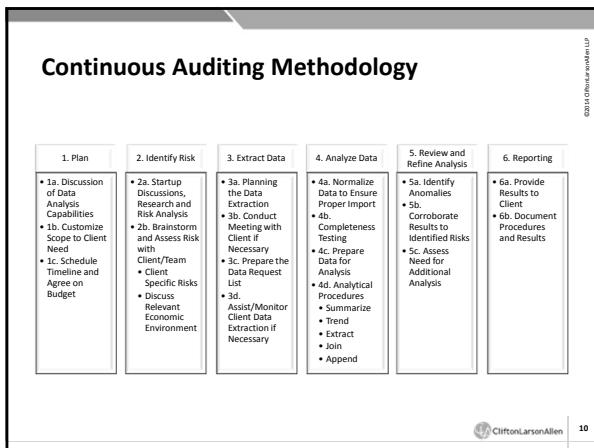
The Benefits of Continuous Auditing

Key Benefits:

<ul style="list-style-type: none"> • Uncover fraud waste and abuse • Independence and autonomy • Evaluation of management's monitoring • Improvements to financial operations • Reductions in financial errors and potential fraud • Increased profitability • Increased ability to mitigate risks • Reductions in the cost of assessing internal controls 	<ul style="list-style-type: none"> • Increased confidence in financial results • Real time snapshot of risk • Ability to assess IT controls • Improve governance • Efficiencies in auditing
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Developing Your Own Program in 10 Easy Steps

Step 1 — Decide What to Monitor:

How to monitor and where to monitor can mean almost anything to any organization's department. So it is important to determine what needs to be monitored and set monitoring policies around those needs.

Identify what areas you want to focus on (usually risk based).

Develop a plan for implementation including the scope, objectives, timeline.

Identify resources and partners.

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Developing Your Own Program in 10 Easy Steps

Step 2 — Develop Policy Requirements:

A good starting point is to conduct interviews with officials within the organization as well as others in organizations that have similar goals and operations.

Also read reports about incidents that have occurred in the past, collect and review any use cases that have been written, evaluate findings from recent internal and third-part audits and automated assessments, and review and evaluate organizational assets and risk management processes.

The more thorough and accurate the requirements analysis is, the more effective the continuous monitoring effort will be.

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Developing Your Own Program in 10 Easy Steps

Step 3 — Know What to Monitor:

Continuous monitoring does not require that everything – all systems, applications, networks, end point, infrastructure, security processes, and so on – be monitored everywhere and all the time. Identify information sources and ensure you have access.

Develop a Pilot:

Start with processes that you know well for example, fraud testing.

Focus on something pretty easy with a good return like duplicate payments. Use the functionality in the existing system. Partner with accounting management. Set a schedule. Partner with a consulting firm who does this full time.

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Step 4 — Prioritize Your Risks:

Identify a three-tiered impact system – low, moderate, and high impact – to use when developing monitoring policies.

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Developing Your Own Program in 10 Easy Steps

Step 5 — Identify Triggers:

Once it is determined what systems and processes need monitoring, policy should include events that would trigger these systems to send alerts.

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Developing Your Own Program in 10 Easy Steps

Step 6 — Determine Monitoring Intervals:

Continuous monitoring does not imply true, real-time 24x7, nonstop monitoring and reporting. Instead, it means implementing monitoring and oversight processes that provide a clear picture of security state at a given time, while also providing a mirror of control effectiveness over time.

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Step 7 — Obtain Executive Buy-In:

It is critical that you have everyone on board with your program. Executive level support is key to success in the beginning. Anticipate their insights and challenges.

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Developing Your Own Program in 10 Easy Steps

Step 8 — Execute Your Pilot:

This will enable you to identify your successes and opportunities for improvement. It also allows you to evaluate the skillset level and future direction for education and training. Ensure you have data integrity and have the necessary validation protocols.

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Step 9 — Refine Your Pilot:

Now you know your successes and flaws, you are ready to remediate, improve your efficiency level and expand your program to your higher risk areas.

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Developing Your Own Program in 10 Easy Steps

Step 10 — Manage the Program:

The pilot is a success. Now is the time to manage the CA program and develop your execution strategy. You will be able to inculcate the activities into your Internal Audit plan and specific projects.

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Uses of Continuous Auditing



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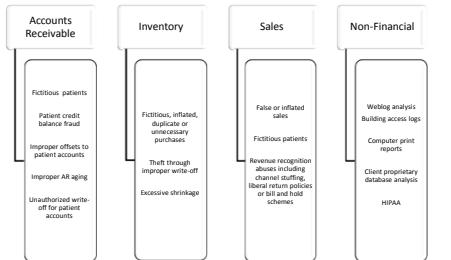
Continuous Auditing Uses

Accounts Payable	Purchase Cards	Payroll	Travel and Entertainment Expense	Journal Entries
Fictitious vendors Fictitious, inflated and / or duplicate invoices Structured payments Conflicts of interest Kickbacks Bid rigging Operational efficiencies	Duplicate purchasing Medicare/Medicaid reimbursement schemes Unauthorized and/or improper purchases Unauthorized users Unauthorized SIC codes	Ghost employees Improper supplemental payments Improper bonus or incentive compensation payments Inflated salaries Inflated hours	False or inflated reimbursement submissions Improper use of corporate credit card Purchase for personal use Duplicate purchasing and reimbursement schemes	Unbalanced journal entries Improper management override Improper expense capitalization Improper revenue recognition Entries to unusual or seldom used accounts Improper or unauthorized user activity Entries during non-business hours

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Continuous Auditing Uses



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Demonstration



Continuous Auditing Using Data Analytics

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Open Discussion and Q&A

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The Quality Tsunami: PQRS, Practice Guidelines, Healthcare Fraud, & Malpractice



**D. Scott Jones, CHC
Richard E. Moses, D.O., J.D.**

Presented by
HPIX
HEALTHCARE PROVIDERS INSURANCE EXCHANGE



Speakers' Disclaimer

- **Richard E. Moses, DO, JD** and **D. Scott Jones, CHC** do not have any financial conflicts to disclose.
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Presentation Goals

- Examine the quality reporting mandates, timeliness, and reimbursement penalties of PPACA.
- Discuss establishing compliance systems that meet and monitor these standards.
- Review the risk to compliance programs, including health care fraud, and medical malpractice/fraud.

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INTRODUCTION



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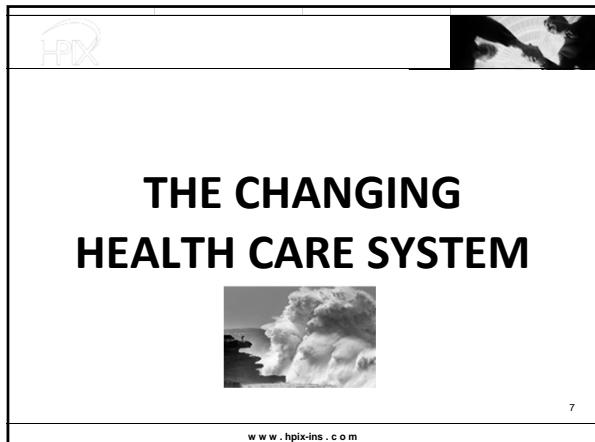


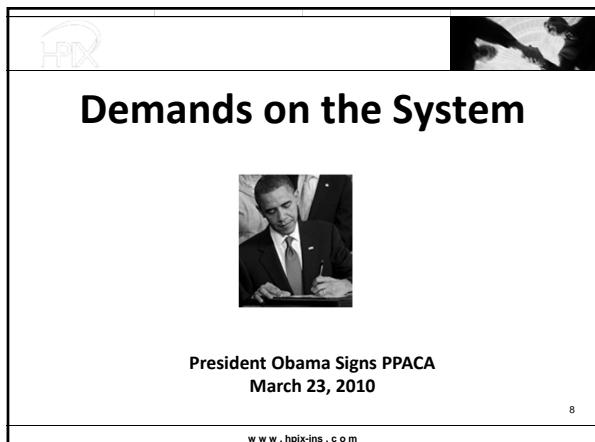

INTRODUCTION

- The Changing Health Care System
- Quality Reporting Measures Under PPACA
- Risk to Compliance Programs
- When Quality Fails: Healthcare Fraud & Medical Malpractice
- Summary & Conclusions

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DEMANDS: Major Intersection

- **Healthcare Reform Goals**
 - Improve Access
 - Universal Coverage
 - Increase quality reporting to include outcomes for reimbursement
 - Increase integration of care through partnerships of physician networks & hospitals
 - Cost control & cost reduction
- **Government is focused on reducing “unnecessary” medical costs**

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Demands on the System

- Patient Protection and Affordable Care Act (PPACA 2010) was amended by the Health Care and Education Affordability Reconciliation Act (HCERA 2012)
 - 21.3% scheduled reduction in Medicare physician pay (postponed by the Continuing Extension Act of 2010)
 - Quality and Cost Payment (Title III, §§ 3002, 3003, 3007) – Adjusts physician payments based on quality and cost through a value-based modifier, beginning January 1, 2015
 - PQRS – possible penalties for not reporting beginning in 2015 up to 2% of the prevailing fee schedule
 - Fee-for-service → value based reimbursement (“quality”)

www.physiciansfoundation.org/uploads/default/Physicians_Foundation_2012_Biennial_Survey.pdf

www.oascl.org/documents/Health/oeaca-consolidated.pdf

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Demands on the System

- **Increase from 260.2 Million Americans with health insurance to 292.6 Million under PPACA**
 - US Census Bureau 2012 Current Population Survey, Annual Social and Economic Supplement
- **32 Million Americans may acquire new health insurance with PPACA**
- **U.S. physician workload expected to increase by 29% from 2005-2025**
- **Over 50% of physicians are health system employees**

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Demands on the System

- Fee-for-service → Value-based/Quality-based reimbursement system
 - Goal is to reward doctors & hospitals for improving quality of care
- Subsequent trends:
 - Outcome-based payments
 - Lower demand for hospitals
 - Increased number of insured patients
 - Improving patient experience
 - Hospital competition on outcomes and total value
 - Increased physician employment

Health Affairs October 11, 2012
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QUALITY REPORTING MEASURES UNDER PPACA



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Hospital Value-Based Purchasing

- PPACA Title III, Subtitle A: Transforming the Health Care Delivery System
 - Incentive Payments to Hospitals meeting performance standards in
 - MI, Heart Failure, Pneumonia, Surgery, Infections, Pulmonary Embolism and DVT Prophylaxis, Stroke
 - ED, Readmissions, Children's Asthma
 - Performance Scores increase/decrease DRG payments
 - Incentives up to 2% of the Medicare FS by 2017
 - Data and Scores on Hospital Compare Internet Site
 - GAO reports October 2015 and January 2016

<http://www.medicare.gov/hospitalcompare>
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Hospital Acquired Conditions Payment Reductions

- **PPACA Section 3008**
 - FS Payments for Hospital Acquired Conditions will equal 99% of the FS
 - The Secretary will determine a list of “hospital acquired conditions”
 - Confidential reports to hospitals tracking conditions
 - This program will be expanded to all other types of providers
 - Possible CMS reports on Hospital Compare Internet Site
 - Effective FY 2015

www.medicare.gov/hospitalcompare

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Long Term Care, Rehabilitation, Hospice, PPS Exempt Cancer Hospitals, SNF, HHA



Integrated Care Demonstration Project

- PPACA Section 2704
- Project continues through December 31, 2016
- Goal: Establish bundled payments for services and providers involving an episode of care and hospitalization
- Severity of illness adjusted payment
- Data collection monitors outcome, cost, quality
- Report to Congress: December 31, 2017



Medicaid Global Payment System Demonstration Project

- 2010-2013 Demonstration Project
- Five States
- Establishes a Global Capitated Payment Model to replace the Fee for Service (FFS) system
- Safety Net Hospitals and Networks serving Medicaid beneficiaries
- Center for Medicare and Medicaid Innovation (CMI) issued full report in December 2013



Physician Compare Website

- PPACA Section 10331(a)(1)
 - PQRS Measures Reported
 - Assessment of Patient Health Outcomes
 - Assessment of continuity and coordination of care
 - Assessment of efficiency and cost
 - Assessment of patient experience
 - Assessment of safety, effectiveness, and timeliness of care
 - 2014: User Interface; reports published online
 - January 1, 2015: CMS Report to Congress



Physician Compare Website

- **Website required by Affordable Care Act**
 - § 10331(a)(1)
- **Provides information regarding**
 - Physicians enrolled in Medicare Program
 - Other eligible professionals participating in PQRS
- **Information is publicly displayed**



Physician Compare Website

- **Site Must Include:**
 - Measures collected under PQRS
 - Assessment of patient health outcomes & functional status of patients
 - Assessment of continuity & coordination of care & care transitions
 - Assessment of efficiency
 - Assessment of patient experience & patient, caregiver, & family engagement
 - Assessment of safety, effectiveness, & timeliness of care

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Physician Compare Website

- **CMS must allow physicians & other professionals to have reasonable opportunity to review their results before posting**
 - 30 day preview period for all measurement data
- **CMS will provide details of review process**
 - www.cms.gov

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PPACA Section 10331(a)(2): CG-CAHPS

- **Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG-CAHPS)**
 - Patient surveys begin 2014...individual physician surveys by 2015
 - Timely care, appointments, information
 - How well doctors communicate
 - Patient ratings of doctors
 - Health promotion and education
 - Shared decision making
 - Health status/functional status as a result of care rendered
- **"Certified Survey Vendor" created**

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PPACA Rule CMS-1600-P Quality Reporting Measures

- Physician Quality Reporting System (PQRS) 2014:
 - 9 Measures must be reported
 - 3 from National Quality Strategy domains
 - For 50% of the entire Medicare-eligible patient population
- Effect of not reporting PQRS occurs in 2016
- Failure to report a selection of the measures = up to 2% reduction in prevailing Medicare Fee Schedule (FS)
- Qualified Clinical Data Registries created for sub-specialists dealing with specific diagnoses, conditions (\S 1848(m)(3)(E)(ii))

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Value Based Modifier (VBS)

- How quality data reported under PQRS equals modification to payments under the Fee Schedule
- VBS use begins 2015; full implementation 2017
- Physician groups of 10 or more must report beginning 2016; expect all physicians to report by 2017
- Quality tier system results in FS reductions of up to 2%
- QRUR (Quality and Resource Use Reports) will report how the value based modifier will impact individual physician reimbursement, beginning 2014

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National Strategy for Quality Improvement in Health Care

- PPACA Part S, Subpart I, Section 399HH(2)(B)(i-iii)
- Establishes Priorities that will:
 - Have the greatest potential for improving health outcomes, efficiency, and patient-centeredness...
 - Identify areas...that have the potential for rapid improvement in the quality and efficiency of patient care...
 - Address gaps in quality...

