

**INFLUENCING DECISION MAKING**  
Jenny O'Brien, Chief Compliance Officer, UnitedHealthcare  
Kim Otte, Chief Compliance Officer, Mayo Clinic



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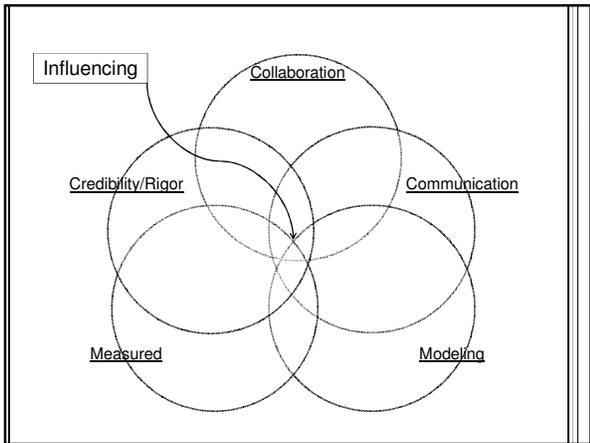
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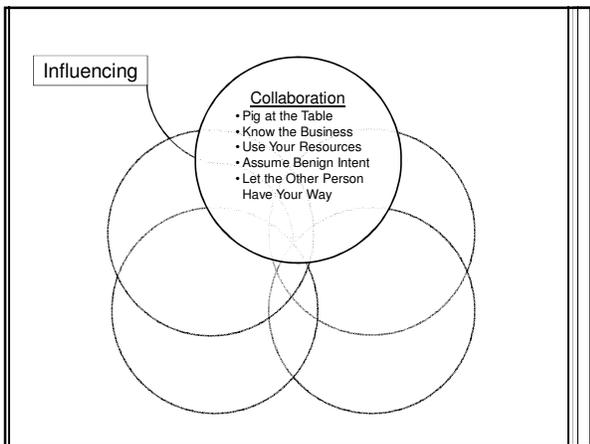
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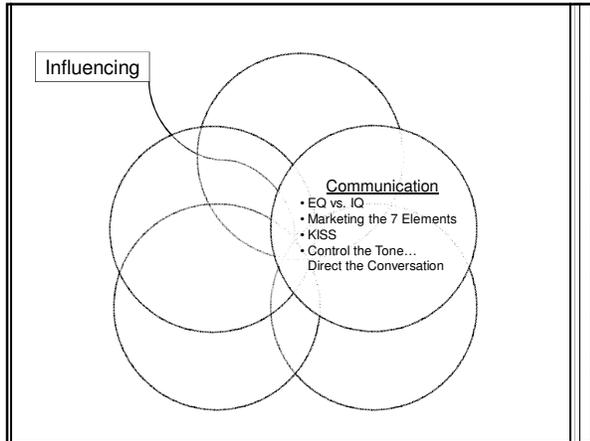
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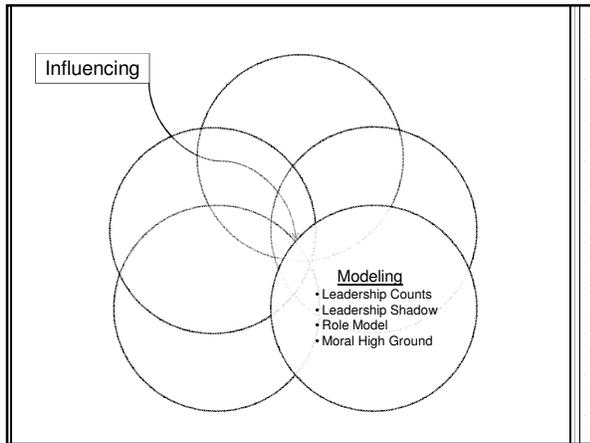
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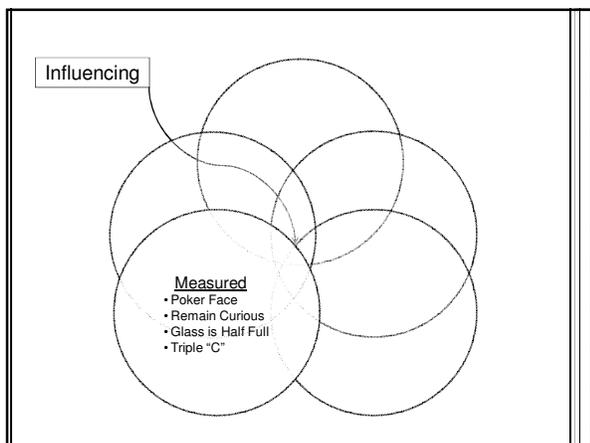
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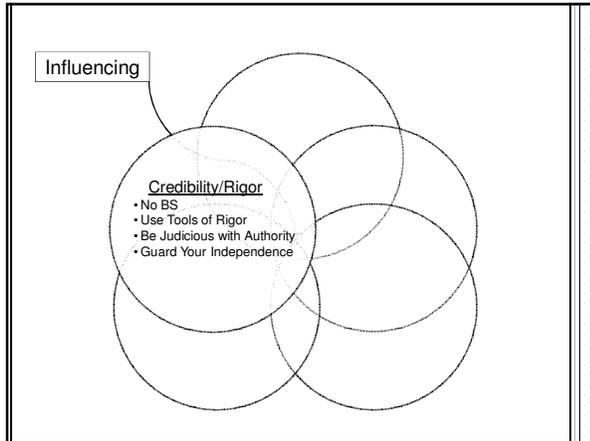
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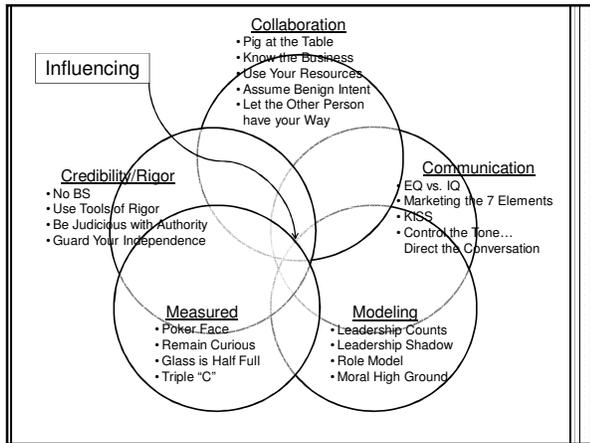
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**THANK YOU!**  
**Questions?**



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**Health Care Compliance Association | HCCA**

**Compliance Institute**

**Session 501: Implementing a System-Wide Access Monitoring Program**

Brian D. Annulis  
 Meade, Roach & Annulis, LLP  
 Aegle Compliance & Ethics Center, LLP  
 4147 N. Ravenswood Avenue  
 Suite 200  
 Chicago, Illinois 60613  
 (773) 907-8343 (Direct)  
 (773) 634-7877 (Fax)  
 (312) 218-7258 (Cell)  
 bannulis@meaderoch.com  
 www.meaderoch.com  
 www.aegle-compliance.com

April 1, 2014




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**Agenda & Objectives**

- Background and Regulatory Overlay
- OCR Statistics/
- UCLAHS Resolution Agreement
- Practical Considerations & Solutions




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**HIPAA Security Rule**

- Administrative Safeguards (45 CFR 164.308(a)(4))
  - A CE/BA must implement p&ps for authorizing access to ePHI that are consistent with the Privacy Rule
  - Addressable implementation specifications include access authorization and access establishment and modification




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**HIPAA Security Rule**

- Technical Safeguards (45 CFR 164.312(a), (b), (c), (d))
  - A CE/BA must implement technical p&ps for electronic information systems that maintain ePHI to allow access only to the persons or programs that have been granted access rights
    - Implementation specifications include unique user IDs (required), emergency access (required), automatic logoff (addressable) and encryption/decryption (addressable)

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**HIPAA Security Rule**

- Technical Safeguards (45 CFR 164.312(a), (b), (c), (d))
  - A CE/BA must also implement hardware, software and/or procedural mechanisms that record and examine activity in information systems that contain or use ePHI
  - A CE/BA must implement p&ps to protect ePHI from improper alteration or destruction
  - A CE/BA must implement p&ps to verify that a person or entity seeking access to ePHI is the one claimed

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**Accounting of Disclosures—HITECH Act Changes**

- HITECH Act expanded the accounting of disclosure right for individuals to include disclosures made through an electronic health record ("EHR") for treatment, payment and health care operation ("TPO") purposes.
- When a covered entity uses or maintains an electronic health record with respect to PHI:
  - Disclosures for TPO must be logged for accounting requests
  - Right to accounting of disclosures associated with EHR PHI applies only for 3 years prior to the date of the request
    - Accounting for other accountable disclosures applies for 6 years
- Note:
  - Does not withdraw other "exceptions" in 164.528
  - Does not require covered entity or BA to account for disclosures that it does not make itself
- Allows fee:
  - "Not greater than the entity's labor costs in responding to the request."

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**Privacy Rule—Accounting of Disclosures—HITECH Act Changes**

- Effective date: Not earlier than January 1, 2011
- Depends on when EHR is acquired:
  - If covered entity acquired an EHR as of January 1, 2009, then applies to disclosures on and after January 1, 2014
  - If covered entity acquires an EHR after January 1, 2009, then applies to disclosures on and after the later of
    - January 1, 2011; or
    - Date covered entity acquires an EHR
- HHS option to change tiered effective dates to not later than 2018 or 2014

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**Privacy Rule—Accounting of Disclosures—Proposed Rule**

- HITECH Final Rule did NOT address the expanded accounting of disclosures provision under the HITECH Act; to be addressed in later rulemaking
- However, on May 31, 2011, HHS published a Proposed Rule regarding the expanded accounting of disclosure right for individuals
- If finalized as proposed, the changes would be significant

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**Accounting of Disclosures – Proposed Rule**

- Despite the plain language of the HITECH Act, the Proposed Rule does not expand the disclosure accounting right to include TPO activities;
- Rather, OCR creates a new “access report” right that would govern all “accesses” of an individual’s PHI (whether for use or disclosure) if that PHI is maintained in an electronic DRS

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### Accounting of Disclosures – Proposed Rule

#### "Expansion" of the Accounting of Disclosure Right under the Proposed Rule

- The disclosure accounting right would only apply to PHI maintained in a DRS
- The Proposed Rule would explicitly list the types of disclosures that must be tracked and accounted for
- The Proposed Rule would eliminate the need to account for disclosures made as part of IRB-approved research projects
- The Proposed Rule would expand upon the information that must be provided in a disclosure accounting report (e.g., if exact date of disclosure is unknown, month and year must be provided, at a minimum);
- Responses to requests for an accounting of disclosures must be provided within 30 days. Under the current rule, responses are due within 60 days. An opportunity for an extension would still be available.

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### Accounting of Disclosures – Proposed Rule

#### New "Access Report" Right

- HHS proposes to expand an individual's HIPAA rights to include an "access report" addressing both disclosure and use of all PHI in an electronic DRS
- The access report would need to include:
  - The date of access;
  - The time of access;
  - The name of the person accessing the information (if available), otherwise the name of the entity accessing the electronic designated record set;
  - A description of the information accessed; and
  - A description of the action taken (e.g., create, modify, access, delete).

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### Accounting of Disclosures – Proposed Rule

#### New "Access Report" Right

- Responses to a request for an access report must be made within 30 days (with an opportunity for an extension).
- Access reports must address uses and disclosures by the covered entity's business associates of electronic DRS information maintained by the business associates.
- An individual has the right to one access report every 12-months without charge. The covered entity may charge a reasonable, cost-based fee for additional reports

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**OCR Breach Notification Highlights**  
September 2009 through February 20, 2013

- Unauthorized/improper access has consistently been one of the top 5 issues investigated by OCR
- Top types of large breaches
  - Theft
  - Unauthorized Access/Disclosure
  - Loss

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**OCR Spotlight on Largest Breaches of 2012**

- Hacking network server – 780,000 affected
- Backup tapes stored at hospital cannot be found and are presumed lost– 315,000 affected
- Unencrypted emails sent to employee's unsecured email address -- 228,435 affected
- Theft of laptop from employee's vehicle– 116,506 affected
- Unauthorized access to e-PHI stored in database-- 105,646 affected
- Hacking database stored on network server – 70,000 affected

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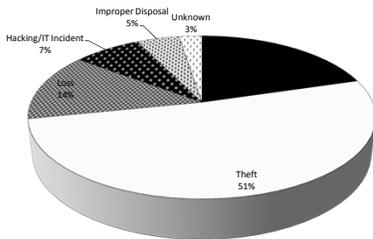
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**Breach Notification: 500+ Breaches by Type of Breach**



Data as of January 2013

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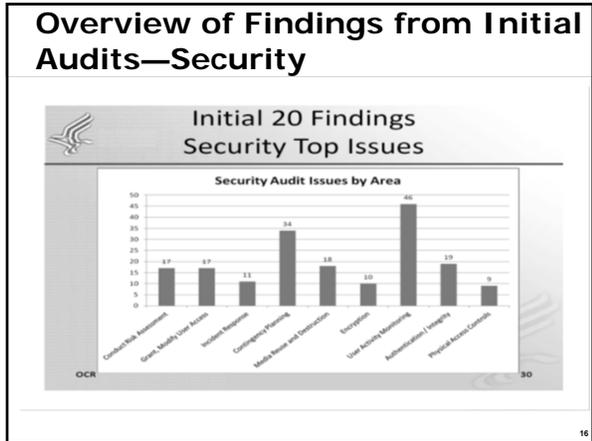
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### The UCLAHS Case (Resolved 2011)

- Approximately 850 employees of the University of California at Los Angeles Health Systems (UCLAHS) obtained PHI about two celebrity patients by using UCLAHS' electronic medical record data bases.
- The employees had no work-related need for the celebrities' PHI as they were not involved in the treatment of either celebrity (i.e., snooping).
- Upon a referral by OCR, the Department of Justice (DOJ) conducted a **criminal investigation** which resulted in one UCLAHS employee pleading guilty to obtaining PHI for commercial advantage.
- OCR negotiated a Resolution Agreement and a Corrective Action Plan with UCLAHS.

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### “Covered Conduct” by UCLAHS

- OCR’s investigation “indicated” that UCLAHS had engaged in the following “covered conduct:”
  - Throughout the period from 2005 through 2008, UCLAHS failed to provide and/or document necessary and appropriate Privacy and Security Rule **training** for all members of its workforce to carry out their functions within UCLAHS;
  - During the period from 2005 through 2008, UCLAHS failed to apply appropriate **sanctions** on workforce members who impermissibly examined ePHI; and
  - During the period from 2005 through 2009, UCLAHS failed to implement security measures sufficient to reduce the risks of **impermissible access** to ePHI of its patients by unauthorized users to a reasonable and appropriate level.

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### Resolution of UCLAHS Case

- In July, 2011, UCLAHS executed a Resolution Agreement and Corrective Action Plan with OCR. These documents are on OCR's website.
- UCLAHS paid **\$865,000** as a resolution amount.
- The **Corrective Action Plan (CAP)** that UCLAHS executed required it to create new or revised policies and procedures. These policies must include a "need to know" approach to records access so as to prevent a recurrence of the massive breach that occurred in this case.
- UCLAHS was also required to appoint an **Independent Monitor**, subject to OCR's approval, who will evaluate UCLAHS's compliance with the CAP for three years.

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### Lessons Learned from the UCLAHS Case

- Management of health care providers which rely strongly on electronic medical records must take affirmative steps to secure those records internally.
- Management needs to adopt a "need to know" strategy for allowing access to electronic PHI and implement that strategy throughout its electronic data systems.
- Only workforce members with a bona fide work-related reason to access a particular patient's electronic records should be able to do so.

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### Lessons Learned from the UCLAHS Case

- Management, especially the compliance department, must be vigilant in testing the reliability of its security systems for the safeguarding of electronic PHI.
- Clear and well documented administrative and physical safeguards are necessary for the storage devices and removable media which handle ePHI.
- Encryption of data at rest on any desktop or portable device/media storing ePHI is essential.

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### Compliance Institute

#### Session 501: Lessons Learned: Implementing a System-Wide Access Monitoring Program

Frank DePrisco  
Vice President Global Customer Operations  
FairWarning, Inc.  
13535 Feather Sound Drive  
Suite 600  
Clearwater, FL 33762  
[Frank@FairWarning.com](mailto:Frank@FairWarning.com)  
[www.FairWarning.com](http://www.FairWarning.com)

April 1, 2014

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### Today's Agenda

- Why I'm here today
- Common myths to implementing a system-wide access Monitoring Program
- Recommendations to make your monitoring effective and efficient
- Suggestions to help avoid pitfalls during implementation and on-going operations

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### Common Myths to Implementing an Effective Access Monitoring Program

- It will cost too much
- We don't have the time or resources (manpower)
- Our people are all trained on the laws and know not to access information without a need
- We trust our people
- What we don't know can't hurt us
- If we monitor and find inappropriate access, we will have to do something
- There will be too many false positives that will overload us

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## Breaking down the Myths: Myth #1

### It will cost too much to monitor access

- Average cost of a data breach for an organization has dropped for the third straight time in 9 years of studies to \$5.4 million, Ponemon Institute found in its 7<sup>th</sup> Annual Data Breach report.
- Total cost is not the only thing that dropped, as the average cost per compromised record decreased to \$136, according to the [2013 data breach report](#).

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## Myth #1 continued

This decline suggests that organizations represented in this study have **improved** their performance in both **preparing for** and **responding** to a data breach.

As the findings reveal, more organizations are **using** data loss prevention technologies; fewer records are being lost in these breaches; and there is less customer churn.

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## Myth #2

### We don't have the time or the resources

Based on the previous slide can we afford not to throw resources at this issue?

Often times, the issue becomes who should be responsible for the monitoring - IT or Privacy? Both play a role.

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### Myths #3 and #4

**Our people are all trained on the laws and know not to access information without a need**

**We trust our people**

Just look at any of the recent headlines

Understand with access to Electronic Health Records - staff develop a sense of entitlement. "Since I have access, I am entitled to look at what I want", that is unless they know you are monitoring."

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### Myth #5

**What we don't know can't hurt us**

Massachusetts General Hospital settlement with HHS: they agreed to pay \$1 million and enter into a 3-year Corrective Action Plan because an employee took patient information home to work on it and left it on a commuter train.

Do you think they knew?

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### Myth #6

**If we monitor and find inappropriate access, we will have to do something**

This seems to be a common theme among organizations when it comes to monitoring. What if we find something - what do we do? I believe this is often driven because the right people are not included in the decision to monitor, what to monitor and how to process findings.

We will explore this more.

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## Myth #7

**False Positives** - It is true that a monitoring program that has not been well thought out could overburden staff due to a large number of false positives. This impact can be reduced or eliminated by taking some reasonable steps:

- Understand the workflow
- Understand what types of activity you want to monitor
- Create a good data set
- Start small, tune your alerts to eliminate false positives to the degree possible

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## 10 Recommendations for Success

- ❖ Define clear goals
  - ❖ Compliance
  - ❖ Checking a box
  - ❖ Something greater
- ❖ Develop supporting workflows and validation process
  - ❖ Who is going to do the monitoring
  - ❖ Business or non business reason
- ❖ Develop Executive support
  - ❖ HR, Legal, Operations Officer, CMO
  - ❖ CIO, IT Managers, System Admins, DBAs

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## 10 Recommendations for Success

- ❖ Communicate through multiple channels
  - ❖ Media
  - ❖ Education
- ❖ Ensure solution can scale
  - ❖ Number of applications to audit
  - ❖ Long term storage and expansion
- ❖ Who runs it
  - ❖ Certification training
  - ❖ Managed service

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## 10 Recommendations for Success

- ❖ Select the right monitoring approach
  - ❖ Applications to monitor
  - ❖ Behaviors to monitor
- ❖ Assign application data experts to the project
  - ❖ Understand your data
  - ❖ Filtering of false positives
- ❖ Track incidents
  - ❖ Centralized tracking
  - ❖ Ability to report
- ❖ Have an overall governance plan
  - ❖ Measure
  - ❖ Benchmark your progress

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## 10 Pitfalls to Avoid

- ❖ Starting to big
  - ❖ 100 systems that contain PHI
  - ❖ I want every report I can get
- ❖ Changing the scope
  - ❖ Defined for a reason
  - ❖ Weak project management
- ❖ Start a science project
  - ❖ I think there's a way you can tell me ...
  - ❖ Follow the script

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## 10 Pitfalls to Avoid

- ❖ Fail to gain full buy-in
  - ❖ Executive staff, HR
  - ❖ Line managers, staff
- ❖ Under invest in training
  - ❖ Monitoring staff
  - ❖ Organization
- ❖ Fail to include business users
  - ❖ COO, CNO
  - ❖ CMO

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**10 Pitfalls to Avoid**

- ❖ Lack of clear documented processes
  - ❖ Tribal knowledge
  - ❖ Application upgrades
- ❖ Start backups and archives
  - ❖ Don't lose all your hard work
- ❖ Stop maintaining your system
  - ❖ Monitoring notifications
  - ❖ Period review of user accounts, audit history, extraction code
- ❖ Not fully utilizing your system
  - ❖ Monitor your progress
  - ❖ Benchmarking

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**Thank you!**



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## Contract Compliance

Getting Full Value from Your Business Arrangements  
Healthcare Contract Compliance  
April 2014  
Sue Ulrey

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CLAnet.com



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### Objectives of Today's Session and Agenda

- Why is Contract Compliance Important?
- Current Market Dynamics
- Techniques of Contract Compliance Reviews and Monitoring
- The Benefits of Establishing a Healthcare Contract Compliance Program
- Considerations in Reviewing Healthcare Contracts
- Your Questions Answered

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### Why is Contract Compliance Important?

- An increasing number of companies are engaging in commercial relationships with third parties in which payments and receipts are based upon *self-declarations* or *self-reporting*.
- Any company that has portions of its business, (especially Information Technology, healthcare and pharmacy benefit management), conducted by another party inherently faces control, revenue, and expense risks.
- Problems arise when risks associated with these relationships are not properly monitored and evaluated. For example, changing market conditions may trigger changes to key contract terms, such as:
  - Utilization Triggers
  - Service Level Agreements/Performance Guarantees
  - Pricing Tiers/Margins
  - Volume Discounts
  - Changes in Market Conditions
  - Changes in Regulatory Requirements

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**Current Market Dynamics**

- **Driving Factors**
  - Increasing competition
  - Disclosure and transparency of pricing
  - Broker involvement and increased focus on performance guarantees
  - Drivers from regulatory changes
  - Increased efficiency and timeliness
- **Impacts to Organizations**
  - Health care claim audits (for self-insured companies)
  - Rights to audit
  - Performance guarantees
  - Pricing tiers
  - Vendor relationships and rebates/pricing
- **All lead to increased focus on efficiency and effectiveness of business relationships**

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**Current Market Dynamics**

**The Causes of Undetected Reporting Errors are Typically Unintentional, yet the Consequences are Significant**

| Most Common Causes of Reporting Errors  | Results   |
|---|---|
| <ul style="list-style-type: none"><li>• Failure to devote sufficient resources to managing the contractual relationship</li><li>• System weaknesses result in failure to support compliance with contractual obligations</li><li>• Misunderstood, complex, and ambiguous agreements</li><li>• Failure to review self-report information provided by a business partner</li><li>• Less frequently, fraud (or upcoding/overutilization)</li></ul> | <ul style="list-style-type: none"><li>• SLAs operating levels not attained</li><li>• Most-favored customer pricing is not passed on</li><li>• Unauthorized purchase expenditures are bundled and billed to contract invoices</li><li>• Use of inaccurate contract billing rates</li><li>• Inappropriate use of sublicensing of intellectual property, processes, or equipment</li><li>• Inappropriate discounts or deductions</li><li>• Sub-licensed products without vendor authorization</li><li>• Contract non-compliance leading to breach in contract and vendor liability</li></ul> |