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National Strategy for Quality Improvement

- HHS Annual Report to Congress, 2012
- “Key Measures and Long Term Goals”
 - “...reducing the harm caused in the delivery of care...reduce harm from inappropriate or unnecessary care....”
 - CDC: 5% of hospital patients acquire health care associated infections
 - 145 Health Care Acquired Conditions (HACs) occur per 1,000 admissions
 - AHRQ: Hospital Readmissions occur at a rate of 14.4%
 - **Compliance Officers are now Quality Officers**

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RISK TO COMPLIANCE PROGRAMS:

**CONNECTION BETWEEN
COMPLIANCE, QUALITY OF CARE,
HEALTH CARE FRAUD, &
MEDICAL MALPRACTICE**

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INTERDISCIPLINARITY

- No one discipline can accomplish compliance
- Integration between compliance disciplines is necessary
- Interdisciplinarity uses integration to produce a cognitive advancement resulting in a positive and productive outcome

Repkov AF. Interdisciplinary Research: Process & Theory. 2nd ed. Sage Publications Inc. 2012

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INTERDISCIPLINARITY

- PPACA INTERDISCIPLINARITY**
 - Electronic Medical and Health Records
 - Quality of Care Reporting
 - Risk Management
 - Medical Error Reduction
 - Medical Error Disclosure
 - Self Disclosure of Overbilling
 - Patient–Staff–Physician Communications and Portals
 - Quality of Care Violations/Medical Malpractice
 - Physician/Medical Practice Management

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INTERSECTION: Compliance, Quality, Fraud, & Malpractice

- OIG Work Plan 2014
- PPACA & Quality
- Government Accountability Office (GAO)
 - "...beneficiaries...who receive healthcare from providers who **adhere to PPACA**...may receive **higher quality of care**...Conversely, those who receive care from providers who fail to do so may receive **lower quality of care**."

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www.gao.gov/assets/590/589657.pdf

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INTERSECTION: Compliance, Quality, Fraud, & Malpractice

- General Accounting Office (GAO)
 - "...it is possible that, if these (PPACA) standards and guidelines become accepted medical practice, they could impact the standard of care **against which provider conduct is assessed in medical malpractice litigation.**"

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www.gao.gov/assets/590/589657.pdf

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When Quality Fails: Enforcement, Repayment, & Compliance



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Never Events

- **§5001(c) of the Deficit Reduction Act of 2005 (DRA)**
 - Never events are not reimbursable by CMS
 - Hospital acquired conditions are not reimbursable
 - Implementation Timeline
 - ❖ Medicare 2008
 - ❖ Medicaid 2011
 - ❖ States July 2012

www.cms.gov/Regulations-and-Guidance/Legislation/LegislativeUpdate/Downloads/Dra.pdf

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Office of Evaluations & Inspections (OEI)

- **July 19, 2012**
 - "...hospitals reported only 1% of (never) events. Most of the events...were not identified by internal hospital incident reporting systems."
- **Compliance Officer responsibilities**
 - Monitor frequency of reports & quality of data
 - Educate staff members on reporting
 - Monitor billing for all adverse medical events
- **National Academy for State Health Policy (NASHP)**
 - List of never event reporting requirements

<https://oig.hhs.gov/oei/reports/oei-06-09-00092.pdf>

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www.nashp.org/pst-state-list

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PPACA Repayment Obligation Rule

- PPACA: Provider must report & repay Medicare overpayment within 60 days after the overpayment is identified...or by the date a corresponding cost report is due
- Overpayment is identified “ when the provider has actual knowledge...or acts in deliberate indifference or reckless disregard of the existence of an overpayment”
- Look back provision: providers must report any overpayment that occurred within the past 10 years

Proposed rule: 77 FR 9179, 401,303 37

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PPACA Reportable Overpayments

- Medicare payments for non-covered services
- Medicare payments in excess of allowable amount
- Errors in cost reports
- Duplicate payments
- Receipt of Medicare payment when another payer has the primary responsibility for payment
 - Medicare Secondary Payer Act (MSP)

Proposed rule: 77 FR 9179, 401,303 38

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Duties of Overpayment Contractors

- Preventing fraud
- Identifying potential fraud
- Investigating fraud allegations: beneficiaries, providers, CMS, OIG, MFCU, & corporate anti-fraud unit
- Deny or suspend payments
- Refer case to OIG for civil & criminal prosecution
- Refer providers to OIG for exclusion from program
- Recommend prospective review of claims

CMS Program Integrity Manual 2.2 39

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CONCLUSIONS & SUMMARY

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HEALTH SYSTEM

What's FMV Got to Do With It? The Role of Fair Market Value in Physician Employment Arrangements

March 31, 2014

Overarching Hypothetical

- Assume:
 - Community-based, non-profit health system ("System") with several hospitals
 - System's physician growth and alignment strategy committee and the CEO of one of the System's wholly-controlled hospitals ("Hospital") desire to employ physician specialist ("Physician")
 - Hospital has an affiliate:
 - An organization, which (1) is wholly controlled by System, and (2) serves as the System's principal "physician organization" ("Phy. Org."), meaning that it employs many of the physicians on the Hospital's medical staff
 - State law also permits Hospital to employ physicians directly, and some physicians are in fact employed directly by the Hospital
 - Thus, the System has two legitimate options: employ Physician through Hospital or through Phy. Org.

- Questions?
 1. Does it matter which option System selects for employing Physician?
 2. What if: Physician demands a flat fee salary of \$1,200,000, but independent valuation company issues written report, stating that based on its review of national compensation surveys and Physician's historic productivity (as measured by personally worked relative value units, "worked RUVs"), it could support – as being consistent with fair market value ("FMV") -- aggregate compensation of \$1,075,000 per annum, which would place the Physician just above the 75th percentile for compensation in the Physician's specialty on a nationwide basis, provided, however, Physician achieves a personal productivity threshold at or around the 75th percentile or above?
 3. What if: Physician's aggregate compensation will be comprised of two components: (a) flat fee of \$800,000 and (b) personal productivity bonus equal to 10 percent of bonus pool comprised of net revenue of Physician's clinical department at Hospital, subject to a maximum total cap of \$1,200,000?

Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))

- **Prohibition:** Unlawful for one person, **knowingly and willfully**, to offer/pay (or solicit/accept) remuneration to a second person to induce it/him/her to refer patients/generate business that is **covered**, in whole or in part, by a Federal health care program.
 - **Elements:**
 - **State of mind:** knowingly and willfully (L.S. ex rel. Starks)
 - **Inducement:** "one purpose" test
 - **Conduct:** to refer, order, purchase, lease, recommend or arrange for
 - **Covered Items/Services:** Paid for, in whole/in part by a Federal health care program
 - **Exceptions/Safe Harbors:** Immunity
 - **Risk analysis/Policy objectives:** (1) overutilization/increased program costs; (2) patient freedom of choice; (3) market competition and (4) patient access to care

March 31, 2014

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Anti-Kickback Statute: Employment Exception and Safe Harbor

- Statutory exception, 42 U.S.C. § 1320a-7b(b)(3) = AKS prohibitions do not apply to "any amount paid by an employer to an employee (who has a *bona fide* employment relationship with such employer) for employment in the provision of covered items or services"
 - Regulatory exception (42 C.F.R. § 411.357(c)) = "remuneration" does not include "any amount paid by an employer to an employee, who has a *bona fide* employment relationship with the employer, for employment in the furnishing of an item or service for which payment made be made in whole or in part under Medicare, Medicaid or other Federal health care programs"
 - Term "employee" has the definition set forth in Section 3121(d)(2) of the Internal Revenue Code
 - IRS has developed a 20-factor test to determine who is a *bona fide* employee
 - Focus on employer "control" and "direction"

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Federal Physician Self-Referral ("Stark") Law (42 U.S.C. § 1395nn et. seq.)

- Two prohibitions.
 1. Referral Prohibition. A physician may not refer a patient to an entity for the furnishing of certain designated health services ("DHS") that may be paid by Medicare, and
 2. Billing Prohibition. The entity may not bill Medicare or anyone else for DHS provided to such improperly referred patients, if
 - A financial relationship exists between the physician and the entity; and
 - No statutory or regulatory exception applies.

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Stark Law: Overview (cont'd)

- Observations.
- 1. DHS = hospital inpatient and outpatient services (other than lithotripsy)
- 2. **Financial relationship** = sin qua non of Stark Law
 - direct or indirect and may take the form of ownership/investment interests or compensation arrangements
- 3. **Sanctions.**
 - Violation can result in refund obligations, various civil monetary penalties, and permissive program exclusion
 - Also may give rise to civil **False Claims Act** ("FCA") cause of action: claim for reimbursement that violates the Stark Law's billing prohibition is inherently false (present and/or cause to present)
 - Failure to refund may trigger reverse false claim liability

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Stark Law: Compensation Arrangements

- A **direct** compensation arrangement involves an direct exchange of "remuneration" between physician and DHS Entity, meaning that there is no "intervening person or entity" between them, 42 C.F.R. § 411.354(c)(1)
- "Stand in the Shoes" provisions (effective December 4, 2007): a physician-owner of a "physician organization" (e.g., a group practice) is deemed to stand in the shoes of his/her physician organization for purposes of physician organization's compensation arrangements
- **Effect?** Causes physician practice not to serve as an "intervening entity" with respect to physician owners of practice
- If there is one or more intervening entity/person(s), then arrangement cannot be direct

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Indirect Compensation Arrangement: Definition

- An **indirect** compensation arrangement exists if three separate requirements are met, 42 C.F.R. § 411.354(c)(2)
 1. There is an unbroken chain of two or more "financial relationships" between the referring physician and the DHS entity
 2. The **aggregate** compensation (in the compensation arrangement closest to the physician) "varies with or takes into account" the "volume or value of referrals or other business generated" (the "Volume/Value standard") between the referring physician and the DHS Entity
 3. The DHS Entity knows or should know that prong #2 above is satisfied

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Stark Law: Special Rules on Compensation

- **Unit-Based (including Percentage-Based) Payment Methodologies**, such as \$55 per worked RVUs or 10 percent of net sales or net earnings
 - Satisfy the "set in advance" standard, and
 - Do not trigger the Volume/Value standard
 - provided that (1) the unit or percentage value is consistent with fair market value ("FMV"), and (2) the unit or percentage does not vary during the term of the arrangement in a manner that reflects the volume/value of referrals or other business generated,42 C.F.R. § 411.354(d)

March 31, 2014

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Stark Law: Special Rules on Compensation (cont'd)

- An **employer**, consistent with the **common law duty of loyalty** owed by an employee to his/her employer, **may require its employee to refer patients to the employer** and/or its provider/supplier/practitioner network, provided certain safeguards are honored, 42 C.F.R. § 411.354(d)(4)
 - **Safeguards** include, for example:
 - Written employment agreement that includes requirement
 - Referral requirement must give way to:
 - Patient's best clinical interests
 - Patient's freedom of choice
 - Payer/managed care network preferences/limitations

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Stark Law: Employment Exception (42 C.F.R. § 411.357(c))