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**Techniques of Contract Compliance Reviews and Monitoring**

- Evaluate performance based on deliverables within the contract
- Process needs to be:
  - Conducted Regularly
  - Deliverables are Measurable
  - Measures are Verifiable
  - Proactive
- Address Themes and Emerging Trends
- Address Training/Education Needs
  - Clarity
  - Policies and Procedures
- Contingency Plans
- Dispute Resolution and Communication Protocols
- Exit Strategies
- Access to Records/Audit Rights
- On-Site/Off-Site Expectations
- Renew/Refresh Contracts
- Post Contract Review and Knowledge Sharing

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**Benefits of Establishing a Healthcare Contract Compliance Program**

- **Financial**
  - Recoveries can be/should be passed through to the organization
  - Pricing errors
- **Business Process Improvement**
  - Do you incorporate contractual provisions for operational and business opportunities?
  - Improved decision making on structure, costs, etc.
  - Performance reporting
- **Enhanced Contract Language**
  - Reduced ambiguity
  - Measurement of terms
  - Inclusion of audit rights and other performance requirements
- **Compliance with Qualitative Contract Terms**
  - Performance guarantees
  - Enhanced insight into operational and QA Processes
  - Rebates and pricing structures

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**Benefits of Establishing a Healthcare Contract Compliance Program**

- **Return on Investment**
  - Recovered cash
  - Self reporting of operational/claim units is often different than internal audit, corporate performance, or other audit units
  - Contracts must stipulate audit requirements
  - Pass through of Rebate volume discounts
- **Business Process Improvement**
  - Improved quality of information
  - Improved internal control and governance environment regarding costs
- **Enhance Contract Language and SLAs**
  - Enhance and refine SLAs
  - Improved measurement terms and metrics

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**Considerations in Reviewing Healthcare Contracts**

- Ownership of data. Often times, vendors will not allow direct access to audit claim information/files – but will include provisions for third parties to perform audits.
- Services Covered
- Settlement Authority
- Performance Guarantees/Penalties
- Exclusions
- Right to Audit Clauses
- Access to Data
- Record Retention Requirements
- Record Retention
- Regulatory – HIPAA, BAA

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**Considerations in Reviewing Healthcare Contracts**

**Governance**

- Does your organization have effective controls for timely and accurate reporting of key regulatory requirements?
- If organization does have access to claim files and related data – are appropriate compliance and access controls implemented:
  - Disclosure monitoring and reporting?
  - HIPAA?
  - Others (hotlines, etc.)

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**Your Questions Answered**

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## Therapy Utilization in Long-Term Care: Is It Really “Over-Utilization”

Shawn Halcsik DPT, MEd, OCS, RAC-CT, CPC, CHC  
Vice President of Compliance  
Evergreen Rehabilitation

Judith Bartlett  
Program Analyst  
Office of Evaluation and Inspections  
HHS Office of Inspector General

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Shawn Halcsik DPT, MEd, OCS, RAC-CT, CPC, CHC is the VP of Compliance at Evergreen Rehabilitation, a long term care contract therapy provider. In addition to bringing her vast experience as a physical therapist to the role, she also spent 3 ½ years as a Senior Medical Reviewer at a Medicare PSC where she provided subject matter expertise in coding, reimbursement, documentation, and Medicare regulations to internal and external customers including FBI, OIG, AG, and AUSA; performed pre/post pay review to identify overpayments, cost savings, and fraud/abuse issues; participated in onsite audits; and provided medical review perspective to data analysis, allegation triage, and special fraud/abuse proactive identification projects.

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Judy Bartlett, PhD, MPH, has been a Program Analyst with the evaluation branch of the HHS Office of Inspector General for 7 years. She has focused mostly on Medicare Part A (hospitals and SNFs). She has also worked in Medicare appeals, DME, and food safety. Prior to OIG, Judy worked at a federally-funded community health center in rural Virginia for many years. She developed and ran a Lay Health Promoter Program and later served as Chief Information Officer.

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### Objectives

- Brief overview of OIG Reports alleging therapy “overuse” from the perspective of both the OIG and the Provider
- Learn how to use OIG Reports combined with your PEPPER report and other data sources to identify areas of “overuse”
- Learn how to implement proactive continuous audit prep strategies to minimize audit risk

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### OIG’s Role: Therapy Utilization in SNFs

- OCIG/OI—Office of Counsel to the Inspector General
  - Acts as a full-service, in-house legal counsel
  - Offers advice and representation on HHS programs and operations, employment, administrative law issues, and criminal procedure;
  - Imposes program exclusions and civil monetary penalties on health care providers;
  - Represents OIG in the global settlement of cases arising under the civil False Claims Act, develops and monitors corporate integrity agreements, develops compliance program guidance; and
  - Renders advisory opinions on OIG sanctions and issues fraud alerts and other industry guidance
- OAS—Office of Audit Services
  - Provides assistance in criminal, civil, and administrative investigations conducted by OIG’s Office of Investigations and the Department of Justice;
  - Oversees non-Federal audit activity, including conducting quality control reviews of audits of State and local governments, colleges and universities, and nonprofit organizations; and
  - Oversees HHS’s annual financial statement audits conducted under the Chief Financial Officers Act and HHS’s annual Federal Information Security Management Act audits.
- OEI— Office of Evaluation and Inspections
  - Conducts national evaluations of HHS programs from a broad, issue-based perspective. The evaluations offer practical recommendations to improve the efficiency and effectiveness of HHS programs, with a focus on preventing fraud, waste, and abuse.

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**OEI's Role:  
Therapy Utilization in SNFs**

- OEI has a long history of evaluating the SNF Prospective Payment System
  - Is the PPS functioning well for beneficiaries, for SNFs, and for Medicare?
- Many of OEI's findings and recommendations have focused on therapy use in SNFs.
  - Is the PPS optimally designed to best align beneficiaries needs and SNFs therapy practices? If not, what changes are needed?
  - Are certain SNFs abusing the PPS? If so, how?
  - What interventions are needed to prevent abuse—e.g., audits, investigations, policy changes, etc.

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**OEI's Role:  
Therapy Utilization in SNFs**

- OEI policy recommendations
  - PPS rules and regulations
  - Guidance to contractors
- Implemented OEI recommendations
  - Therapy payment
- OEI referrals of individual SNFs
  - CMS
  - Other OIG branches
- OEI recommendations for provider education

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**OEI Reports: Non-Therapy**

- Medicare Nursing Home Resident Hospitalization Rates Merit Additional Monitoring, 11/13
- Hospital memo re: observation (had a finding regarding beneficiaries with long outpatient stays who don't qualify for SNF care), 7/13
- Care Planning & Discharge Planning Requirements, 2/13
- Report to Congress evaluating the Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long Term-Care Facilities and Providers, 10/12
- Gaps Continue To Exist in Nursing Home Emergency Preparedness and Response During Disasters, 4/12
- Payments for Medicare Part B Services During Non-Part A Nursing Home Stays, 7/11

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**OIG Report 12/2010:  
Questionable Billing By SNFs**

- SNFs increasingly billed for higher paying RUGS from 2006 to 2008 even though beneficiary characteristics remained largely unchanged
- Ultra high therapy RUGS increased from 17% in 2006 to 28% in 2008, resulting in payments increasing by nearly 90% from \$5.7 billion to \$10.7 billion
- Higher level of assistance with ADLs
- For-profit SNFs

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**OIG Report 11/2012:  
Inappropriate Payments to Skilled Nursing Facilities  
Cost Medicare More Than a Billion Dollars in 2009**

- SNFs billed one-quarter of all claims in error in 2009, resulting in \$1.5 billion in inappropriate Medicare payments.
  - 20.3% claims were upcoded
  - 2.5% downcoded
  - 2.1% did not meet Medicare coverage requirements.
- CMS should use its Fraud Prevention System to identify and target SNFs that have a high percentage of claims for ultrahigh therapy and for high levels of assistance with activities of daily living.

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**OIG Report 11/2012:  
Inappropriate Payments to Skilled Nursing Facilities  
Cost Medicare More Than a Billion Dollars in 2009**

- SNFs misreported information on the MDS for 47 percent of claims
  - **30.3% Therapy (i.e., physical, occupational, speech)**
  - 16.8% Special Care (e.g., intravenous medication, tracheostomy care)
  - 6.5% Activities of Daily Living (e.g., bed mobility, eating)
  - 4.8% Oral/Nutritional Status (e.g., parenteral feeding)

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2014 OIG Work Plan:  
Medicare Part A billing by skilled nursing facilities (new)

Policies and Practices. OIG will describe SNF billing practices in selected years and will describe variation in billing among SNFs in those years. Context—Prior OIG work found that SNFs increasingly billed for the highest level of therapy even though beneficiary characteristics remained largely unchanged. OIG also found that SNFs billed one-quarter of all 2009 claims in error, resulting in \$1.5 billion in inappropriate Medicare payments. CMS has made substantial changes to how SNFs bill for services for Medicare Part A stays. (OEI; 02-13-00610; 00-00-0000; various reviews; expected issue date: FY 2014; work in progress)

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OIG Report 11/2012:  
Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than a Billion Dollars in 2009:  
**What is Not Addressed in OIG Report**

- Quality of Care
- Provider Outcomes
  - Successful d/c to community??
  - Successful increase in function??
  - Successful decrease in caregiver burden??

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OIG Report 11/2012:  
Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than a Billion Dollars in 2009:  
**What does this mean to providers?**

- Increased scrutiny
  - Therapy Treatment Intensity
    - RU
    - RV
- Expect increased audits
  - MAC Probe/TMR
  - RAC
  - ZPIC

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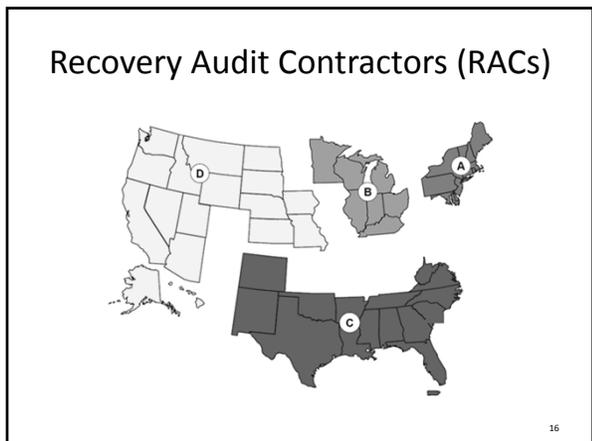
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### Recovery Audit Contractors (RACs)

Region A: Performant Recovery; Region B: CGI Federal, Inc;  
Region C: Connolly, Inc; Region D: HealthDataInsights, Inc.

| RAC                   | Issue   | Description   |
|-----------------------|---|---|
| C-Connelly            | Skilled Nursing Facility and Coding Validation – C004472013 | Will review Skilled Nursing Facility claims to determine the extent to which the Minimum Data Set (MDS) is accurate and supported by the patient's medical record. The entire benefit period will be reviewed to determine if the patient's level of care was appropriately billed. |
| D-HealthData-Insights | SNF Medical Necessity                                       | SNF stays will be reviewed for documentation of covered SNF services that are medically reasonable and necessary  |

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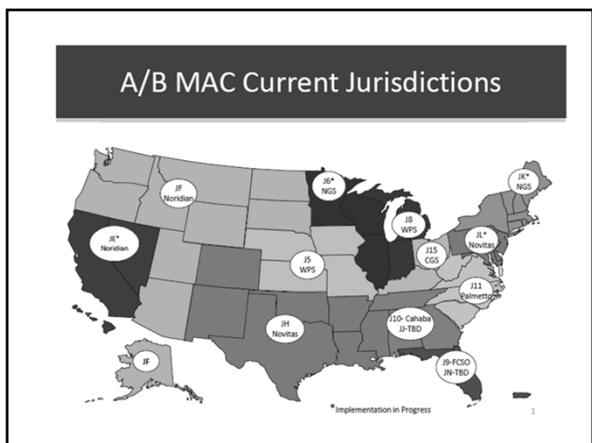
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### Medicare Administrative Contractors (MACs)

- Noridian JE
  - NV: RV
  - HI, MP, GU, AS: RU & RV
- WPS J8 and J5
  - RU, RV & RH
- Novitas JL
- Palmetto J11
- CGS J15
  - RUB10 and RUC10

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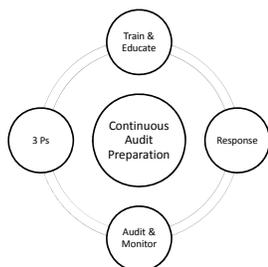
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### Mitigating Audit Risk with Continuous Audit Preparation Strategies

*It is not if you get audited, but when...*



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### Mitigating Provider Risk Strategy #1: Policy, Procedure & Process

- Minimize potential for misreporting on the MDS by evaluating and re-evaluating P&P related to MDS completion to ensure accurate reporting
  - Scheduled Assessment ARD Communication
  - Unscheduled Assessment Monitoring & Communication
  - **MDS Section O Verification**
- RUG Level Setting Process
  - How would therapists respond to question from investigator “How amount/intensity of treatment is determined for their patient?”
- LOS Determination Process
  - How would therapists respond to question from investigator related to pressure to keep on therapy

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**Mitigating Audit Risk Strategy #2:  
Audit and Monitor**

- Data, Data, Data
  
- Audit Tools
  - MDS Section O
  - COT
  
- Documentation Review

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**Mitigating Audit Risk Strategy #2:  
Audit and Monitor--Data**

- Let your data guide you
  - Monitoring to determine focus areas
    - Audit Plan
- Build Your Provider Profile
  - Use the same claim data as CMS, FI/MACs, RACs, and ZPICs
  - Good Starting Point: PEPPER Report
    - Next release: May 5 through May 12, 2014
  - Incorporate Clinical Outcomes with your Billing Data to create profile that examines quantity AND quality
    - CARE Tool, FIM, NOMS
- Evaluate and Explain
  - Know your data profile as good as, if not better than CMS, ZPICs, FI/MACs, and RACs

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**PEPPER Target Areas**

- Potentially at Risk for improper Medicare payments:
  - Therapy RUGs with High ADLs
  - Nontherapy RUGs with High ADLs
  - Change of Therapy Assessments
  - Ultrahigh Therapy RUGs
  - Therapy RUGs
  - 90+ Day Episodes of Care

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### COT

- If at/above 80th percentile:
  - SNF may be experiencing challenges with delivering services to the beneficiary
  - Look at factors that lead to the need for the COT
    - Communication between disciplines
    - Missed therapy due to appointments, scheduling
    - Scheduling conflicts
- If at/below 20th percentile (\*High risk for audit):
  - Review process in facility for IDT review of minutes
  - MDS audits: Coding correctly?
  - Consider LOS impact

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### 90+ Day Episode of Care

- If at/above 80th percentile:
  - Could indicate that the SNF is continuing treatment beyond point where services are medically necessary
- If at/below 20th percentile:
  - Review to assure that patients receive all necessary treatments prior to discharge

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### Ultra High Therapy RUGs Therapy RUGs

- If at/above 80th percentile
  - Could indicate SNF is improperly billing for therapy services.
  - Is clinical intensity appropriate based on patient need?
- If at/below 20th percentile
  - Is clinical intensity appropriate based on patient need?
  - Is staffing appropriate?

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### PEPPER Data Reports--SNF

- National Target Area Analysis
- National Top 20 Resource Utilization Groups (RUGs)
- National Top 20 Resource Utilization Groups (RUGs) for 90+day episodes of care
- State Target Area Analysis
- State Top 20 Resource Utilization Groups (RUGs)
- State Top 20 Resource Utilization Groups (RUGs) for 90+day episodes of care
- SNF Target Percent Boundaries for Free-standing SNFs and Short-term Acute Care Hospital-based SNFs

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| Target Area                        | FY2012 National |
|------------------------------------|-----------------|
| Therapy RUGs with High ADLs        | 34.5%           |
| NonTherapy RUGs with High ADLs     | 21.5%           |
| Change of Therapy (COT) Assessment | 10.4%           |
| Ultra High Therapy RUGs            | 52.7%           |
| Therapy RUGs                       | 90.3%           |
| 90+ Day Episodes of Care           | 8%              |

Source: PEPPER State Target Analysis; <http://www.pepperresources.org/Data.aspx#SNF>  
Handout provides breakdown by state.

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### Mitigating Provider Risk Strategy #2 Audit & Monitor--Audit Tools

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### Outcome Example

| Provider | LOS  | Target | Variance |
|----------|------|--------|----------|
| A        | 12.7 | 10.5   | 21%      |
| B        | 14.2 | 14     | 2%       |

| Provider | D/C Score | Target | Variance |
|----------|-----------|--------|----------|
| A        | 44        | 49     | 10%      |
| B        | 33.6      | 34     | 1%       |

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### Mitigating Audit Risk Strategy #2: Audit and Monitor--Documentation Review

- Medical Necessity = Therapy Plans of Care are individual, pt. centered, and match patient clinical presentation
  - RUG Level (treatment intensity) and LOS (treatment duration)
    - # disciplines
    - d/c destination
    - **Level (severity) of decline from PLOF**
    - Diagnosis vs. Complexities/co-morbidities

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### The Relation Between Therapy Intensity and Outcomes of Rehabilitation in Skilled Nursing Facilities

Jette, Warren & Wirtalla  
Archives of Physical Med & Rehab Vol 86, March 2005

- Higher therapy intensity was associated with shorter LOS

| Total Tx Intensity | Stroke LOS | Ortho LOS | Cardiopulm LOS |
|--------------------|------------|-----------|----------------|
| <1                 | 21.4       | 14.9      | 14             |
| 1-1.5              | 16.9       | 12.4      | 11.9           |
| >1.5               | 15.5       | 10.8      | 9.5            |

- Increased Intensity and Function
  - Mobility Domain Increased with Increased Intensity in PT, OT and ST
  - ADL Domain Increased with Increased Intensity in PT and OT

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### Documentation Review

- Daily Skill Supported in Documentation
  - Therapy services are considered skilled when they are so inherently complex that they can be safely and effectively performed only by, or under the supervision of, a qualified therapist.
- Technical Minute Recording
  - Eval Time recorded as NonMDS
  - Modality Minutes only skilled counted as MDS
  - Set Up Time
  - Re-eval Time
  - Co-treat minutes
- Static Patterns
  - Eval Time
  - Treatment time distribution

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### Mitigating Provider Risk Strategy #3: Training and Education

- MDS vs. non MDS minutes
  - Eval vs. re-eval
  - Modality Time
  - Set up
- Individual, Concurrent, Group Definitions
- Documentation
  - Technical
  - Skill

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### Mitigating Provider Risk Strategy #4: Audit Response

- Be prepared to respond to documentation requests
  - FI/MAC Probe, ZPIC Audit, RAC Audit
- Process for identifying ADRs and submission in place
  - Timely
  - Ongoing
  - Coordination with Therapy Provider
  - Submit all necessary documentation not just requested dates!!
- Process in place for denial response and appeal
- Performance Improvement Plans Addressing Denial Trends

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### What Do I Include?

#### PPS

- Physician certification for the PPS stay
  - Admission
  - The first re-certification is required no later than the 14th day.
  - Subsequent re-certifications are required no later than 30 days after the date of the most recent prior re-certification.
- Physician's admission history and physical notes, consultations and progress notes
- Orders
- Hospital discharge summary and transfer referral form
- Social service notes
- Medication administration notes
- Test results
- Itemized bill

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### What Do I Include?

#### PPS

- MDS assessments
- Nurse's notes
  - Nursing skilled service support
  - ADL score support
- Rehabilitation records must include:
  - Initial evaluation
  - All reevaluations
  - Progress notes
  - Treatment Encounter Notes
  - Service Log Matrix showing **minutes of services** rendered for physical, occupational, speech, and/or nursing rehabilitation records
- Interdisciplinary Team notes

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### Importance of the Look Back Period Example

ADR for dates of service 5/1/2010-5/19/2010

| Assessment | ARD  | Payment Dates   | Look Back Period |
|------------|------|-----------------|------------------|
| 5 Day      |      | 1-14: 4/7-4/20  |                  |
| 14 Day     | 4/17 | 15-30: 4/21-5/6 | 4/11-4/17        |
| 30 Day     | 4/27 | 31-60: 5/7-5/19 | 4/21-4/27        |

**Critical Dates to Support RUG Require April Documentation**

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## Appeal Process

- Review your results carefully
  - Denial Reason, Sampling, Overpayment Calculation
- Don't miss a deadline

| Appeal Level                    | Time To Submit | Reviewer   |
|---------------------------------|----------------|--|
| Redetermination                 | 120 days       | Medicare Administrative Contractor (MAC), carrier, or Fiscal Intermediary (FI) |
| Reconsideration                 | 180 days       | Qualified Independent Contractor (QIC)   |
| ALJ                             | 60 days        | ALJ  |
| Medicare Appeals Council review | 60 days        | The Appeals Council is within HHS  |
| US District Court               | 60 days        | U.S. District court judge  |

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### Mitigating Provider Risk Strategy #4: Audit Response--Performance Improvement Plans

- Monitor denial rates
- Monitor denial trends
- Based on root cause analysis
  - 5 whys
- Desired outcome must be objective and measurable

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## Take Away Checklist

- Zero Tolerance for MDS Misreporting
  - MDS Section O verification
  - Scheduled Assessment ARD Communication
  - Unscheduled Assessment Communication
  - Triple Check--RUG level and days
- Therapy Intensity (RUG) Setting must be based on clinician input and clinical judgment
- Discharges (LOS) are timely and based on clinical presentation of patient
- Must look at quantity AND quality

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 **Questions** 

Shawn Halcsik  
[shalcsik@evergreenrehab.com](mailto:shalcsik@evergreenrehab.com)  
414-791-9122

Judy Bartlett  
[Judith.bartlett@oig.hhs.gov](mailto:Judith.bartlett@oig.hhs.gov)  
212-264-2254

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**Change of Therapy (COT) Assessment Audit Tool**

| Patient Id'r |            | COT Checkpt #1 | COT Checkpt #2 | COT Checkpt #3 | COT Checkpt #4 | COT Checkpt #5 | COT Checkpt #6 | COT Checkpt #7 | COT Checkpt #8 | COT Checkpt #9 | COT Checkpt #10 | COT Checkpt #11 | COT Checkpt #12 | # Match | # COT Checkpts |
|--------------|------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|-----------------|-----------------|-----------------|---------|----------------|
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG supp'd |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |
|              | RUG billed |                |                |                |                |                |                |                |                |                |                 |                 |                 |         |                |