- Arrangement must be for identifiable services
 - Arrangement must be commercially reasonable, even in absence of referrals
 - Arrangement must provide for:
 - compensation which is fair market value, and
 - which is determined in a manner that does not take the volume/value of physician-employee's referrals into account
 - Note. Employer may pay employee a productivity bonus based on employee's personally performed services

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Stark Law: Indirect Compensation Arrangements Exception (42 C.F.R. 411.357(p))

- Closest compensation arrangement to the referring physician must be:
 - For identifiable services
 - Commercially reasonable, even in absence of referrals
 - Fair market value for items/services actually provided
- Moreover, the compensation itself must not be determined in a manner that takes into account the volume/value of referrals or other business generated for the DHS entity
- Finally, overall arrangement cannot violate the Anti-Kickback Statute or rules/regulations governing billing/claims submission

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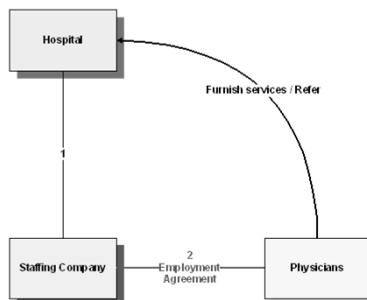
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Halifax Medical Center: A Case Study

- *United States of America ex rel. Baklid-Kunz v. Halifax Hospital Medical Center, et al. (“Halifax”)*
- No. 6:09-CV-1002-ORL-31 DAB (M.D. Fla. 2009)

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Halifax Medical Center: Diagram



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Halifax Physician Employee Compensation

- Base salary
 - Incentive compensation
 - Bonus pool for medical oncologist employees was funded using monies from the operating margin of Halifax's Medical Oncology program
 - Specifically, the parties agreed to allocate 15 percent of the operating margin, if any, to an incentive bonus pool for the medical oncologist employees
 - Once the pool was established, Halifax Staffing Company allocated it among the medical oncologists based on their relative productivity, as measured by each physician's personally performed professional services

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Halifax: Defense Strategy/Dilemma

- Eliminate Halifax Staffing Company, Inc. on grounds that it is a mere "instrumentality" of Halifax Hospital Medical Center *versus* presenting Halifax Staffing Company, Inc. as a separate and distinct legal entity?
 - The former enabled Halifax's attorneys to argue the physicians are direct employees of Halifax Hospital Medical Center, thereby placing their compensation squarely within the ambit of the broadly worded AKS exception and safe harbor for payments by an employer to a *bona fide* employee
 - The latter would have permitted the defense to try to take advantage of the flexibilities inherent to the Indirect Compensation Arrangements definition and exception under the Stark Law
 - Defense chose former strategy
 - Court stated that, ultimately, it was a difference with no meaning because the applicable exceptions had essentially overlapping requirements

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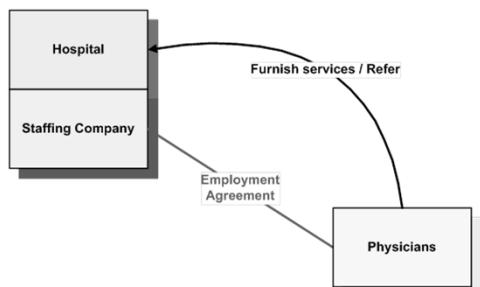
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Halifax Hospital Medical Center - Altered Diagram



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Halifax: Court's AKS Ruling

- Defense contended that physicians (e.g., medical oncologists) were *de facto bona fide* employees of Halifax Hospital Medical Center
- **Defense:** Compensation including incentive bonus payments protected by AKS exception/safe harbor for "any amounts" paid by employer to its *bona fide* employees
- **Relator:** Exception/safe harbor do not protect outright payments for referrals
- **Court:**
 - In an Order dated November 26, 2013, granted summary judgment in favor of Halifax Hospital Medical Center with respect to the AKS allegations, ruling that relator's position would eviscerate the AKS's *bona fide* employment exception and safe harbor
 - In sum, AKS exception/safe harbor protect payments to *bona fide* employees even if payments are expressly for referrals

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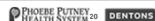
Halifax: Court AKS Ruling (cont'd)

- In determining whether the AKS exception/safe harbor applied, Halifax Court undertook two step analysis:
 - **First**, were medical oncologists *bona fide* employees?
 - Court ruled that the term "employee" has the definition set forth in Section 3121(d)(2) of the Internal Revenue Code, which focuses on the right to "control" and "direct" the individual, not just regarding what gets done, but also about how it gets done
 - Although IRS focuses on a 20 factor test, Court enumerated 25 separate factors to consider in the **totality**
 - **Note.** Neither the 20 factor nor the 25 factor test mentions *fair market value*

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Halifax: Court AKS Ruling (cont'd)

- **Second**, Court followed long-standing proposition that, consistent with the common law duty of loyalty, an employer is entitled to control and direct its physician-employees referrals
 - See AKS Safe Harbors Final Rule, 56 Fed. Reg. 35952, 35981 (July 21, 1991)
 - **HHS-OIG Advisory Opinion** (04-09) (favorable opinion regarding \$50 per hour payment for services to employed physicians in a position to refer patients)
 - **HHS-OIG Advisory Opinion** (09-02) (favorable opinion regarding payment by outpatient mental health clinic to employed professional counselor, even though payment was based not only on counselor's revenues, but those of clinic as a whole)
 - **HHS-OIG Advisory Opinion** (98-09) (favorable opinion regarding hospital's proposal to pay employed non-physician clinicians a bonus based on the number of inpatient hospital admissions they can bring about)
 - Text of the AKS exception: "any amount"
 - So, what is DOJ and valiators doing – delta theory

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Halifax: Court AKS Ruling (cont'd)

- **United States ex rel. Obert-Hong v. Advocate Health Care**, 211 F. Supp. 2d 1045 (N.D. Ill. 2002)
 - *Qui tam* relator challenged health system's decision to compensate employed physician's based on the volume of his referrals
 - Court ruled:
 - "AKS does not 'prohibit[] hospitals from requiring that employee physicians refer patients to that hospital,'" 211 F. 2d Supp. at 1050
 - AKS does not prohibit hospitals from paying employed-physicians for patient referrals. *Id.* at 1050

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Halifax: AKS Observations

- Observations
 - An employer can mandate employee's referrals
 - An employer can pay for employee's referrals
 - *Bona fide* employee is defined without regard to quantum of payment or fair market value ceiling
 - Does it really hold that an employee ceases to become a bona fide employee because, in government's view, he or she is paid too much?
 - As an initial matter, statutory and regulatory immunity is extended to "any amount," NOT an amount that is consistent with fair market value
 - Moreover, why is it okay to pay some amount of money for referrals, but not a lot of money for referrals?

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Overarching Hypothetical

- Refresher: What if: Physician's aggregate compensation will be comprised of two components: (a) Flat fee of \$750,000, and (b) personal productivity bonus equal to 10 percent of bonus pool comprised of net revenue of Physician's clinical department at Hospital, subject to a maximum total cap of \$1,200,000? Third party valuation report supports \$1,050,000.
 - Conventional wisdom (based on some notorious settlements) suggests that Health System, Phy. Org. or Staffing Company should not agree to pay physician \$1,200,000. But why?
 - Standard response: if physician is compensated in an amount that exceeds fair market value then, by definition, he or she is not being paid for services rendered, but for referrals.

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Overarching Hypothetical (cont'd)

- Contrary viewpoint:
 - Third party valuation is not the equivalent of the market; it is a proxy of the market
 - Account for increased conservatism among valiators
 - Exception and safe harbor use words, "any amount"
 - Effort to "write in" FMV is inappropriate and arguably *ultra vires*
 - Congress and HHS-OIG know how to expressly require FMV
 - Neither common law nor IRS precedent look to FMV as an index of whether an individual is or is not a *bona fide* employee.
 - Courts and HHS-OIG have made it quite clear that when it comes to a *bona fide* employee, employer may require and pay for referrals

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Stark Law Analysis

- Overarching Hypothetical asks whether it makes a difference which entity employs the referring physician
 - Halifax litigants and Court downplayed the difference
 - Under Stark Law, however, there potentially is a world of difference
 - Halifax Hospital Medical Center had/has no physician owners
 - "Financial relationship", if any, had to take the form of a direct or an indirect compensation arrangement
 - Government pled/argued in the alternative
 - Defense counsel argued that Halifax Staffing Company was not an "intervening entity," but an instrumentality that should be collapsed into Halifax Hospital Medical Center
 - Court accepted defense's position

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Stark Law Analysis (cont'd)

- Given Halifax Hospital Medical Center's position, Stark Law analysis turned to the direct compensation arrangement between Halifax Hospital Medical Center and the medical oncologists -- i.e., the base salary and incentive bonus
 - Defense argued that incentive bonus fit squarely within the statutory and regulatory carve out, which states that an employee's compensation is not determined in a manner that takes into account for purposes of the bona fide employment exception if it takes the form of a productivity bonus based on services performed personally by the referring physician
 - Court rejected the argument on the grounds that bonus was not "based on services performed personally"; rather, it was it was "divided up" based on services personally performed

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Stark Law Analysis (cont'd)

- What appears to have bothered the Court in Halifax is that the size of the bonus pool would vary with the volume/value of the medical oncologists' referrals to Halifax Hospital Medical Center
- In other words, the source of the monies to pay the bonus was not only the Hospital's collections for professional component services, but also facility fees (*i.e.*, DHS) generated as a result of the medical oncologists' referrals
- The problem with that particular logic, however, is that is always the case whenever a DHS entity (such as a hospital) offers to pay a physician-employee compensation
- Specifically, because money is fungible, and because a hospital, by way of example, derives the majority of its revenues from facility fees, the rationale of the Halifax Medical Hospital Court would eviscerate the vast majority of hospital-physician employee compensation arrangements, including those that are structured on an exclusively flat fee basis

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Stark Law Analysis (cont'd)

- By accepting Halifax's position regarding the Halifax Staffing Company, Court focused on the private aspects of a litigation – *i.e.*, to resolve a dispute between a small handful of litigants
- But, Court also has an obligation to attend to the public aspects of a dispute, namely, to uphold and maintain the law
- At the time CMS considered and adopted the physician stand in the shoes provisions, it also considered whether to adopt organizational stand in the shoes provisions
 - The latter doctrine would allow a parent company to be collapsed into and become as one with its wholly-owned DHS entity
 - Thus, under that proposed doctrine, the Halifax Staffing Company and Halifax Hospital Medical Center would collapse into one another
- The organizational stand in the shoes doctrine was ultimately rejected, however, raising the question whether a private litigant may essentially revive it because of a strategy that it believed suited its objectives?

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Stark Law Analysis (cont'd)

- Arguably, Court should have held Halifax Hospital to its own corporate structure, meaning that the Staffing Company should have been treated as an "intervening entity" between the referring medical oncologists and Halifax Hospital Medical Center
- In that event, the financial relationship between and among the parties would have to take the form of an indirect compensation arrangement ("ICA") or nothing at all

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Stark Law Analysis (cont'd)

- As noted above, the definition of an ICA has three requirements.
 - Prong #1.** An unbroken chain of financial relationships is met through the chain: Hospital → Staffing Company → Medical Oncologist
 - Prong #2.** Arguably, this prong is met because, in the aggregate, the size of the bonus pool and, derivatively, the size of each individual bonus varies with the volume/value of the referrals of the medical oncologists
 - Prong #3.** A bit of a toss up, depending on analyses performed by Hospital and its counsel, including any legal advice it may have received
 - Assuming, for sake of argument, that ICA Definition is satisfied, then, the analysis turns to whether "financial relationship" satisfies the requirements of a statutory or regulatory exception

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Stark Law Analysis (cont'd)

- ICA Exception:
 - Closest compensation arrangement to the referring physician (i.e., the salary/incentive bonus) is:
 - For identifiable services (✓)
 - Commercially reasonable, even in absence of referrals (✓)
 - Fair market value for items/services actually provided (✓)
 - Overall arrangement does not violate the Anti-Kickback Statute or rules/regulations governing billing/claims submission (✓)
 - And, the compensation itself must not be determined in a manner that takes into account the volume/value of referrals or other business generated for the DHS entity

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Stark Law Analysis (cont'd)

- ICA Exception:
 - This leaves one last question: is the compensation determined in a manner that takes into account the volume/value of referrals or other business generated for the DHS entity?
 - Not the same inquiry as ICA Definition because in this context:
 - We do not have to contend with the words “vary with”
 - We do not have to contend with the word “aggregate”
 - We can rely on “special rules on compensation”

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Stark Law Analysis (cont'd)

- **Unit-Based (including percentage-based) payment methodologies**, such as a physician's pro rata share (*i.e.*, percentage) of a bonus pool does not "take into account the volume or value of referrals or other business generated"
 - provided that (1) the unit or percentage value is consistent with fair market value ("FMV"), and (2) the unit or percentage does not vary during the term of the arrangement in a manner that reflects the volume/value of referrals or other business generated, 42 C.F.R. § 411.354(d)(2), 411.354(d)(3)
 - In Halifax, the percentage varied from year to year, but the variance was based on each physician's personally performed services, which, by definition, do not constitute "referrals" or "other business generated"

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- According to CMS, the statute in general and the special rules in particular permit a percentage based payment methodology for personal services "even when the physician receives the payment through a DHS referral, as long as as the individual payment is set at fair market value at the inception of the arrangement and does not subsequently change during the term of the arrangement in a manner that takes into account DHS referrals." 69 Fed. Reg. 16054, 16068 (March 26, 2004)

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Final Review of Overarching Hypothetical

- Physician demands a flat fee salary of \$1,200,000, but independent valuation company issues written report, stating that it could support -- as being consistent with fair market value ("FMV") -- aggregate compensation of \$1,075,000 per annum, which would place the Physician just above the 75th percentile for compensation in the Physician's specialty on a nationwide basis.
 - Overarching Hypothetical asks whether it makes a difference which entity employs the referring physician
 - We have studied the Halifax approach.
 - But, what if Physician were hired as a *bona fide* employee of Phy. Org.?
 - In that event, Phy. Org would serve as an "intervening entity" and the inquiry would turn on whether Phy. Org.'s aggregate compensation to the physician "varies with or takes into account" the "volume or value of referrals or other business generated" between the referring physician and the DHS Entity

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Final Review of Overarching Hypothetical

- \$1,200,000 per annum is a flat fee and, by definition, does not vary with anything?
- But, does it in the aggregate take the volume/value standard into account?
 - Theories:
 - Required referrals (42 C.F.R. § 411.354(d)(4))
 - CMS has taken the position in preamble that a flat payment could trigger the Volume/Value standard if it exceeds FMV
 - This remains untested in the courts
 - Moreover, its application to employed-physicians in light of 42 C.F.R. § 411.354(d)(4) is dubious at best

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Thank you



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340B Drug Discount Program: A New World of Increased Scrutiny and What This Means to Your Organization

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March 31, 2014



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Review of the Federal 340B Drug Pricing Program

Objectives

- 1 Provide an overview of the Federal 340B Drug Pricing Program requirements
- 2 Describe the current regulatory landscape and recent program developments
- 3 Outline the Health Resources and Services Administration (HRSA) audit process
- 4 Provide recommendations for monitoring compliance.

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Speaker Biographies

Speaker Biographies



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Karolyn is a Senior Manager in Deloitte's Business Risk Health Sciences practice. She has more than 13 years of experience working with large hospital systems in California, Washington, Arizona and New Mexico on a variety of compliance and operations related engagements.

Her consulting career has been specialized in compliance auditing and monitoring activities, gap assessments, internal control management, policy and procedure development, and process re-design and improvement. She focuses on specific regulatory compliance matters such as 340B compliance, Medicare and Medicaid/Medi-Cal billing compliance, physician arrangements, and compliance program requirements.

She has worked with clients on 340B projects for health systems and acute care hospitals on engagements such as program compliance assessments, HRSA mock audits, program expansion into contract pharmacies, and Medicaid billing compliance.

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Debra is Senior Vice President /Chief Audit, Ethics and Compliance Officer for Community Medical Centers (CMC) in CA. She previously served as Chief Audit and Compliance Officer for Central Connecticut Health Alliance.

She is a leader with 30 years experience which 26 years' experience is in the audit and compliance healthcare profession. She is well versed in matters of compliance, internal auditing, internal controls, and various regulations. Debra's professional experience includes having the responsibilities for startup, implementing and maintaining Corporate Internal Audit and Compliance Offices in Healthcare systems. She has developed, administered and operated internal audit and compliance programs for all healthcare entities, including hospitals, home health agencies, nursing homes, providers and other health systems.

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Overview of the Federal 340B Drug Pricing Program

What is 340B?

- Veterans Health Care Act of 1992 requires pharmaceutical manufacturers whose drugs are covered by Medicaid to provide discounts on outpatient covered drugs purchased by eligible covered entities serving the nation's most vulnerable patient populations.
- Eligible entities enrolled in the program receive discounts on 340B covered outpatient drugs.
- Program sits under the Health Resources and Services Administration (HRSA) administered by the Office of Pharmacy Affairs (OPA).
- Provides the 3rd deepest discount on pharmaceuticals., trailing only behind the Department of Defense and Veterans Healthcare Administration contracts.
 - Typically 25% to 35% savings off Group Purchasing Organization (GPO) cost for drugs
 - Savings are often most significant for brand name drugs



Source: US Department of Health and Human Services, Health Resources and Services Administration (HRSA). Veterans Health Care Act of 1992, Public Law 102-688. <http://www.hrsa.gov/policy/programs/340b/elements/12088.htm>

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Covered Entities (CE)

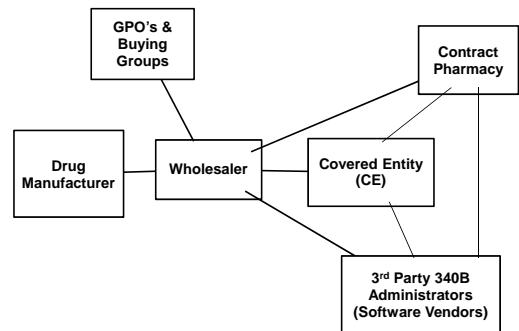
Module 3: 340B Drug Pricing Program
Populations Served and Qualifications

Covered Entity Type	Non-profit/Govt. Contract	DSH%
Disproportionate Share Hospital (DSH)	Yes	> 11.75%
Children's Hospital	Yes	> 11.75%
Free Standing Cancer Hospital	Yes	> 11.75%
Sole Community Hospital	Yes	≥ 8%
Rural Referral Center	Yes	≥ 8%
Critical Access Hospitals	Yes	No
AIDS Clinics and drug programs	Yes	No
Black Lung Clinics	Yes	No
Hemophilia Treatment Centers	Yes	No
Urban Indian Clinics/638 Tribal Centers	Yes	No
Title X Family Planning Clinics	Yes	No

Source: U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA)

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Active Participants in 340B



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Program Prohibitions

DUPLICATE DISCOUNT

CE is prohibited from accepting a discount for a drug that would also generate a Medicaid rebate to the State.

DIVERSION

CE shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

GPO EXCLUSION

DSH hospitals, children's hospitals, and free-standing cancer hospitals may not obtain covered outpatient drugs through a GPO or other group purchasing arrangement.

ORPHAN DRUGS

Free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals may not purchase selected rare disease drugs at 340B prices.

Source: U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), Section 340B of the Public Health Service Act, F-3
<http://www.hrsa.gov/opa/programrequirements/federaldefinitionsofpatient.pdf>

Source: U.S. Department of Health and Human Services Health Resources and Services Administration (HRSA) Policy Release

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Diversion

- Drugs must be administered to an **eligible patient**

- CE has established a relationship with the individual, such that the CE maintains *records of the individual's health care*; and
- Individual receives health care services from a *health care professional* who is either employed by the CE or provides health care under contractual or other arrangements such that responsibility for the care provided remains with the CE; and
- Individual receives health care service(s) from the CE which is consistent with the services(s) for which grant funding or federally-qualified health center look-alike status has been provided to the entity.

- Not considered a patient if the only health care service is the dispensing of a drug for self-administration
- In 2007, HRSA published proposed guidance to clarify the eligible patient definition. Chose not to issue final guidance at that time.



Source: US Department of Health and Human Services, Health Resources and Services Administration (HRSA), Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of "Patient", 1543-1548, Federal Register Vol.72 No. 8, January 12, 2007.
<http://www.hrsa.gov/opa/programrequirements/federaldefinitionsofpatient.pdf>

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Diversion - Scenario 1

Nonexclusive Physician

Physician practices part time at a CE, but also has a private practice. Physician first sees an individual at the CE. On a separate occasion, physician sees the individual at his private practice and writes a prescription. The individual fills the prescription at the CE's contract pharmacy.

How CE's are handling this scenario:

- Prescription is **340B-eligible** because CE uses a list of all credentialed prescribers. No way to differentiate between prescriptions written at the physician's private practice vs. originating from CE.
- Prescription is **not 340B-eligible**. CE uses a prescriber list of only those prescribers who work exclusively at the CE.
- Prescription **may or may not be 340B-eligible**. Software flags those prescribers who do not work exclusively at the CE and sends them to a queue for CE research.

Source: U.S. Department of Health and Human Services Office of Inspector General Memorandum Report: Contract Pharmacy Arrangements: In the 340B Program. OEI-05-13-00431

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Diversion - Scenario 2

Time limit after patient's visit

Physician sees an individual at CE and writes a prescription. Four months after filling the original prescription, the individual refills the prescription at the CE's contract pharmacy. The individual has not been seen at the CE during those 4 months.

How CE's are handling this scenario:

- Refill is **not 340B-eligible**. Only 340B-eligible if filled within 60 days of the patient's most recent visit to the CE.
- Refill is **340B-eligible** because the CE has set longer time limits regarding patient visits (e.g., 12 months)
- Refill is **340B-eligible** because CE does not have a time limit on how long after the patient's visit a prescription can be filled for 340B purposes.

Source: U.S. Department of Health and Human Services Office of Inspector General Memorandum Report: Contract Pharmacy Arrangements in the 340B Program. OEI-05-13-00431
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Diversion - Scenario 3

Prescription from a referred physician

Physician sees an individual at a CE and refers the individual to a specialist who is not affiliated with the CE. Specialist writes a prescription, and the individual fills the prescription at the CE's contract pharmacy.

How CE's are handling this scenario:

- Prescription is **not 340B-eligible**. CE uses a list of all credentialed prescribers and the specialist would not be on this list.
- Prescription is **340B-eligible**. CE also uses a prescriber list. However, the software queues prescriptions written by prescribers who are not on the prescriber list to the CE for manual review. CE categorizes this prescription as 340B-eligible even though it originated outside the CE because records indicate the patient was referred by CE physician.

Source: U.S. Department of Health and Human Services Office of Inspector General Memorandum Report: Contract Pharmacy Arrangements in the 340B Program. OEI-05-13-00431
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Diversion - Scenario 4

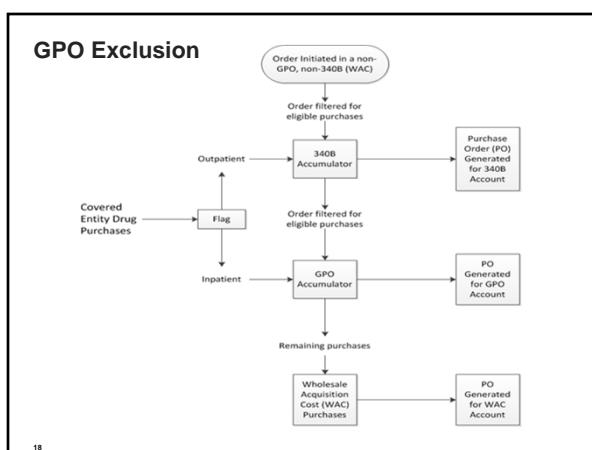
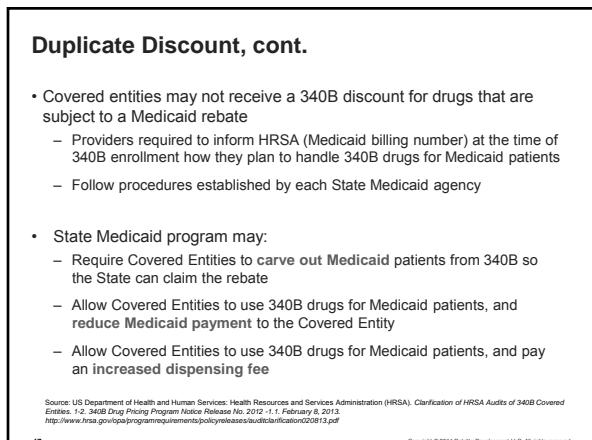
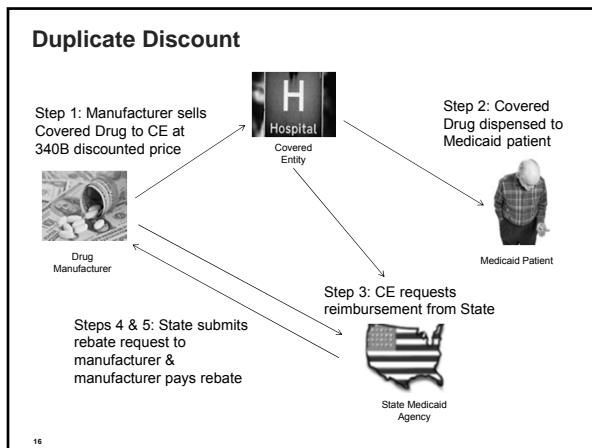
Matching prescription to clinical information

Physician sees an individual at CE for chest pain and writes the individual a prescription for a blood pressure medication. During that visit, physician also writes the individual a prescription for a sleep medication (related to a previously diagnosed condition).