**PEPPER Target Area Summary FY2012**

| State         | Therapy RUG with High ADL % | NonTherapy RUG with High ADL % | COT % | UltraHigh RUG % | Therapy RUG % | Therapy RUG Avg. LOS | 90+ Day Episode of Care % |
|---------------|-----------------------------|--------------------------------|-------|-----------------|---------------|----------------------|---------------------------|
| Alabama       | 37.7                        | 26.1                           | 9.1   | 52.7            | 90            | 18                   | 7.1                       |
| Alaska        | 24.6                        | 3.2                            | 15.4  | 10.7            | 69.4          | 18                   | 6.5                       |
| Arizona       | 27.8                        | 12.9                           | 10.4  | 56.8            | 91            | 16.6                 | 3                         |
| Arkansas      | 35.6                        | 26.7                           | 10    | 48.4            | 86.5          | 19.9                 | 6.7                       |
| California    | 37                          | 16.6                           | 7.8   | 63.4            | 91.4          | 20.8                 | 9.3                       |
| Colorado      | 31.4                        | 15.8                           | 11.7  | 58              | 92.7          | 17.3                 | 4.8                       |
| Connecticut   | 36.1                        | 22.1                           | 10.6  | 43.3            | 86.5          | 16.9                 | 5.4                       |
| Delaware      | 32.4                        | 15.8                           | 9.7   | 65.9            | 93.4          | 20.7                 | 7.4                       |
| DC            | 33.1                        | 28                             | 10.7  | 37.8            | 91.4          | 18                   | 5.7                       |
| Florida       | 34.6                        | 23.7                           | 9.7   | 70.4            | 93.3          | 20.3                 | 8.3                       |
| Georgia       | 34.1                        | 22.4                           | 11    | 43.6            | 87.3          | 19.9                 | 9.1                       |
| Hawaii        | 24.2                        | 14.7                           | 11.9  | 52.9            | 86.9          | 19.8                 | 6                         |
| Idaho         | 31.8                        | 13.3                           | 14.4  | 49.8            | 90            | 17.9                 | 6.6                       |
| Illinois      | 28.2                        | 20.5                           | 9.3   | 49.2            | 93.2          | 21.1                 | 10.2                      |
| Indiana       | 35.4                        | 23.2                           | 10.4  | 46.6            | 93.1          | 22.2                 | 13.5                      |
| Iowa          | 33.2                        | 14.8                           | 9.7   | 23.7            | 88.7          | 17.4                 | 3.6                       |
| Kansas        | 29.4                        | 19.4                           | 10.9  | 41.9            | 90.5          | 19.8                 | 5.8                       |
| Kentucky      | 45.5                        | 25.5                           | 10    | 47.4            | 87.5          | 19.8                 | 9.5                       |
| Louisiana     | 33.4                        | 25.8                           | 7.2   | 43.4            | 91.5          | 25.5                 | 17.5                      |
| Maine         | 30.2                        | 15.7                           | 11.6  | 49.2            | 90.2          | 16.2                 | 3.6                       |
| Maryland      | 30.6                        | 17.4                           | 10.6  | 57.8            | 88.5          | 18.2                 | 6                         |
| Massachusetts | 33.7                        | 19.8                           | 10.6  | 59.3            | 87.9          | 17.5                 | 5.7                       |
| Michigan      | 28.4                        | 17.5                           | 10.7  | 53.7            | 91.5          | 19                   | 6.6                       |
| Minnesota     | 30.6                        | 16.5                           | 10.7  | 33.9            | 90.2          | 16                   | 3.5                       |
| Mississippi   | 38.3                        | 29.3                           | 8.3   | 46.8            | 90.7          | 23.7                 | 15.5                      |
| Missouri      | 27.1                        | 17.4                           | 11.2  | 37.8            | 90.5          | 19.3                 | 6.6                       |
| Montana       | 25.4                        | 12.8                           | 13.4  | 22.4            | 86.9          | 17.9                 | 6.8                       |
| Nebraska      | 29.8                        | 17.4                           | 11.9  | 35              | 89.1          | 18.7                 | 6                         |
| Nevada        | 31.9                        | 11.6                           | 12.3  | 58.7            | 89.6          | 18.5                 | 6.4                       |
| New Hampshire | 30.3                        | 14.4                           | 12    | 62.3            | 87.1          | 18.5                 | 9.4                       |
| New Jersey    | 33.7                        | 22.7                           | 8.4   | 63.5            | 90.6          | 18.5                 | 4.9                       |
| New Mexico    | 28                          | 16.7                           | 11.6  | 50.5            | 89.9          | 18.4                 | 6.4                       |
| New York      | 36.9                        | 32.6                           | 7.6   | 48.9            | 86.9          | 20.6                 | 7.9                       |
| N. Carolina   | 32.1                        | 15.5                           | 12.5  | 45.4            | 89.9          | 18.6                 | 8                         |
| N. Dakota     | 38                          | 21.1                           | 10.4  | 20.9            | 79.3          | 18.1                 | 5.4                       |
| Ohio          | 35.6                        | 22                             | 10.7  | 55.9            | 91.6          | 19.2                 | 6.9                       |
| Oklahoma      | 27.2                        | 16.5                           | 8.2   | 38.6            | 86.8          | 20.1                 | 6.3                       |
| Oregon        | 34.7                        | 12.8                           | 13.5  | 50.5            | 92.8          | 16.7                 | 3.9                       |
| Pennsylvania  | 46.5                        | 25.1                           | 10.7  | 51              | 91.4          | 19.2                 | 7.1                       |
| Puerto Rico   | 4.8                         | 0.8                            | na    | 1.9             | 65.6          | 11.4                 | na                        |
|               |                             |                                |       |                 |               |                      |                           |

**PEPPER Target Area Summary FY2012**

| State        | Therapy RUG with High ADL % | NonTherapy RUG with High ADL % | COT % | UltraHigh RUG % | Therapy RUG % | Therapy RUG Avg. LOS | 90+ Day Episode of Care % |
|--------------|-----------------------------|--------------------------------|-------|-----------------|---------------|----------------------|---------------------------|
| Rhode Island | 25.1                        | 12.9                           | 8     | 61.8            | 91.4          | 18.2                 | 4.8                       |
| S. Carolina  | 32.1                        | 20                             | 12.6  | 50.6            | 90.8          | 20.2                 | 10.3                      |
| S. Dakota    | 30.3                        | 17                             | 11.6  | 30.1            | 86.9          | 19.7                 | 7.7                       |
| Tennessee    | 42.2                        | 26.9                           | 12.7  | 55.4            | 88.2          | 20.6                 | 12.4                      |
| Texas        | 36.1                        | 23.8                           | 11.8  | 52.3            | 89.7          | 21                   | 11.5                      |
| Utah         | 34.7                        | 17.4                           | 10.8  | 61.3            | 95.3          | 18.6                 | 5.4                       |
| Vermont      | 35.8                        | 16.1                           | 13.4  | 43.9            | 85            | 18                   | 8.4                       |
| Virginia     | 30.6                        | 17.9                           | 14.9  | 43.3            | 89.5          | 18                   | 6.6                       |
| Washington   | 37.4                        | 19                             | 13.7  | 57.3            | 88.4          | 17.8                 | 7.2                       |
| W. Virginia  | 42.2                        | 21.2                           | 12.7  | 48              | 88.3          | 19.3                 | 8                         |
| Wisconsin    | 32.8                        | 18                             | 11.2  | 42.1            | 91.8          | 18.5                 | 6.4                       |
| Wyoming      | 28.7                        | 14.9                           | 14.7  | 42.7            | 83.3          | 19.3                 | 10.3                      |
| National     | 34.5                        | 21.5                           | 10.4  | 52.7            | 90.3          | 19.5                 | 8                         |

Source: PEPPER State Target Analysis; <http://www.pepperresources.org/Data.aspx#SNF>

**Section O Audit Tool**

| Patient Id'r | ARD |       | Physical Therapy |      |     |      | Occupational Therapy |      |     |      | Speech Therapy |                  |              |      | Score   |            |
|--------------|-----|-------|------------------|------|-----|------|----------------------|------|-----|------|----------------|------------------|--------------|------|---------|------------|
|              |     |       | Individ          | Conc | Grp | Days | Individ              | Conc | Grp | Days | Individ        | Conc             | Grp          | Days | # Match | # Possible |
|              |     | MDS   |                  |      |     |      |                      |      |     |      |                |                  |              |      |         | 12         |
|              |     | Doc'n |                  |      |     |      |                      |      |     |      |                |                  |              |      |         |            |
|              |     | MDS   |                  |      |     |      |                      |      |     |      |                |                  |              |      |         | 12         |
|              |     | Doc'n |                  |      |     |      |                      |      |     |      |                |                  |              |      |         |            |
|              |     | MDS   |                  |      |     |      |                      |      |     |      |                |                  |              |      |         | 12         |
|              |     | Doc'n |                  |      |     |      |                      |      |     |      |                |                  |              |      |         |            |
|              |     | MDS   |                  |      |     |      |                      |      |     |      |                |                  |              |      |         | 12         |
|              |     | Doc'n |                  |      |     |      |                      |      |     |      |                |                  |              |      |         |            |
|              |     | MDS   |                  |      |     |      |                      |      |     |      |                |                  |              |      |         | 12         |
|              |     | Doc'n |                  |      |     |      |                      |      |     |      |                |                  |              |      |         |            |
|              |     | MDS   |                  |      |     |      |                      |      |     |      |                |                  |              |      |         | 12         |
|              |     | Doc'n |                  |      |     |      |                      |      |     |      |                |                  |              |      |         |            |
|              |     | MDS   |                  |      |     |      |                      |      |     |      |                |                  |              |      |         | 12         |
|              |     | Doc'n |                  |      |     |      |                      |      |     |      |                |                  |              |      |         |            |
|              |     | MDS   |                  |      |     |      |                      |      |     |      |                |                  |              |      |         | 12         |
|              |     | Doc'n |                  |      |     |      |                      |      |     |      |                |                  |              |      |         |            |
|              |     | MDS   |                  |      |     |      |                      |      |     |      |                |                  |              |      |         | 12         |
|              |     | Doc'n |                  |      |     |      |                      |      |     |      |                |                  |              |      |         |            |
|              |     | MDS   |                  |      |     |      |                      |      |     |      |                |                  |              |      |         | 12         |
|              |     | Doc'n |                  |      |     |      |                      |      |     |      |                |                  |              |      |         |            |
|              |     | MDS   |                  |      |     |      |                      |      |     |      |                |                  |              |      |         | 12         |
|              |     | Doc'n |                  |      |     |      |                      |      |     |      |                |                  |              |      |         |            |
|              |     |       |                  |      |     |      |                      |      |     |      | <b>SCORE</b>   | <b>% Correct</b> | <b>Total</b> |      |         |            |

## Links to OEI Reports Related to Nursing Homes

(See next page for Links to OEI reports on SNF Part A Billing)

| Title (and hyperlink)  | OEI Number      | Date of Publication | Nursing Home Topic                  |
|--|-----------------|---------------------|-------------------------------------|
| <a href="#">Hospitals' Use of Observation Stays and Short Inpatient Stays for Medicare Beneficiaries</a>   | OEI-02-12-00040 | July 2013           | Access to SNF Care                  |
| <a href="#">Skilled Nursing Facilities Often Fail To Meet Care Planning and Discharge Planning Requirements</a>  | OEI-02-09-00201 | February 2013       | Care Planning / Discharge Planning  |
| <a href="#">Medicare Hospices That Focus on Nursing Facility Residents</a>   | OEI-02-10-00070 | July 2011           | Hospice in SNF/NFs                  |
| <a href="#">Adverse Events in Skilled Nursing Facilities: National Incidence Among Medicare Beneficiaries</a>  | OEI-06-11-00370 | February 2014       | Adverse Events                      |
| <a href="#">Medicare Nursing Home Resident Hospitalization Rates Merit Additional Monitoring</a>   | OEI-06-11-00040 | November 2013       | Hospitalization of SNF/NF Residents |
| <a href="#">Payments for Medicare Part B Services During Non-Part A Nursing Home Stays in 2008</a>   | OEI-06-07-00580 | July 2011           | Part B Billing in SNF/NFs           |
| <a href="#">Nursing Facility Assessments and Care Plans for Residents Receiving Atypical Antipsychotic Drugs</a>   | OEI-07-08-00151 | July 2012           | Atypical Antipsychotic Drugs        |
| <a href="#">Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents</a>   | OEI-07-08-00150 | May 2011            |                                     |
| <a href="#">Nationwide Program for National and State Background Checks for Long-Term-Care Employees-Results of Long-Term-Care Provider Administrator Survey</a> | OEI-07-10-00421 | October 2013        | Background Checks for Employees     |
| <a href="#">Criminal Convictions for Nurse Aides With Substantiated Findings of Abuse, Neglect, and Misappropriation</a>   | OEI-07-10-00422 | October 2012        |                                     |
| <a href="#">Nursing Facilities' Employment of Individuals With Criminal Convictions</a>  | OEI-07-09-00110 | March 2011          |                                     |
| <a href="#">Gaps Continue To Exist in Nursing Home Emergency Preparedness and Response During Disasters: 2007-2010</a>   | OEI-06-09-00270 | April 2012          | Emergency Preparedness              |

## Links to OEI reports on SNF Part A Billing

(See next page for associated recommendations)

| Title (and hyperlink)  | OEI Number      | Date of Publication | Primary Methodology                             | Analysis Timeframe                            |
|--|-----------------|---------------------|---|---|
| <a href="#">Questionable Billing by Skilled Nursing Facilities</a>   | OEI-02-09-00202 | December 2010       | Analysis of SNF claims                          | 2006 to 2008                                  |
| <a href="#">Changes in Skilled Nursing Facilities Billing in Fiscal Year 2011</a>                                      | OEI-02-09-00204 | July 2011           | Analysis of SNF claims                          | Last half of FY 2010 to first half of FY 2011 |
| <a href="#">Inappropriate Payments to Skilled Nursing Facilities Cost Medicare More Than a Billion Dollars in 2009</a> | OEI-02-09-00200 | November 2012       | Medical record review of a sample of SNF claims | 2009  |
| To be determined   | OEI-02-13-00610 | ~Fall 2014          | Analysis of SNF claims                          | FYs 2011 to 2013                              |

## **Recommendations to CMS from OEI Reports on SNF Part A Billing**

### **Regarding the Design of the Payment System**

Change the current method for determining how much therapy is needed to ensure appropriate payments

Monitor overall payments to SNFs and adjust rates, if necessary

Adjust payment rates to address the significant increases in payments to SNFs

Make RUGs and Medicare payments more consistent with beneficiaries' care and resource needs

### **Regarding the Use of the Payment System**

Strengthen monitoring of SNFs that are billing for higher paying RUGs

Use Its Fraud Prevention System To Identify SNFs That Are Billing for Higher Paying RUGs

Increase and Expand [Medical] Reviews of SNF Claims

Monitor Compliance With the New Therapy Assessments

Improve the Accuracy of MDS Items

Follow up on the SNFs identified as having questionable billing

Follow up on the SNFs That Billed in Error



## Privacy and Security Challenges in Integrated Care

Presented by: **H. M. (Tim) Timmons, Jr.**  
CCEP, CHPC, CHP, CHSS

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## Personal Introduction

Current responsibilities

- ♦ Corporate integrity (compliance and privacy) officer for an organization that used to be a managed care organization delivering mental health services to Medicaid beneficiaries in 16 rural counties in Oregon
- ♦ GOBHI is now a partner or stakeholder in three coordinated care organizations in Oregon covering 17 rural counties

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## What are the Objectives of Integrated Care?

Adopted by the Centers for Medicare and Medicaid (CMS), the goals of the *Triple Aim* are defined as:

- ♦ Improving the patient experience of care (including quality and satisfaction)
- ♦ Improving the health of populations
- ♦ Reducing the per capita cost of healthcare

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### Weaknesses of the Current Health Care Delivery System

The existence of silos in the health care delivery system results in:

- ◆ Unnecessary costs – redundancy of tests, paperwork
- ◆ Limited access to health care – for segments of the population
- ◆ Operational inefficiencies and the potential for compromised outcomes and quality due to lack of communication among providers

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### Weaknesses of the Current Health Care Delivery System

- ◆ More fundamentally, it does not support an integrated effort to improve the health of the population by addressing the conditions that drive both the need for and the cost of medical care

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### Information Needs to Achieve the Triple Aim

- ◆ To achieve the Triple Aim, information has to flow synergistically across all domains, through all business process and among all authorized users
- ◆ In order for that to happen, however, existing privacy and security laws need to be re-examined within the context of integrated care

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# Privacy Challenges

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## Patients' Lack of Trust

- ♦ If individuals and other participants in a network lack trust in the exchange of information due to perceived or actual risks to their individually identifiable health information, or the accuracy and completeness of such information, they may be unwilling to consent to the disclosure of electronic PHI

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## Consequences of Lack of Trust

A lack of willingness to consent to the disclosure of PHI to all the integrated care stakeholders:

- ♦ Could have life-threatening consequences
- ♦ Would compromise the efficiency of the delivery system
- ♦ Would make it much more difficult to capture the analytics necessary to report on outcomes, cost efficiency of treatment, provider performance, quality of care and improvements in the health of the population

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### Barriers to Sharing PHI

Some of the stakeholders are not HIPAA covered entities

- ♦ Schools – partners in addressing the needs of children
- ♦ Child welfare agencies – child abuse investigations
- ♦ Senior services agencies – elder abuse investigations
- ♦ Developmental disabilities agencies
- ♦ County commissioners – the county jail ends up being the last resort for untreated, chronically ill individuals

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### Paradigm Shift

- ♦ In order to accomplish health system transformation, coordinated care organizations need to identify the underlying causes of the need for health care services (the social determinants of health), their current capacity to address those causes, and then develop and implement a plan for improvement (including benchmarks and evaluation points)

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### Paradigm Shift

Examples of the social determinants of health include:

- ♦ Poverty
- ♦ Early childhood development
- ♦ Social exclusion/discrimination
- ♦ Unemployment
- ♦ Social support networks
- ♦ Addiction
- ♦ Availability of healthy food
- ♦ Availability of transportation

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### Paradigm Shift

- ◆ Personal information related to some of those factors, such as addiction or discrimination based on sexual preference, is extremely sensitive and may be difficult to capture

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### A&D Restrictions on the Disclosure of PHI

- ◆ 42 CFR Part 2 raises the bar for protecting PHI belonging to individuals seeking or receiving treatment in alcohol and drug treatment programs
- ◆ Part 2 applies to any individual or entity that is federally assisted and holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment (42 CFR § 2.11)
- ◆ No TPO exceptions for the disclosure of A&D PHI without authorization

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### A&D Restrictions on the Disclosure of PHI

Two of the very few exceptions to the requirement for all disclosures of PHI to be authorized are:

- ◆ Disclosures to qualified service organizations (similar to business associates)
- ◆ The minimum necessary information may be shared with the organization that has administrative control over the A&D program

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### A&D Restrictions on the Disclosure of PHI

Part 2 authorization requirements are sometimes more stringent than those in the Privacy Rule

- A prohibition against any further disclosure of the PHI by the party receiving the information

The Privacy Rule requirements are sometimes more stringent than those contained in Part 2

- A statement that the provider cannot require the patient to sign the authorization in order to receive treatment or payment or to enroll or be eligible for benefits

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### Security Challenges

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### Paradigm Shift

- The Triple Aim signals a significant shift in emphasis from medical treatment to improving the health of the population and the patients' experience when receiving health care
- In order to fulfill the Triple Aim, there is a need to facilitate electronic health information exchange in a way that supports the exchange of PHI among participating providers to transform a volume-based, transaction oriented system to a value-based delivery system

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### Performance Metrics

The plan for improvement should include benchmarks and evaluation points in the following areas:

- Analytics used in reporting outcomes measures to the CCO’s provider network to assess indicators such as provider performance, effectiveness and cost-efficiency of treatment
- Quality reporting to support quality improvement within the CCO’s provider panel and to report the data on quality of care necessary for the CMS or a state agency to monitor the CCO’s performance

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### Security Challenges Associated with Patient Choice

- ONC Privacy & Security Program Information Notice (PIN):

“Where HIE entities serve solely as information conduits for directed exchange of individually identifiable health information (IIHI) and do not access IIHI or use IIHI beyond what is required to encrypt and route it, patient choice is not required beyond existing law.”

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### Security Challenges Associated with Patient Choice

- But, the ONC goes on to say “Where HIE entities store, assemble, or aggregate IIHI beyond what is required for an initial directed transaction, HIE entities should ensure individuals have meaningful choice regarding whether their IIHI may be exchanged through the HIE entity. This type of exchange will likely occur in a query/response model or where information is aggregated for analytics or reporting purposes.”

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### Tension Between Existing National Policy Priorities

- ♦ The need for all the providers and stakeholders involved in improving health status and providing health care to have timely access to the patient's health information

AND

- ♦ The importance of giving individuals the right to exercise some degree of control over access to their health information

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### Consequences of Opting Out

Patients opting out:

- ♦ Force providers to either go back to faxing or mailing records, or to use directed exchange to share PHI for treatment purposes, which obviously decreases operational efficiency and realistically precludes multiple exchanges with multiple integrated providers
- ♦ Makes it practically impossible to collect the analytics required for reporting outcomes measures and other performance metrics

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### Security Challenges Associated with Patient Choice

- ♦ Among the population opting out of allowing ePHI to be shared without authorization, the chronically ill patients (who account for the majority of the costs to the Medicaid system and whose quality of care and access to care are often compromised) are perhaps more likely to opt out than the general population, compromising the ability to gather the statistics on the efficacy of health reform for this critical group of patients

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### HIE Challenges for Behavioral Health Programs

- ◆ Behavioral health providers who meet certain criteria can receive incentive payments for the adoption of health information technology, but behavioral health programs do not
- ◆ The Behavioral Health Information Technology Act (H.R. 2957 and S.1517) would add community mental health centers, psychiatric hospitals, mental health treatment programs and substance abuse treatment centers to the list of organizations eligible for federal incentive payments

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### HIE Challenges for Behavioral Health Organizations

- ◆ Lack of broadband capabilities in rural/remote areas
- ◆ Lack of funds to invest
- ◆ Lack of expertise in smaller provider organizations
- ◆ EHR systems that don't communicate with each other
- ◆ Lack of comprehensive security policies and safeguards
- ◆ Independence of county behavioral health programs

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### Other HIE Challenges

- ◆ Beyond the actual technology issues involved with keeping patient data exchange secure are deeper worries related to governance – HIEs require competing healthcare entities to trust one another
- ◆ Besides fears among competing healthcare providers sharing data about one's patients, other worries include whether a healthcare provider will be somehow dragged into a negative public spotlight or be liable if one of their HIE partners experiences a data breach

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### Other HIE Challenges

- ◆ Sustainability is a function of the number of partners participating in the HIE and commitment by large organizations that carry the regional effort
- ◆ If an HIE loses a big player over issues involving trust or secure data access and exchange, sustainability will be compromised

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### The Ultimate Challenge

- ◆ The ultimate problem, however, is that you're dependent upon the people sharing the health information to comply with Federal and State laws and your privacy and security policies and procedures
- ◆ That highlights the importance of a culture of compliance which is supported by ongoing education, auditing and monitoring, and ensuring there are consequences for non-compliance

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### The Ultimate Challenge

- ◆ Healthcare providers need to earn the patient's trust that his/her ePHI will be protected and not made accessible to someone who shouldn't or doesn't need to see it if HIE is going to contribute to the success of integrated care
- ◆ News about the compromise of the security of personal information at the NSA, Target and others only exacerbate the fears regarding the effectiveness of security measures
- ◆ Our work is cut out for us

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**QUESTIONS?**

Tim Timmons  
Corporate Integrity Officer  
Greater Oregon Better Health Initiative

[tim.timmons@gobhi.net](mailto:tim.timmons@gobhi.net)  
Phone: 503-931-9867

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## Common Compliance Mistakes In Physician Practices

**Sandy Giangreco, RHIT, CCS, RCC, CPC, CPC-H, CPC-I, COBGC, PCS**

Senior Consultant - The Haugen Consulting Group

**Kim Huey, MJ, CPC, CCS-P, PCS, CPCO**

KGG Coding and Reimbursement Consulting, LLC

2014 HCCA Compliance Institute

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## First Rule of Healthcare Compliance

If it makes sense from a  
business standpoint,  
you generally can't do it in  
healthcare.