How CE's are handling this scenario:

- Prescription for **blood pressure medication only is 340B-eligible**. CE's software uses clinical information from patients' visits (i.e., diagnosis and procedure codes) to identify 340B-eligible prescriptions. Prescription for sleep medication does not relate to that diagnosis, so is categorized as not 340B-eligible.
- **Both prescriptions are 340B-eligible** since the CE does not use clinical information from patients' visits to identify 340B-eligible prescriptions. Both prescriptions were written at the CE by an eligible prescriber.

Source: U.S. Department of Health and Human Services Office of Inspector General Memorandum Report: Contract Pharmacy Arrangements in the 340B Program. OEI-05-13-00431
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Regulatory Landscape and Recent Program Developments

340B Recertification Requirements

- Affordable Care Act requires HRSA to develop and maintain procedures for CEs to regularly update their 340B information
- Importance of maintaining current and accurate 340B database information
 - Used by manufacturers to screen CEs
 - Publicly available at <http://opanet.hrsa.gov/opa>
 - Requires registration of all contract pharmacy arrangements
- Registration changes may only be submitted the first 15 days of the quarter (October 1-15; January 1-15; April 1-15; July 1-15)
 - Become effective the start of the following quarter



Source: PPACA § 7102(a); Public Health Service Act, 42 U.S.C. § 256b(d)(2)(b)

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340B Recertification Requirements, cont.

Covered Entity will attest to the following:

1. All information listed on the 340B program database for that Covered Entity is complete, accurate, and correct
2. Has continuously met all 340B program eligibility requirements
3. Complying with all requirements and restrictions of Section 340B of the Public Health Service Act and any accompanying regulations or guidelines including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity
4. Maintains auditable records demonstrating compliance with the requirements outlined above.
5. Has systems/mechanisms in place to ensure ongoing compliance with the requirements outlined above
6. If the Covered Entity uses contract pharmacy services, the arrangement is being performed in accordance with OPA requirements and guidelines including, but not limited to, that the Covered Entity obtains sufficient information from the contractor to ensure compliance with applicable policy and legal requirements, and the Covered Entity has utilized an appropriate methodology to ensure compliance (e.g., through an independent audit or other mechanism)
7. Acknowledges its responsibility to contact OPA as soon as reasonably possible if there is any material breach by the Covered Entity
8. If the entity does not notify OPA in a timely fashion, the entity acknowledges that it may be required to remit payment back to manufacturers which would represent the difference between the 340B discounted price and the drug's non-340B purchase price

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Contract Pharmacy Expansion

- HRSA allows CE's to use an in-house pharmacy and contract with a retail pharmacy.
 - Starting in 2010, HRSA allows CE's to utilize multiple contract pharmacies which greatly expands access to 340B drugs.
 - Since 2010, percentage of CE's that use contract pharmacies has risen from **10%** to **22%**.
 - Number of unique pharmacies serving as contract pharmacies has grown by **770%** and the total number of contract pharmacy arrangements has grown by **1,245%**.



Source: US Department of Health and Human Services, Health Resources and Services Administration, Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 10272-10279, Federal Register Notices Vol. 75, No. 42, March 5, 2010.
<http://www.hrsa.gov/opa/program/regulations/federalregister/notices/contractpharmacyservices/230510.pdf>

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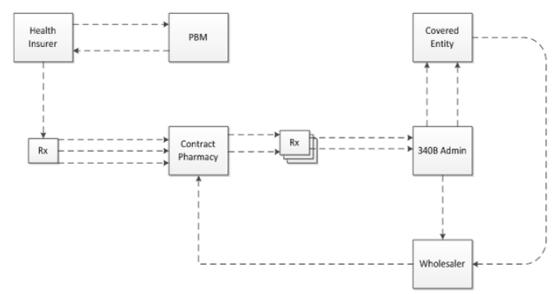
Contract Pharmacy Expansion, cont.

- “Ship-To/Bill-To” arrangements
 - CE pays for drugs at 340B price under its contacts with manufacturers
 - Drugs are shipped to the contract pharmacy, which maintains inventory
 - Contract pharmacy fees are subject to negotiation
 - Inventory and cash-flow is usually managed by a software system and/or third party intermediary.
 - CE's must establish a mechanism to screen individuals to determine if they qualify as a patient of the CE, and track ordering, receipt, and dispensing of 340B drugs
 - Limited guidance on requirements
 - Compliance with 340B program rules is always the responsibility of the Covered Entity



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Contract Pharmacy Process Flow



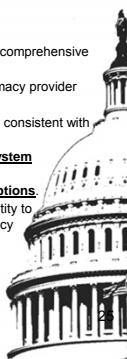
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HRSA Guidelines - 2010 Contract Pharmacy Federal Register Notice

1. Covered entity must purchase the 340B drug
2. Contract pharmacy agreement must specify that the parties will provide comprehensive pharmacy services
3. Covered entity must inform patients that they are free to choose a pharmacy provider
4. Both parties will adhere to federal, state and local laws
5. Contract pharmacy must provide the covered entity with reports that are consistent with standard business practice
6. Both parties will work together to **establish and maintain a tracking system sufficient to prevent diversion and verify patient eligibility**
7. Drugs purchased under 340B will **not be used to fill Medicaid prescriptions**.
8. Both parties will identify information that is necessary for the covered entity to evaluate whether the program is in compliance and the contract pharmacy will make such information available for use in **independent audits performed by covered entity**
9. Both parties will be subject to outside audits
10. Copy of the contract must be provided to the OPA upon written request

Source: US Department of Health and Human Services, Health Resources and Services Administration, Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 10272-10279, Federal Register Notices Vol.75, No.42, March 5,2010.
<http://www.hrsa.gov/opa/programrequirements/federalregisternotices/contractpharmacistervices030510.pdf>

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In the News



- **Congress Agrees to More than Doubles Program Funding**
 - Rise from its current \$4.4 million to \$10.2 million budget
- **340B Mega-Regulation**
 - Expected to be released for public comment in June 2014.
 - To cover definition of an eligible patient, compliance requirements for contract pharmacy arrangements, hospital eligibility criteria, and eligibility of off-site facilities.
- **Orphan Drug Exclusion Lawsuit**
 - Drug industry lawsuit challenges legality of HRSA's October 2013 regulation that allows certain rural and free-standing cancer hospitals to buy orphan drugs at 340B pricing when prescribed for non-orphan indications
- **Office of Inspector General (OIG)**
 - Releases its first report on 340B contract pharmacy programs

Source: US Department of Health and Human Services, Health Resources and Services Administration, Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 10272-10279, Federal Register Notices Vol.75, No.43, March 5,2010.
<http://www.hrsa.gov/opa/programrequirements/federalregisternotices/contractpharmacistervices030510.pdf>

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Overview of HRSA Audit Process

Health Reform: New Sanction Authority for 340B Violations

- Historically, relied on self-policing, subject to potential audits by HRSA or by manufacturers
- Health care reform, as well as inquiries by Congress and the GAO, have led HRSA to take a more active oversight role
- Expanded access via increased use of contract pharmacies has led to increased risks
- Potential Sanctions:
 - Forfeiture of 340B discounts to the manufacturer
 - Monetary penalties: applicable interest for being aware of violations and not reporting to the OPA, and intentional violations
 - Disqualification from the program for systematic and egregious violations
 - Possible referral to OIG or other federal agencies for further review
 - Disqualification and prohibited re-entry in the 340B program

Source: Public Health Service Act, 42 U.S.C. § 256b(d)(2)(B)(iv)
 Source: US Department of Health and Human Services 42 CFR Chapter I, 340B Drug Pricing Program Manufacturer Civil Monetary Penalties, 57230-57232; Federal Register Proposed Rules Vol 75, No. 181, p. 57230-57232, April 20, 2010. <http://www.hrsa.gov/opa/programrequirements/federalregister/monetarypenalties/2010/04.pdf>
 Source: US Department of Health and Human Services, Health Resources and Services Administration (HRSA), Statutory Prohibition on Group Purchasing Organization Participation, 1-2, 340B Drug Pricing Program Notice Release No. 2013-1, February 7, 2013. <http://www.hrsa.gov/opa/programrequirements/policyreleases/prohibitionongroupparticipation020713.pdf>
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Health Reform – Right to Audit

Patient Protection and Affordable Care Act (ACA) establishes 340B integrity provisions and auditing expectations. Permits drug manufacturers to perform audits of 340B covered entities where they have "*reasonable cause*" to believe that the covered entity is not in compliance with 340B regulations

- Manufacturer audit activities:
 - Implementation of 340B program monitoring activities to assess and monitor covered entity compliance with 340B requirements and identify "reasonable cause" to perform 340B audits
 - Submission of a "reasonable cause" letter and audit work plan to the OPA for approval
 - Retention of an "independent auditor" to perform audits of covered entities
- HRSA also authorized to conduct audits

Source: US Department of Health and Human Services, Health Resources and Services Administration (HRSA). The Affordable Care Act, Section by Section, <http://www.hrsa.gov/healthcare/reform/aca.htm>
 Source: US Department of Health and Human Services, Health Resources and Services Administration (HRSA), Clarification of HRSA Audits of 340B Covered Entities, 1-2, 340B Drug Pricing Program Notice Release No. 2012-1, February 8, 2013. <http://www.hrsa.gov/opa/programrequirements/policyreleases/auditclarification020813.pdf>
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HRSA OPA Begins Compliance Audits in 2012

Audit Scope:

- Early audits focused on duplicate payments and drug diversion
- Random audits focus on program types with "higher risk" due to volume of purchases, complexity of program administration, or use of contract pharmacies
- Focus areas:
 - Verification of eligibility
 - Review of policies and procedures and how they are operationalized
 - Review of internal controls to prevent diversion and duplicate discounts
 - Review of contract pharmacy compliance
 - Test of 340B drug transaction records on sample basis



Source: U.S. General Accounting Office (GAO), Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, GAO-11-836. Washington, DC: General Accounting Office, 2011. <http://www.gao.gov>

HRSA OPA Audit Process

- Audit notification letter received from HRSA OPA
 - Onsite findings will be considered preliminary and a basis for further review
 - Arrangements and workable spaces for up to 1-2 HRSA staff

• Arrangements and works

- 340B policies and procedures
 - Most recently filed Medicare Cost Report (worksheets S, A, C, and E)
 - Listing of providers eligible to make 340B drug orders or prescription
 - Listing of 340B purchase orders (PO) made in the six-month period
 - 340B drug orders and prescriptions over a six-month period
 - Pharmacy service agreements for contract pharmacies
 - Sample of drug orders and prescriptions:
 - Individual records must be available for review in either electronic or paper format



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HRSA OPA Audit Process, cont.

Example interview topics

- Identification of eligible patients
 - Identification of eligible providers
 - Use of 340B drugs
 - Diversion of 340B drugs
 - Transfer of drugs between 340B and non 340B sites
 - Medicaid (carved in/out) specific to your state
 - Type of replenishment practices
 - What wholesaler accounts are used to manage?
 - Use of splitting software
 - Who does the splitting and how often?
 - The need to purchase at WAC
 - Where is inventory kept?
 - How do you determine quantity to order?
 - Who reviews invoices for payment?
 - How do you minimize your risk of ordering on the GPO account?



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HRSA OPA Audit Process, cont.

- Sample selections:

- For both hospital drug orders and contracted pharmacies (total of 50-100 patient records for each)
 - Sample sizes will vary based on size and complexity of the covered entity
 - Original list of 25-50 samples of patient records with 340B drug use and replenishment
 - Spare list of 25-50 samples
 - Additional samples from the top five high use drugs may be requested

- Testing:

- Tracer a sample of individual medication orders/scripts from dispensing or administration through to drug replenishment.



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Recommendations for Monitoring Compliance

Compliance Challenges

- Typically only one individual is well-versed on 340B program requirements
- Budgeting the necessary time and resources for auditing and monitoring
- Program requirements are complex:
 - Interpretation of an eligible patient/provider and covered outpatient drugs
 - Maintenance of an accurate Charge Description Master (CDM) to National Drug Code (NDC) crosswalk used to convert CDM billing quantities to package sizes
 - Conversion of units of drugs administered to patients to the correct Healthcare Common Procedure Coding System (HCPCS) billing units
- Operational changes, such as new electronic medical record system, addition of new eligible locations, new contract pharmacy arrangements
- Reliance on split billing software and third party contract pharmacy software vendors to ensure 340B compliant IT systems and accurate drug utilization capture
- Duplicate Discount prevention requirements are state specific



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Compliance Program Considerations

- **Develop a resource plan**
 - Identify a project team, including executive support, with defined responsibilities for each team member
 - Develop a project management tool and conduct regular meetings to review project status
 - For larger hospitals, consider hiring a dedicated 340B resource
- **Establish a training program**
 - Ensure all employees involved in the 340B program are trained, well-versed, and understand the rules and compliance requirements
 - Conduct regular staff training and competency assessments
 - Share updates to policies and standard operating procedures with affected staff
- **Annual review of registered eligible services and sites**
 - Review covered entity's compliance prior to recertification
 - Ensure all records and information on the 340B database are kept up-to-date

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Compliance Program Considerations, cont.