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## Physician Responsibility

Physicians are responsible for knowing  
Medicare (federal health care) policy if:

- The Medicare contractor (MAC) gives written notice to the particular physician
- The Medicare contractor (MAC) provides general notice to the medical community concerning the policy or rule
- The policy or rule is in the Federal regulations

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**Mandatory Compliance Plans?**

Mandated under PPACA – but CMS has not released the regulations and requirements and has indicated that they have many other higher priorities –

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**Seven Steps to Compliance**

OIG Compliance Program Guidance for Individual and Small Group Physician Practices

- Conducting internal monitoring and auditing
- Implementing compliance and practice standards
- Designating a compliance officer or contact
- Conducting appropriate training and education
- Responding appropriately to detected offenses and developing corrective action
- Developing open lines of communication
- Enforcing disciplinary standards through well-publicized guidelines

<https://oig.hhs.gov/authorities/docs/physician.pdf>

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**Compliance Mistakes**

- Not checking the exclusion list(s)
- Not auditing or auditing with the wrong focus
- Not evaluating the gray areas in coding and billing
- Not monitoring relationships
- Extending “professional courtesy”
- Not conducting exit interviews
- Believing everything a vendor tells you
- Implementing electronic medical records without coding/compliance involvement

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### Excluded from Medicare

Cannot employ anyone who has been excluded from the Medicare program

Cannot receive funds from any federal program during period of exclusion

Check exclusion list for all employees

<http://oig.hhs.gov/fraud/exclusions/listofexcluded.html>

Possible penalty of \$10,000 for each claim/service

Separate exclusion list for Medicaid that should be checked monthly.

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### Not Auditing?

- "Head in the Sand" approach
- Many smaller practices have no guidance with coding issues
- Minimal amount spent on auditing today could save maximum amounts of money in recoupments

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### Auditing

- Coding and Billing
- HIPAA
- Other areas such as Stark, Anti-Kickback, employment policy

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### Auditing with the Wrong Focus?

- Internal auditing only
- Choosing the wrong auditor
- Auditing based on the wrong parameters
- Not repaying or resubmitting after audit
- No followup education
- Thinking that Attorney-Client privilege provides unlimited protection

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### Internal Auditing Only?

- “Fox watching the henhouse” effect
- Physicians may listen more attentively to an outside consultant
- Outside auditors bring experience and ideas from other clients
- Expertise that you cannot afford on a daily basis

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### Choosing The Wrong Auditor?

Although you want to have at least some of your audits performed by an outside auditor, you want to choose someone with:

1. Experience in your specialty
2. Familiarity with your payers

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### Why Audit?

- As part of compliance plan
- Concurrent with payer review
  
- Because you think you ought to?
  
- The WHY determines the scope, the sample, the methodology, the reporting....

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### Federal False Claims Act

- Filing a claim that you knew or should have known was “false” – i.e., codes billed not matching documentation
- No proof of specific intent to defraud is required
- \$5500-\$11,000 per claim plus treble damages and paying attorneys fees for whistle blowers
- HITECH makes not refunding overpayments within 30 days a false claim
- Many states have False Claims Acts that may be even more stringent.

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### Have you read the back of the CMS-1500 claim form?

“I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were furnished by me, or were furnished incident to my professional services by my employee under my immediate supervision.  
NOTICE: Any one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal laws.”

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**Medicare Claims Processing Manual  
Section 30.6.1**

“...Medical necessity of a service is the overarching criterion for payment in addition to the individual requirements of a CPT code. It would not be medically necessary or appropriate to bill a higher level of evaluation and management service when a lower level of service is warranted. The volume of documentation should not be the primary influence upon which a specific level of service is billed. Documentation should support the level of service reported....”

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**Determining the Scope of the Audit**

- OIG Work Plan
- CERT Issues
- RAC Issues
- Top ten denials for the practice
- Top ten services billed for the practice
- Specific issues brought to your attention

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**OIG Work Plan for 2014**

- Place of Service Errors
- Coding of Evaluation and Management Services
- Chiropractic
  - Noncovered services
  - Questionable billing and maintenance therapy
- Outpatient PT by Independent Therapists
- Polysomnography

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- High Utilization of Sleep Testing
- Electrodiagnostic Testing – Questionable Billing
- Anesthesia – Personally Performed Services
- Diagnostic Radiology – Medical Necessity of High-Cost Tests
- Ophthalmologists’ Questionable Billing
- Error-Prone Providers
- Laboratory – Questionable Billing – increased volume and medical necessity
- Noncompliance with Assignment Rules

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- CERT Issues**
- [http://www.cms.gov/CERT/Downloads/CERT\\_Report.pdf](http://www.cms.gov/CERT/Downloads/CERT_Report.pdf)
- Signatures
  - Orders for diagnostic testing
  - Lack of documentation to support codes billed

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- RAC Issues**
- List available at each individual contractor website  
Example of Current Physician Issues
- |  |                                |
|--|--------------------------------|
| • Barium Swallow Units Billed            | • Services after Date of Death |
| • Blood Transfusions                     | • Dolasetron                   |
| • Bronchoscopy                           | • Duplicate Claims             |
| • Cetuximab                              | • Photophoresis                |
| • Chemotherapy Administration            | • Medically Unlikely Units     |
| • Co-surgery not billed with modifier 62 | • Global Period                |
|  | • Etc., Etc., Etc.             |

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### Auditing for Diagnosis Coding

- Often ignored in physician audits
- In the past has not affected physician payment
- Review for the correct code assignment and correct code sequence
- Will affect the payment more often in the future
- ICD-10-CM will provide for more specificity

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### Choosing the Audit Sample

This will depend on the type of audit

- If there is no specific problem being investigated – 10 encounters per provider for a proactive or compliance audit
  - “Random” sample – one days’ visits, first 10 on EOB, etc.
  - Also called a judgment sample – cannot be extrapolated to a larger population since it is not truly random

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- If investigating a specific problem, may consider a statistically valid random sample
- Probe sample followed by larger sample with a targeted confidence and precision
  - Probe usually 30, 40, or 50 items
- CMS requires that the sampling methodology be reviewed by a statistician or someone with equivalent experience

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### Time Frame?

- The time frame to be reviewed will also depend on the reason for the audit
  - Proactive or compliance audit – may be more helpful to choose recent claims – if the purpose is education, better to work with recent visits that the provider may remember – there may have also been changes in documentation patterns
  - Audit for a specific problem will need to be for the time frame for which the problem is suspected

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### RAT-STATS

- Software program used by the OIG to identify statistically valid random samples

<http://oig.hhs.gov/organization/oas/ratstats.asp>

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### CIA?

Corporate Integrity Agreement

- “forced” compliance plan when an organization had entered into a settlement for fraud allegations
- Require periodic audits to ensure that the coding/billing problems are resolved
- Requires a 95% accuracy

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### What You Need To Look At

- Documentation of encounter
- Superbills/Encounter Forms
- Claim Forms
- EOBs/Remittance Advice
- Payer Policies
  
- Depending on service audited, may also need to review other documentation

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### Involve An Attorney?

- Some protection may be provided by auditing under attorney-client privilege.
- Requires:
  - Attorney-client relationship
  - Attorney acting in capacity as attorney
  - Communication made in confidence between the attorney and client
  - For the purpose of securing legal advice

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### Work-Product Doctrine:

- Documents tangible things – interview memos and notes
- Prepared in anticipation of litigation – temporal and intent
- By or for a party's attorney are protected against discovery unless the party seeking disclosure can demonstrate:
  - Substantial need
  - That it would produce undue hardship without discovery

Routine audit reports may not be protected

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### Questions?

- What is an error?
  - Just overpayments or any deviation
- Prospective or retrospective?
- What will be your acceptable error rate?
  - CIAs allow 5%
  - In other situations, CMS has stated 7%
- What will you do with the results?
  - Education, followup auditing, penalties?

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### Followup Education?

How effective is this compliance and auditing program if you never educate the providers on how to "do it right"?

Education should be:

- Timely
- Targeted
- Group or Individual?

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### HIPAA Audits

Office of Civil Rights enforces HIPAA – now undertaking audits –

Audit Protocol –

<http://www.hhs.gov/ocr/privacy/hipaa/enforcement/audit/protocol.html>

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### Tiered Civil Penalties

| Circumstance of Violation                            | Minimum Penalty  | Maximum Penalty                                 |
|--|--|---|
| Entity did not know (even with reasonable diligence) | \$100 per violation (\$25,000 per year for violating same requirement) | \$50,000 per violation (\$1.5 million annually) |
| Reasonable cause, not willful neglect                | \$1,000 (\$100,000)  | \$50,000 (\$1.5 million)                        |
| Willful neglect, but corrected within 30 days        | \$10,000 (\$250,000)   | \$50,000 (\$1.5 million)                        |
| Willful neglect, not corrected                       | \$50,000 (\$1.5 million)   | None  |

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### Gray Areas

Coding, especially evaluation and management coding, is full of gray areas. How will your practice interpret these?

Examples –

- Which components for established patients?
- Is “noncontributory” acceptable documentation?
- What is a detailed examination under the 1995 CMS Documentation Guidelines

Some of these may be answered by your MAC – but will you extend those definitions to all payers?

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### Monitoring Relationships

Must be concerned with relationships your physicians may have with other entities –

- Stark and Anti-Kickback Implications

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### Stark

The physician referral law (section 1877 of the Social Security Act) prohibits a physician from referring patients to an entity for a designated health service (DHS), if the physician or a member of his or her immediate family has a financial relationship with the entity, unless an exception applies.

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Stop  
That  
Ain't  
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### Anti-Kickback Statute

- prohibits the offer or receipt of certain remuneration in return for referrals for or recommending purchase of supplies and services reimbursable under government health care programs
- Do you waive copays or provide "professional courtesy" to other physicians and their employees?
- Intent requirement relaxed under PPACA

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### Exit Interviews

- One of the best ways to head off a qui tam suit is to conduct an exit interview –
- *qui tam pro domino rege quam pro se ipso in hac parte sequitur*  
he who brings a case on behalf of our lord the King, as well as for himself
- The False Claims Act allows a private individual with knowledge of past or present fraud on the federal government to sue on the government's behalf to recover compensatory damages, civil penalties, and triple damages.
- "Relator" eligible for up to 30% of the recovery
- Also beneficial to see the practice from another viewpoint.

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### Vendors

Remember that their primary purpose is to sell something to your physicians

Verify any reimbursement or coding information given to you

If it sounds too good to be true....

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### EHR Implementation

The vendor is not a coding and compliance expert!

Beware of imbedded coding programs – they can only count "beans"

Many issues with diagnosis coding as well

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What are the auditors looking for?