- **Define auditable prescription capture criteria**
 - Definition for "Covered Outpatient Drug" should be consistent with section 1927(k) of the Social Security Act
 - Utilize a separate GPO and wholesaler account to purchase drugs that do not meet the definition.
 - "Patient" and "Provider" definitions should ensure appropriate medical record ownership and responsibility of care for captured 340B prescriptions.
 - **Validate data after making changes to system configuration**
 - Review accuracy of patient location mapping and status indicators
 - Scrutinize hospital eligible prescriber list against established criteria
 - Identify causes of any accumulation discrepancies (i.e. excessive positive/negative inventory)
 - Conduct testing outside of a production environment

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Compliance Program Considerations, cont.

- **Maintain accurate records documenting compliance**
 - Develop policies, procedures and controls designed to document compliance with the rules regarding diversion, duplicate discounts and GPO exclusion that are regularly reviewed and updated
 - These policies and procedures need to be operationalized and reflect actual practice
 - Maintain a complete “audit trail” from prescription to pick-up by the patient to replenishment
 - **Understand State Medicaid agency’s 340B billing requirements**
 - Review hospital billing system compliance
 - Validate accuracy of wholesaler price catalogs
 - Obtain confirmation regarding carving in/ carving out Medicaid Fee for Service (FFS) and Managed Care Organization (MCO) Medicaid prescriptions for both in house and contract pharmacy programs

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Compliance Program Considerations, cont.

- **Develop specific desktop procedures**
 - Covers drug processing from patient/drug presentation to replenishment
 - Consists of the daily procedures performed by areas such as Pharmacy, Materials Management, IT, Patient Financial Services and Reimbursement
 - Outlines practices at specific locations (i.e., outpatient clinic, mixed-use, contract pharmacy)
 - **Conduct routine monitoring activities and audit them.**
 - Daily, weekly, monthly, quarterly monitoring and a minimum annual audits
 - Patient Eligibility Monitoring
 - Physician Eligibility Monitoring
 - Inventory Monitoring
 - Duplicate Discount Monitoring
 - Compliance with State Medicaid billing and reimbursement guidelines
 - Price Changes
 - Changes in purchasing patterns
 - Annual compliance assessment

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Example Monitoring Plan

Monitoring Tool – Frequency	Method
Purchasing volume analysis - monthly	Purchasing volume for each account is reviewed at a high level to ensure purchases have been transacted on the correct account. Significant changes in purchase volume are also reviewed for appropriateness. Any variances are corrected, using credit and re-bill if necessary.
Validation of utilization data in mixed use areas and ambulatory infusion centers (AIC) pharmacy - monthly	Review 25 patients from mixed use areas which the existing software designated for 340B drug purchase and 25 patients from AIC pharmacy. Check status in the electronic health record and/or pharmacy management system (PMS) to ensure patient status was outpatient and eligible for 340B purchase.
Eligible drug review in mixed use areas and AIC pharmacy - monthly	Review 340B purchases for drugs which are primarily utilized for inpatient use. Select 25 drugs and review to ensure that these were utilized for patients in outpatient status and accumulation is accurate.
Crosswalk review in mixed use areas and AIC pharmacy - monthly	Review the accuracy of the drug crosswalk for 25 medications
Drug purchase review in mixed use areas and AIC pharmacy - monthly	For 10 selected drugs, verify that the correct quantity is purchased on the 340B accounts based on the quantity that was processed in the accumulator.
Review of Medicaid billing in mixed use areas and AIC pharmacy – monthly	Review 10 Medicaid outpatient drug claims for accuracy.
GPO Exclusion File review in mixed use areas- quarterly	Review all drugs listed on the GPO Exclusion File for accuracy.
Review of charges versus purchases in mixed use settings - quarterly	For 30 selected drugs, review 340B eligible patient charges to validate the 340B purchases for the same time period.

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Example Monitoring Plan, cont.

Monitoring Tool – Frequency	Method
Review of eligible 340B prescriptions in Ambulatory Care Center (ACC) pharmacy - monthly	Review that no 340B accumulation occurred for patients with an ineligible plan.
Review of purchases at ACC pharmacy for ineligible sites - monthly	Review purchases for ineligible locations (i.e. disease management) vs. quantity requested to evaluate that purchases were made under the WAC account.
Review of floor stock purchases for ACC clinics - monthly	Compare sample of medications purchased for ACC floorstock locations against utilization file to ensure accuracy of 340B purchase.
Physician database for Contract Pharmacies – monthly	Perform a monthly assessment of the accuracy of the prescriber database to ensure proper designation.
Prescription transaction validation for contract pharmacy - daily	Verify that the number of prescriptions filled matches the number of transactions that cross into prescription splitting software.
Review of insurance type on captured claims - monthly	Review insurance information for all 340B captured prescriptions from contract pharmacy location(s) to ensure no Medicaid prescriptions were replenished with 340B medications.
Patient eligibility review in contract pharmacy - monthly	Select 30 340B claims to validate that an appropriate record of care exists for that patient in the EPIC system.
Provider review in contract pharmacy - monthly	Validate provider information on a random selection of 30 340B claims to ensure that the provider is currently listed on the eligible prescriber list.
Review of pharmacy invoices - monthly	Review of contract pharmacy purchases against pharmacy invoices to validate payments to pharmacy wholesaler.

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Example – Mixed Use Operating Procedure

Scope : These procedures shall govern actions taken in the Inpatient Pharmacy context regarding drugs acquired pursuant to the US Department of Health & Human Services ("HHS"), Health Resources and Services Administration ("HRSA"), and specifically HRSA's 340B Program.

Personnel: These procedures shall govern the actions taken by 340B project team members, the Pharmacy Buyers, and all other management and staff in dealing with drugs acquired through or covered under HRSA's 340 Program.

II. Ordering

- A. Schedule - Controlled Substances: Prior to placing orders for drugs that are classified as "Schedule - controlled substances" (per Title 21 of the Code of Federal Regulations), pharmacy buyers first shall consult the COMPUTER SOFTWARE (i.e. MacroHelix) Schedule - Accumulations Daily Report so doing, pharmacy buyers shall:
 - 1. Verify where the account accumulates, and
 - 2. Manually key in such orders under the responding wholesalers; this action shall include:
 - a. The account under which the order accumulates, and
 - b. The order quantities for each account.
- B. Direct items: Pharmacy buyers shall follow all relevant policies and procedures when purchasing other items, purchased under independent contracts.
- C. Dropship items: Pharmacy buyers shall:
 - 1. Check the COMPUTER SOFTWARE accumulator before placing an order with wholesalers;
 - 2. Validate where the drug accumulations are; and
 - 3. Submit the order to the appropriate wholesaler for an order. When placing an order, the buyers shall note the following:
 - a. The account under which the order accumulates, and
 - b. The order quantities for each account.
- D. IV Room (HOSPITAL NAME): Pharmacy buyers shall:
 - 1. Manually key orders into the COMPUTER SOFTWARE order builder;
 - 2. Preview split orders under the 340B, GPO and WAC accounts;
 - 3. Validate split order quantities to confirm that orders accumulate under the correct accounts;
 - 4. Verify that orders accumulate correctly;
 - a. If no issues are detected in drug accumulation, submit validated orders;
 - b. If issues are detected in drug accumulation, refer to the section entitled, "Issue Identification and Resolution," below;
 - 5. In the event of immediate needs, consult with the 340B Program Manager before submitting the order, and/or contact COMPUTER SOFTWARE;
 - 6. In the event of emergency needs, submit the needed drug orders immediately, regardless of the drug accumulation.

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Example – Mixed Use Operating Procedure, cont.

MIXED-USE OPERATIONAL PROTOCOLS

- E. **HOSPITAL NAME** will manually key in all orders through the **COMPUTER SOFTWARE** order builder. F. Issue Identification and Resolution: Pharmacy buyers shall be trained to detect irregularities within the ordering process. When such issues are detected, and prior to submitting orders with detected irregularities:
1. The pharmacy buyer shall notify pharmaceutical billing analyst and/or 340B Program Manager about the detected issues as soon as possible; and/or contact **COMPUTER SOFTWARE**.
 2. The pharmacy buyer shall document the detected issues and relevant drug information in the **COMPUTER SOFTWARE** issue sheet stored in the Pharmacy folder on the corporate server.
 3. For her/his part, the pharmacy billing analyst and/or 340B Program Manager shall review the documentation in the **COMPUTER SOFTWARE** issue sheet in order to determine if the detected issue(s) is/are valid.
- G. Non-340B Qualified Ordering (GPO) Exclusion items: Pharmacy buyers shall buy items that do not qualify for 340B price under a separate non-340B qualified wholesaler account. Such non-340B qualified items may include:
1. Purchases for non-340B facilities
 2. Drugs bought for borrow / loan
 3. Supplies
 4. Bulk solutions
 5. Gases
 6. Contrast Media
- H. **COMPUTER SOFTWARE Crosswalk ("crosswalk") Updating Process:** When there is a new NDC number under which an order is being placed/when unmatched NDCs are discovered, the 340B Program Manager shall:
1. The pharmacy buyer shall inform the 340B Program Manager of any changes in the crosswalk through the SharePoint site.
 2. The 340B Program Manager shall check SharePoint at end of each day to confirm if there are changes to be made to the crosswalk.
 3. Prior to entering changes to the crosswalk, the 340B Program Manager shall:
 - a. Verify that the existing super ERX can be used;
 - b. Add a new super ERX, if the existing ERX cannot be used;
 - c. Determine BUPP, ERX, package size and package unit based on EPIC billing units during ERX validation; and
 - d. If the foregoing has been executed, no irregularities found, shall input changes into the crosswalk.
- I. **Unmatched NDCs:** It shall be the responsibility of the 340B Program Manager to review and match unmatched items to the corresponding NDC/CDM on a weekly basis. After performing this review, in the event that a 340B program manager discovers remaining unmatched NDCs, the pharmaceutical buyer shall perform a root cause analysis, including review of newly purchased medications and medications previously not on the list to determine and remedy the underlying problem. Buyers and pharmacy analysts will support and research for the 340B Program Manager.
- 340B Program manager to review and update unmatched NDCs monthly to ensure they are current as of the last update. If brand new NDC numbers that have never been bought before are discovered, buyers need to notify analyst for the crosswalk to be updated. See crosswalk update process.

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Example – Mixed Use Operating Procedure, cont.

MIXED-USE OPERATIONAL PROTOCOLS

- J. **Epic and Talyst Default NDCs updates and maintenance:** Pharmacy buyers to notify the Willow Build team in the event that new NDCs are found or used. Refer to the existing policy.
- III. Data Validation
- A. **Validation of Utilization Data:**
- From the utilization data file in the SharePoint site, select a random MRN number and order ID to monitor. Review 30 line items in total at random monthly.
 - Select approximately equal number of MRN records per month at random, picking a different date for each MRN, focusing on targeted areas (For example, High utilizers or high dollar users). Utilization review will be conducted quarterly.
 - When reviewing numbers, compare records with data found in EPIC to ensure MRN in Hospital Account Record (HAR) in the Patient Station.
 - Validate that utilization record has the correct patient class on the correct date and time for the MRN number reviewed. When patient account is open, select the admission in which the utilization occurs and go to Event Management.
 - On Event Management for the selected encounter, patient class will show. Find the date and time of the utilization record being reviewed and validate the patient class in the utilization record with the event date/time.
 - Validate the medication being utilized using the order ID. Validate that the particular medication has been administered and if there is any credits occurring under the same order ID. Go to the Order History tab on Epic and enter the order ID under the MRN number being reviewed.
 - Validate that the quantity administered in the utilization record matches the quantity administered match the medications and the quantity found in the utilization record. Also validate if credits occur in the utilization record occur.
 - Validate that during the selected encounter, patient undergoes any payer changes. This can be found under EPIC hospital billing and account management.
 - Under the account maintenance, select the MRN number being monitored under EPIC account note. uncheck the box indicating "exclude system generated notes" to validate if there is any changes in coverage list.
- B. **Target Drug List:** The 340B project team shall evaluate the target drug list monthly (top 30 drugs with the highest negative GPO and WAC from the **COMPUTER SOFTWARE** net savings report). Any updates or changes made to the target drug list will be made by **HOSPITAL NAME** pharmacy purchasing supervisor. Any updates or changes made to the target drug list will be validated by pharmacy management.
- C. **Crosswalk Review Process:** On a periodic basis, the 340B Program Manager shall review and conduct a random review of the crosswalk and **HOSPITAL NAME** medication list. This monthly review shall consist of:
1. A random review of all crosswalk updates made within the prior month;
 2. A random review of 50 medications, which shall include:
 - a. Crosswalk additions;
 - b. BUPP medications;
 - c. Matching of NDCs, ERXs, package sizes and package units;
 - d. Linkage of each NDC to the corresponding super ERX and
 - e. Validate these with the utilization data.

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Example – Contract Pharmacy Operating Procedure

Introduction: **HOSPITAL NAME** currently contract with # external pharmacy chains to expand access to 340B Medications. Virtual replenishment software systems through several vendors have been implemented in all EXTERNAL PHARMACY STORE locations. EXTERNAL PHARMACY STORES utilize **COMPUTER SOFTWARE**, while other EXTERNAL PHARMACY STORES i.e. uses its own proprietary software.

To help extend access to lower cost drugs, **HOSPITAL NAME** will extend 340B-discounted pricing to uninsured patients that meet patient definition requirements set forth in the 340B Drug Purchasing program policy.

To help **HOSPITAL NAME** expand access to the "safety net" population, **HOSPITAL NAME** will also receive access defers from prescriptions filled at contract pharmacy locations for **HOSPITAL NAME** patients with Medicare or commercial insurance. These patients must also meet patient definition requirements set forth in the 340B Drug Purchasing Program Policy.

I. Operational Procedures

- A. **HOSPITAL NAME** use a replenishment model for contract pharmacy services.
- B. 340B eligible prescriptions may be presented to contracted EXTERNAL PHARMACY STORE locations via e-prescribing, hard-copy, fax, or phone. 340B eligible prescriptions may be presented to contracted External pharmacy store's locations only via e-prescribing.
- C. External pharmacy store and/or **COMPUTER SOFTWARE** verifies patient, prescriber, and outpatient clinic eligibility.
- D. Contract Pharmacy Staff dispenses prescriptions to 340B eligible patients using existing non-340B inventory at the contract pharmacy.
- E. Contract Pharmacy collects payments from patients and payors and distributes payments back to **HOSPITAL NAME** less negotiated dispensing fees to the contract pharmacy and contract pharmacy software vendor.
- F. **COMPUTER SOFTWARE** and/or the contract pharmacy stores place automated 340B orders on behalf of **HOSPITAL NAME** based upon 340B eligible use as determined by the contract pharmacy software's virtual inventory. Orders are triggered by the use equivalent to a full package size and placed by using an automated interface between the pharmacy wholesaler and contract pharmacy software.
- G. **HOSPITAL NAME** pays invoice to Pharmacy Wholesaler for all 340B drugs.
- H. Contract Pharmacy Staff receives 340B replenishment orders by examining the wholesaler invoice against the order, and reports inaccuracies to Pharmacy Wholesaler and 340B Program Manager within 48 hours.

II. Medicaid

- A. All Medicaid prescriptions will be excluded from the program (carved-out).

- B. Prescriptions will be excluded by blocking claims containing identifiers for any Medicaid insurance plan.

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Example – Contract Pharmacy Operating Procedure, cont.

III. Patient Eligibility Determination

- A. **External pharmacy store** Patient Eligibility Determination
 - a. Only prescriptions that are electronically prescribed (e-scribed) from the EPIC system will be evaluated for 340B eligibility. **HOSPITAL NAME** maintain records of care and responsibility for all prescriptions with an e-scribed prescription.
 - b. Prescriptions e-scribed from **External Pharmacy store** will contain a barcode that identifies the patient as 340B eligible. The barcode will contain the 340B-eligible location where the patient was seen.
 - c. Only prescriptions e-scribed from a **HOSPITAL NAME** 340B-eligible location will be processed by **External pharmacy store**. **HOSPITAL NAME** have provided **External pharmacy store** with a list of eligible locations and will review the eligible location list on a quarterly basis.
 - d. **HOSPITAL NAME** have also provided **External pharmacy store** with an eligible prescriber list. Once **External pharmacy store** has validated the script has originating from **HOSPITAL NAME**, the prescription will be reviewed to ensure that it is written by a prescriber on the eligible prescriber list by matching the DEA and/or NPI of the prescribing provider to a DEA and/or NPI on the eligible prescriber list.
 - e. All medical staff coordinator and pharmacy purchasing supervisor are to collaborate to review the providers list monthly. Any changes to the providers list will be made by the medical staff coordinator and the list shall be updated within a day of changes made.
 - B. **COMPUTER SOFTWARE /EXTERNAL PHARMACY STORE** Patient Eligibility Determination
 - a. Only **HOSPITAL NAME** currently contracts with **EXTERNAL PHARMACY STORE** stores.
 - b. **HOSPITAL NAME** provides **COMPUTER SOFTWARE /EXTERNAL PHARMACY STORE** with a patient encounter file out of the EPIC System.
 - c. The patient encounter file includes, at minimum, patient demographical data, patient medical record number, encounter date, encounter location, and diagnosis information.
 - d. **HOSPITAL NAME** maintains a list of exclusive and non-exclusive hospital providers on the eligible prescriber list. The DEA and/or NPI of the prescribing provider will be matched to a DEA and/or NPI on the eligible prescriber list.
 - e. Prescriptions written by an exclusive provider will be captured if there is a record of an encounter within the previous 12 months and the prescription matches the diagnosis of that encounter.
 - f. Prescriptions written by a non-exclusive provider will only be captured if there is a record of an encounter within the previous 12 months and the prescription matches the diagnosis of that encounter.
 - g. All medical staff coordinator and pharmacy purchasing supervisor are to collaborate to review the providers list monthly. Any changes to the providers list will be made by the medical staff coordinator and the list shall be updated within a day of changes made.
 - h. Medical staff coordinator and pharmacy purchasing supervisor are to collaborate to review the providers list monthly. Any changes to the providers list will be made by the medical staff coordinator and the list shall be updated within a day of changes made.

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MONITORING vs. AUDITING

Remember.....

- Keeping current with Regulations
- Education and Training
- Departmental Self Monitoring.....

Remember

- AUDIT the Self Monitoring.....

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Contacts



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Compliance.....

Who Says It Can't Be Fun?

Lorene Bass, CHC, ASQ-CQMOE, CQA
VP Compliance & Quality

Richella Abell-Hawes, CHC,TQM
APD Compliance & Quality

HCCA Compliance Institute
San Diego, CA 2014



Agency Bio

- ▶ Herkimer County:
 - Population 64,000
 - Demographics- Rural
- ▶ Herkimer ARC:
 - Serve 660 people daily – (mostly ID/DD)
 - Approximately 400 staff
 - Annual Budget 2014 \$23 million
 - Operate 38 sites in County (22 Residential)
 - Second largest County employer



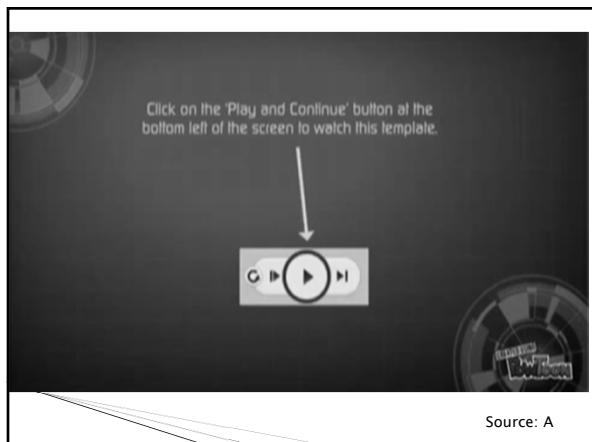
Disclaimer

- ▶ While some of what we talk about is based on fact, most of what we will discuss is based on our personal experiences.
- ▶ We do not claim to be the first to use or to have created some of the concepts that we will discuss.
- ▶ The activities we describe and the results we attain may not be appropriate or duplicated in your organization without some fore thought.

Agenda

- ▶ Culture of Compliance
 - ▶ Discuss Learning Strategies
 - ▶ Modes of Delivering Training
 - ▶ Experience Activities
 - ▶ Sharing/Q&A





Source: A

Culture of Compliance

"Attitudes, feelings, values, and behavior that characterize a group within it...

- ▶ Shared attitude – top down/bottom up.
 - ▶ Assess your values and lead by example.
 - ▶ Work with diverse teams and classes of employees.
 - ▶ Hold people accountable to the values.

..... and have been established through an effective training & education program”

The Facts

- ## ► We Learn...

10% of what we READ

20% of what we HEAR

30% of what we SEE

50% of what we SEE
50% of what we both SEE and HEAR

70% of what is DISCUSSED WITH OTHERS

80% of what we EXPERIENCE PERSONALLY

80% of what we EXPERIENCE PERSONALLY
85% of what we TEACH someone else



Source: B

The Facts continued...

- #### ► Retention Rates...

Only 5% of a Lecture

50% from Discussion groups

75% Practice by doing

90% When we teach others/use immediately

Repetition:

24 repetitions = 80% long-term retention

Habits are formed by the repetition of particular acts. They are strengthened by an increase in the number of repeated acts. Habits are also weakened or broken, and contrary habits are formed by the repetition of contrary acts. ~Mortimer Adler

Source: B

Take A Stance – Activity

- ▶ Create four large signs with the following phrases:
 - Strongly Agree -Agree
 - Disagree -Strongly Disagree
 - ▶ Prepare/post position statements overhead
 - ▶ Facilitate discussion and relate back to Regulation, Code of Conduct or policies when possible.
 - ▶ Variation: Use colored index cards or allow groups to discuss and collectively select a position.

Source: C

Take A Stance...

- ▶ The use of social media is allowable during my work day.
- ▶ It is okay to use white out on documents.
- ▶ Email is a secure way to transmit PHI.

Color Key:

- Strongly Agree
- Agree
- Disagree
- Strongly Disagree

Orientation



A. REFRAIN FROM MISREPRESENTATIONS

- ▶ Report & record information accurately, completely, honestly
 - Patient records, billing, timesheets, financials

Laboratory owner billed Medicaid for tests not done & fraudulently claimed *mileage*

5 years in prison \$2.5 million in restitution



Service Coordinator at OPWDD Finger Lakes, NY
billed for home visits that never happened-
Up to 15 years in prison





Discussion

- › What concept do you think we are trying to reinforce with our staff from this video?
- › Is it acceptable to accept money or gifts from a family member?
- › What might be the perception of other patients/employees if you accepted the money (assuming they saw you take it)?
- › If you take the money, should you report it?
 - Who do you report it too?

Annual Refresher

CaseStudies
Jeopardy
StickyNotes
Exercises
Games
Stories
Compliance
Activities
Antonym/Synonym
Quotes
Roleplay
VideosPuzzles

Source: E

Jeopardy

Code of Conduct	Quality	Acronyms	Documentation	Hodge Podge
Q \$100	Q \$100	Q \$100	Q \$100	Q \$100
Q \$200	Q \$200	Q \$200	Q \$200	Q \$200
Q \$300	Q \$300	Q \$300	Q \$300	Q \$300
Q \$400	Q \$400	Q \$400	Q \$400	Q \$400
Q \$500	Q \$500	Q \$500	Q \$500	Q \$500

Final Jeopardy

Source: F

Case Study: Written

- ▶ You overhear a conversation between a staff and a supervisor. You hear the Supervisor direct the staff to backdate a document that was suppose to have been written eight months ago.
- ▶ What should you do?
- ▶ Does your decision change if they saw you overhear the conversation?



Source: F

Case Study: Video



Source: G

What steps need to be put in place to prevent this from happening again?

- ▶ Training on:
 - Sexual Harassment.
 - False Claims Act.
 - Whistleblower/Anti-Retaliation Policy.
 - Conflict of Interest Policy.
 - ▶ Reinforce ways of reporting, to include anonymously and confidentially.

Publications

Regulatory Updates

Herkimer Area Resource Center
Volume 6, Issue 16
August 1, 2011

Governor Andrew M. Cuomo appoints James Cote as Acting Medicaid Inspector General. Cote has been serving as the Interim Medicaid Inspector General since the appointment of Michael J. Lavelle to the Office of Inspector General as a Regional Inspector General for Region II. Cote has been serving as the Office's Interim Medicaid Inspector General since July 1, 2010. The Office of the Inspector General is located at 200 Broadway, New York City and One, Albany, NY.

The Office of the Inspector General has been established to combat fraud, waste and abuse in state programs by investigating and applying new policies and standards instead of the policies which had been in place during the previous administration.

OMWD Issues Compliance Alerts

The CMS has issued several warning to organizations regarding:

- Compliance with the Health Information Privacy Rule
- Compliance Assessment Tool
- Compliance Audit Protocol
- Compliance Documentation Review Checklist

OPWED Issues Proposed Training Requirements 14-NYCRR Section 033-R, effective November 1, 2011.

Annual Training Required for:

- Employees, Managers, Volunteers & Family Care Providers
- Clinical Staff
- Non-Clinical Staff
- Personal Protective Technologies (COP)
- Personal Protective Equipment (PPE)
- Abuse Prevention and Reporting
- Emergency Evacuation (Fire Safety)

The changes will also affect Board Members as they will be required to receive the above training once every three years.

OPWED Issues Proposed Training Requirements 14-NYCRR section 0524.

The investigation of incidents and allegation of abuse, effective November 1, 2011.

- Preliminary and objective fact-finding by the person in command of directly involved staff performing investigations
- A written report of the findings resulting from the investigation as a member of the provider's incident review committee
- Police reports and other evidence obtained for investigating an allegation
- Accessibility to use outside investigators (paid and non-paid).
- Agencies should develop collaborative agreements with other agencies for cross investigation

If you have any questions, please contact us.

Herkimer ARC Reporting Misconduct

Herkimer Area Resource Center
Volume 6, Issue 03
August 1, 2011

Herkimer ARC Corporate Compliance Program offers multiple ways to report issues or non-compliance

- Direct telephone to Reporters
- Direct reporting to the Ethics Officer
- Submission of an Incident Report
- Confidential Reporting Form
- E-mail reporting
- Anonymously reporting through Ethics Helpline

Policy of Herkimer ARC Corporate Compliance Program

Compliance Plan
Code of Conduct
Ethics Policy
Ethics Helpline Policy
Incident Response
Ethics Helpline
Confidential Reporting Policy
Claims Submission Audit Policy
Internal Investigations Policy
Whistleblower Protection
HEDPA Policy Manual
HEDPA Whistleblower Protection Policy
Initial and annual refresher trainings
Compliance Service Documentation

Report Anonymously on Ethics Helpline

A confidential phone line to report suspected allegation of misconduct, harassment, discrimination, or wrongdoing by the agency or its employees.

315-866-7946



Publications

Publications

"ETHICS QUICK TEST"

HERKIMER AREA RESOURCE CENTER

Before you make a decision, take out this card and ask yourself these questions:

- Is it the **right** thing?
- Does it comply with the **Code of Conduct**?
- If you're not sure, who else can you ask?
- How will it affect the **Heritage?**
- If you know it's wrong, should you do it anyway?
- If you're not sure, who else can you ask?

Source: H

What is the Ethics Helpdesk?

A confidential phone line to report suspected allegations of misconduct or wrong doing by the **Faculty or its employees**.

If in doubt, check it out!
Call the Ethics Helpdesk at 855-7956

Herkimer Area Resource Center
100 Main Street, Suite 100
Herkimer, NY 13348-1526
P.O. Box 1526
1-855-7956

MANAGER/SUPERVISOR SELF-ASSESSMENT: DO I SET AN APPROPRIATE EXAMPLE?

I asked several people say I set a good example for other behaviors.

Do I clearly communicate to staff my expectations for the highest standards of ethical behavior?

Do I hold employees and others accountable for behavior inconsistent with our values, written and code of conduct?

Do I encourage participation in education related to ethical, integrity or compliance issues and concerns?

Do I encourage participation in education related to ethical, integrity or compliance issues?

Can I recall instances where ethical, integrity or compliance issues were brought to my attention?

Do I respond to issues and concerns raised by employees with appropriate speed and seriousness?

Do I think employees for bringing ethical, integrity or compliance issues to my attention?

Do I demonstrate appropriate awareness and sensitivity to potential ethical, integrity or compliance issues?

Have I informed my employees of available resources like ARCS?

Do I make compliance a topic of discussion at meetings?

Do I avoid conflicts of interest and make others aware of potential conflicts?



Newsletter

INSIDE THIS ISSUE:

- **2011 BPC Surveys**
- **Regulatory Deadlines**
- **Disability Services**
- **Bureau News**
- **Community Updates**
- **2011 M.S. Mania**
- **Harkenauer Initiatives**
- **Disability Services**
- **GMHC**
- **Disability Awareness Center**
- **Friends & Family Center**
- **Healthcare**
- **Books & Media**
- **Nursing Services**
- **Books & Publications**

The Query

Compliance & Quality Services Department

BUREAUCRATIC

BPC Survey Changes

OMIG Audit Updates

CONTRACT AUDITS

DISABILITY CONTRACTS WITH OPMC

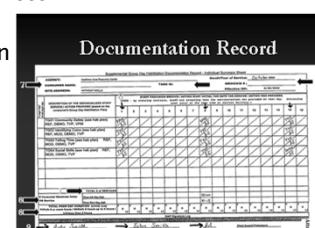
Department Specific

- ▶ Regulatory References
- ▶ Do's & Don'ts
- ▶ Auditor Simulation



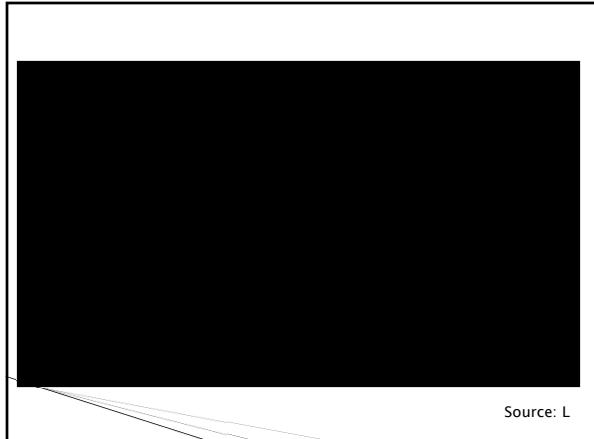
Make use of OIG Videos

Source: J



Documentation Record

Source: K



When Opportunity Knocks...

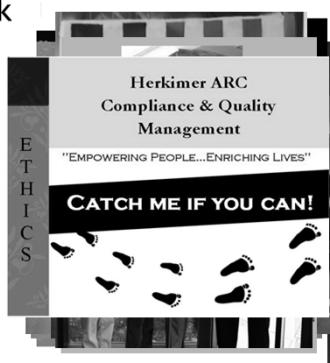
► Brainstorming Activity:

- What are the reasons people do the wrong thing when no one is looking?
 - How can we help each other make better choices?

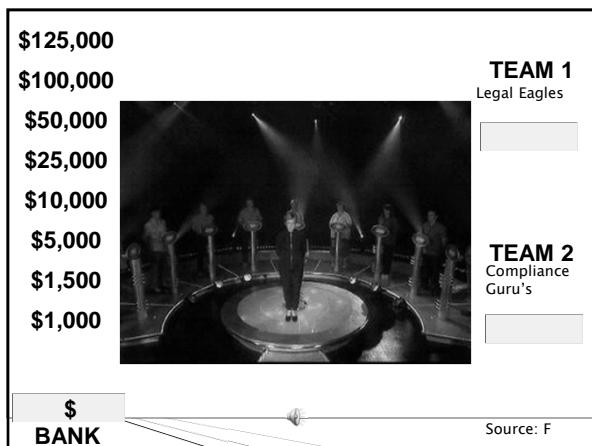


Compliance Week

- Contests
 - Poster contest
 - Puzzle
 - Scavenger Hunt
 - T-shirts
 - Culminating Activity
 - Games
 - Jeopardy
 - Weakest Link
 - Catch Me If You Can



Source: M



Compliance & Ethics Week
Thought for the Day:

“Ethics is a code of values which guide our choices and actions and determine the purpose and course of our lives.”

-Ayn Rand



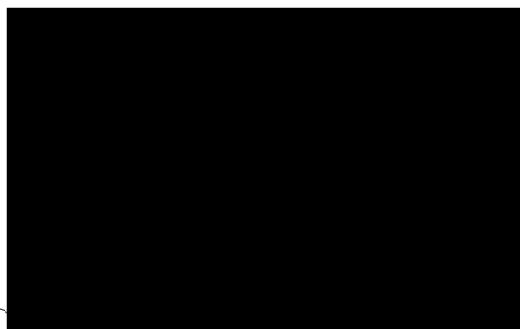
Ponder this:
What are your values?

Are you faithful to these values?

Action Steps:
Determine if you need to re-evaluate your values for the future.

Make the necessary changes to be true to yourself.

Walk the Talk



Source: N

Questions/Sharing/Discussion?



Contact Us:
lbass@herkimerarc.org
rhowes@herkimerarc.org

Sources



- A. www.poptoon.com to create the *Compliance Officer Mission*.
 - B. The Facts Source: Study by Eldon Ekwall and William Glasser
 - C. Take A Stance Activity adaptation from The Brain Friendly Classroom—4 Corners: Carrie Dummer, Hope College dummer@hope.edu
 - D. Movie Clips.com; Ben Stiller & Adam Sandler Video Clip: *Happy Gilmore*
 - E. www.worlde.net colorful word screens
 - F. trainertable.com power point game boards like ...*The Weakest Link & Jeopardy*
 - G. Global Clips: 'Defcon 20' Video Clip, *The Office*
 - H. Ethics Quick Test adaptation from Texas Instruments 2008
 - I. Self Assessment adaptation from Organization Integrity Program
 - J. http://oig.hhs.gov/newsroom/video/2011/heat_modules.asp
 - K. Comic Strip: *Speed bump* www.creators.com
 - L. Video Clip B. Braun Medical Group Corporate Compliance and singing prisoner's www.puzzlemaker.com to create puzzles
 - M. Simple Truths "Walk The Talk" Video <http://www.simpletruths.com> 1-800-900-3427

Thank you to all of our sources for assisting us in making our trainings more educational and fun.

Jeopardy

Code of Conduct	Quality	Acronyms	Documentation	Hodge Podge
<u>Q \$100</u>	<u>Q \$100</u>	<u>Q \$100</u>	<u>Q \$100</u>	<u>Q \$100</u>
<u>Q \$200</u>	<u>Q \$200</u>	<u>Q \$200</u>	<u>Q \$200</u>	<u>Q \$200</u>
<u>Q \$300</u>	<u>Q \$300</u>	<u>Q \$300</u>	<u>Q \$300</u>	<u>Q \$300</u>
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<u>Q \$500</u>	<u>Q \$500</u>	<u>Q \$500</u>	<u>Q \$500</u>	<u>Q \$500</u>

Final Jeopardy

“Catch Me If You Can!”



Compliance & Ethics Week
The Life Size Board Game

GAME RULES

Object of the Game: Players move about the game board facing legal and ethical dilemma's. The player who is successful in “*Walking the Talk*” with the most money and Wow cards is declared the winner.

Set Up:

- The colorful game pieces are randomly laid out on the floor (event side up).
- Each player is given \$100.00 in HARC Money
- One Die is available
- Event Cards are placed upside down
- Action Cards are placed upside down
- Individuals are human game pieces
- Wow cards are available



Play:

- The player who rolls the highest number goes first;
- Players roll to determine the number of spaces to move. More than one player can land on a space at a time.
- If the player lands on an Ethics or Training space, they must draw a card from the corresponding pile. Otherwise, they will draw a card from the Compliance pile. Players must adhere to the directions of the card selected. A card is selected after every turn with the exception of the “Go Directly to Jail” or if the card indicates otherwise.
- Players who end up in Jail, must skip one turn.
- Players who are in Training will skip a turn only when indicated on the card.
- Any player who is successful in making it to the “Walk the Talk” space is awarded a \$500.00 bonus.
- If when moving ahead you land on Ethics or Training you will receive a second card in your turn.
- The audience will act as judges and majority vote by show of hands decides a players fate.
- In the event the game has ended due to time constraints. The player who has the most money and “Wow cards” collected will be declared the winner.



“Catch me if you can!” has been developed by the Herkimer ARC Compliance & Quality Services Department strictly for use as a training tool at HARC.. Use for any other purpose must be approved by Lorene Hartmann VP Compliance & Quality Services.

HARC EMPLOYEE SELF-ASSESSMENT: Do I SET AN APPROPRIATE EXAMPLE?

- ◆ If asked, would people say I set a good example for ethical behavior?
- ◆ Do I demonstrate to my supervisor my understanding of the Code of Conduct?
- ◆ Do I discuss with my supervisor when I exhibit or see others behave in a manner which is inconsistent with our mission and values?
- ◆ Do I engage in open and honest communication of ethical, integrity or compliance issues and concerns?
- ◆ Do I participate in education related to ethical, integrity or compliance issues?
- ◆ Can I recall recent examples where ethical, integrity or compliance issues were brought to my attention?
- ◆ Do I respond to issues and concerns raised by my supervisor with appropriate speed and seriousness?
- ◆ Do I thank others for bringing ethical, integrity or compliance issues and concerns to my attention?
- ◆ Do I demonstrate appropriate awareness and sensitivity to potential ethical, integrity or compliance issues?
- ◆ Have I been informed of available resources within HARC?
- ◆ Do I avoid conflicts of interest and make others aware of my potential conflicts?



MANAGER/SUPERVISOR SELF-ASSESSMENT: Do I SET AN APPROPRIATE EXAMPLE?

- ◆ If asked, would people say I set a good example for ethical behavior?
- ◆ Do I clearly communicate to staff my expectations for the highest standards of ethical behavior?
- ◆ Do I hold employees and others accountable for behavior inconsistent with our mission, values and code of conduct?
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