- Authentication – signatures, dates/times – who did what? (metadata?)
- Contradictions – between HPI and ROS, exam elements
- Wording or grammatical errors/anomalies
- Medically implausible documentation

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**Sandy Giangreco**

[sgiangreco@thehaugengroup.com](mailto:sgiangreco@thehaugengroup.com)

(970)581-5144

**Kim Huey**

[kim@kimthecoder.com](mailto:kim@kimthecoder.com)

(877)893-5583

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**Advanced Stark and Fair Market Value: A Progressive Case Study**

HCCA Compliance Institute Conference  
March 30-April 2, 2014  
San Diego, CA

**Robert A. Wade, Esq.**  
Krieg DeVault LLP  
4101 Edison Lakes Parkway, Ste. 100  
Mishawaka, IN 46545  
Phone: 574-485-2002  
Email: [rwade@kdlegal.com](mailto:rwade@kdlegal.com)



**Kevin McAnaney, Esq.**  
Law Office of Kevin G. McAnaney  
1800 K Street, N.W., Ste. 720  
Washington, D.C. 20006  
Phone: 202-457-0494  
Email: [kevin@mcaneylaw.com](mailto:kevin@mcaneylaw.com)

**Nicole S. Huff, DHA, MBA, CHC, CHSP**  
St. Luke's University Health Network  
801 Ostrum Street  
Bethlehem, PA 18015  
Phone: 484-526-3288  
Email: [Nicole.Huff@sluhsn.org](mailto:Nicole.Huff@sluhsn.org)

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**Stark Act**  
42 U.S.C. 1395nn

- ▶ The Stark II Act prohibits a physician from making a **Referral**
  - to an **Entity**
  - for the furnishing of a **Designated Health Service**
  - for which payment may be made under Medicare or Medicaid
  - if the physician (or an immediate family member)
  - has a **Financial Relationship** with the entity

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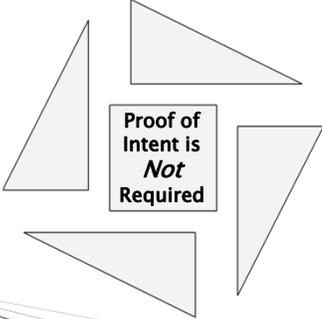
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**Stark II Act**



**Proof of Intent is Not Required**

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# Penalty

Denial of payment or refund; civil money penalties (up to \$100,000) and exclusions from federal and state programs for improper claims or schemes

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# Welcome to the City of Runamuck



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The city of Runamuck has two hospitals, St. All-Angels Align Hospital and Green Haven Medical Center. Both hospitals are fierce competitors.

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### Phase I Actors



**Dr. Kurt Cutthroat**



**Will Doit**  
The CEO



**Cindy Wright**  
Compliance Officer



**Randy Gray**  
General Counsel

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### Employment Agreements

- ▶ Contracts with physicians or their family members must satisfy Stark II
  - Must Meet Safe Harbor or regulatory exceptions
  - Prohibit billing Medicare for services rendered based on improper referral
- ▶ Anti-Kickback Statute (AKS)
  - Prohibits anyone from knowingly and intentionally offering, paying, or receiving remuneration in exchange for referral of patients for goods or services
  - AKS do not apply to bona fide employment contracts

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### Employment Agreements Stark Requirements

- ▶ Written arrangement must be for identifiable services
- ▶ Compensation must be consistent with fair market value (FMV)
- ▶ May not depend on volume or value of referrals
- ▶ Must be commercially reasonable even if no referrals were made

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## Tax-Exemption

- Physician must work full time on a specified schedule
- Physician must work at a hospital owned location
- Hospital must receive the professional fees
- Equipment must be provided by hospital
- Compensation must be reasonable
- Conflict of Interest policy

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## Relative Value Unit (RVU)

- A RVU is the measurement that represents the value of:
  - Physician work
  - Practice Expenses
  - Malpractice Expenses
- Benchmark Data
  - Productivity, Costs and Compensation
  - Weighted average using survey data
- Work RVU (wRVU):
  - Relative time, effort and skill required for provider in the provision of a procedure

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**Orthopedic Surgery: General FY14**

|                            | Compensation |                  |                  |                  |                  |                  |
|----------------------------|--------------|------------------|------------------|------------------|------------------|------------------|
|                            | Valid N      | 10               | 25               | 50               | 75               | 90               |
| Sullivan & Cotter          | 490          | \$264,398        | \$377,778        | \$502,425        | \$607,200        | \$799,950        |
| MGMA                       | 940          | \$282,075        | \$400,389        | \$520,119        | \$682,541        | \$934,059        |
| AMGA                       | 852          | \$205,252        | \$428,282        | \$515,759        | \$625,054        | \$795,993        |
| <b>Blended Annual Rate</b> | <b>2,282</b> | <b>\$249,597</b> | <b>\$405,948</b> | <b>\$514,692</b> | <b>\$644,900</b> | <b>\$853,715</b> |
| <b>Blended Hourly Rate</b> | <b>2,282</b> | <b>\$120.00</b>  | <b>\$195.17</b>  | <b>\$247.45</b>  | <b>\$310.05</b>  | <b>\$410.44</b>  |

|                        | wRVU's       |              |              |              |               |               |
|------------------------|--------------|--------------|--------------|--------------|---------------|---------------|
|                        | Valid N      | 10           | 25           | 50           | 75            | 90            |
| Sullivan & Cotter      | 300          | 5,046        | 6,256        | 7,891        | 10,432        | 13,557        |
| MGMA                   | 769          | 4,500        | 6,201        | 7,981        | 10,723        | 13,795        |
| AMGA                   | 596          | 2,913        | 6,177        | 8,026        | 10,588        | 13,383        |
| <b>Blended Average</b> | <b>1,665</b> | <b>4,030</b> | <b>6,202</b> | <b>7,981</b> | <b>10,622</b> | <b>13,605</b> |

|                        | Compensation per wRVU |                |                |                |                |                |
|------------------------|-----------------------|----------------|----------------|----------------|----------------|----------------|
|                        | Valid N               | 10             | 25             | 50             | 75             | 90             |
| Sullivan & Cotter      | 300                   | \$52.40        | \$60.39        | \$63.67        | \$58.21        | \$59.01        |
| MGMA                   | 769                   | \$62.68        | \$64.57        | \$65.17        | \$63.65        | \$67.71        |
| AMGA                   | 596                   | \$70.46        | \$69.33        | \$64.26        | \$59.03        | \$59.48        |
| <b>Blended Average</b> | <b>1,665</b>          | <b>\$63.61</b> | <b>\$65.52</b> | <b>\$64.57</b> | <b>\$61.02</b> | <b>\$63.20</b> |

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## Revise Proposal

- ▶ Revise the proposal to reflect compensation no higher than 50<sup>th</sup> percentile
- ▶ Term dates
  - Evergreen clauses should be reviewed annually
  - Monitor FMV compensation including any productivity bonuses
- ▶ Include administrative duties as medical director in base compensation
- ▶ AKS does not apply to bona fide arrangements.
  - Avoid perception of hospital relying on physicians' referrals due to low reimbursement or declining volume
- ▶ Payments based on quality measures
- ▶ Covenant not to compete clause

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## Phase II Actors



**Will Doit**  
The CEO



**Randy Gray**  
General Counsel



**Cindy Wright**  
Compliance Officer

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## Phase II Rural Clinic Space Lease

- ▶ Space leases with physicians must satisfy Stark II
  - if lease creates a Stark financial relationship w/ Hospital
    - ▶ Must meet regulatory exceptions
    - ▶ Otherwise any Medicare (and Medicaid?) referrals from physician-lessee to Hospital are prohibited
- ▶ AKS potentially applies
  - AKS prohibits knowing and willful offer, payment, solicitation or receipt of anything of value to induce referrals of federal health care patients or business
  - Safe harbor for leases available but not required

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## Stark II Financial Relationship

- ▶ If lease is between Hospital and physician, there is a direct compensation arrangement and Stark II is triggered
- ▶ If lease is between Hospital real estate subsidiary and physician, Stark II only applies if-
  - There is chain of financial arrangements between Hospital and physician (YES)
  - The compensation arrangement closest to physician (the Lease) varies or takes into account the value or volume of physician's referrals to Hospital (NO but ?)
  - Hospital has reason to know the comp varies with referrals (assume reason to know)

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## Stark II Lease Exception

- ▶ The agreement is set out in writing, is signed by the parties, and specifies the premises it covers
- ▶ The term of the agreement is at least 1 year.
- ▶ The space leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except common areas if the payments based on pro rate allocation.
- ▶ The agreement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

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## Stark Lease Payment Requirements

- ▶ Set in advance,
- ▶ Consistent with fair market value,
- ▶ Not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties;
- ▶ Not determined using a formula based on a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space;

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### AKS Lease Safe Harbor

- ▶ The lease agreement is set out in writing and signed by the parties.
- ▶ The lease covers and specifies all of the leased premises.
- ▶ If the lease is for periodic intervals of time, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
- ▶ The term of the lease is for not less than one year.
- ▶ The aggregate rental charge is set in advance, is consistent with fair market value and is not determined in a manner that takes into account the volume or value of any federal health care referrals or business otherwise generated between the parties
- ▶ The aggregate space rented is appropriate to accomplish the commercially reasonable business purpose of the rental.

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### Fair Market Value

- ▶ \$18/sq ft presumptively the FMV but not necessarily
- ▶ Vacancy premium?
  - Hourly vs. half day?
  - 1000 sq. ft. or only part?
- ▶ FMV rental of equipment and furnishings
- ▶ Supplies?
- ▶ Staff?
- ▶ Utilities?

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### Other Alternatives

- ▶ Payment by physician
  - No writing
  - Only needs to be FMV
  - What does "not specifically excepted" by another exception mean?
    - ▶ Exact same language in "isolated transaction" exception
- ▶ Set up hospital based clinic
  - Hospital pays FMV to physician for sessions
  - Physicians don't need to pay rent

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### Phase III Actors



**Evelyn Free**  
Chief Financial Officer



**Will Doit**  
The CEO



**Cindy Wright**  
Compliance Officer



**Randy Gray**  
General Counsel

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### What Is a Financial Relationship?

Remuneration is defined (42 CFR§ 411.351) as  
 “any payment *or other benefit* made directly  
 or indirectly, overtly or covertly, in cash or *in  
 kind ...*”



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### Non-Monetary Compensation Exception

(Applies to *Compensation Relationships*)

- ▶ Compensation (defined as *any benefit*, not including cash or cash equivalents (i.e., gift certificates that may be redeemed in whole or in part for cash), may not exceed an aggregate of \$385 per year per physician as long as:
  - Benefit is not determined based upon volume or value of referrals
  - Benefit is not solicited by physician or anyone affiliated with their practice
  - Maximum cannot be aggregated to make a larger gift to a group

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## Non-Monetary Compensation Exception

(Applies to *Compensation Relationships*)

- ▶ The current \$385 limit is updated annually.
- ▶ See: [http://cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPI-U\\_Updates.html](http://cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPI-U_Updates.html)
- ▶ See Stark Law Resource Page: <http://www.kriegdevault.com/info/stark-act>

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## Non-Monetary Compensation Exception

(Applies to *Compensation Relationships*)

- ▶ If a hospital inadvertently exceeds the annual limit, the hospital will still be deemed to be in compliance if i) the value of the excess is no more than 50% of the limit, and ii) the physician returns the excess by the end of the calendar year or within 180 consecutive calendar days, whichever is earlier
  - NOTE: Can only be used once every 3 years
- ▶ Hospitals can now hold 1 formal medical staff event per year without including the cost in this exception

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## Non-Monetary Compensation Exception

(Applies to *Compensation Relationships*)

For example:

Cannot give \$1,000 oil painting to 5 physician group and allocate \$200 to each physician



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## Non-Monetary Compensation Exception

(Applies to *Compensation Relationships*)

- ▶ Preamble, on Page 16112 of Phase II, stated that “[the Medical Staff Incidental Benefits Exception] was not intended to cover the provision of tangential, off-site benefits, such as *restaurant dinners or theater tickets, which must comply with the exception for non-monetary compensation up to \$385.*” (emphasis added)



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## Non-Monetary Compensation Exception

(Applies to *Compensation Relationships*)

### CME

“[F]ree CME could constitute remuneration to the physician depending on the content of the program and the physician’s obligation to acquire CME credits.”

Phase II, page 16114

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## Medical Staff Incidental Benefits Exception

(Applies to *Compensation Relationships*)

- ▶ Items or services used on the hospital's campus may be given to members of its medical staff if:
  - Item or service is provided to all members in the same specialty without regard to volume or value of referrals
  - Item or service is provided only during periods when the medical staff members are making rounds or involved in other services that benefit the hospital and its patients

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### Medical Staff Incidental Benefits Exception

(Applies to *Compensation* Relationships)

- ▶ The item or service is reasonably related to the delivery of medical services at the hospital
- ▶ Each item or service is less than \$32 per benefit (updated annually)



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### Medical Staff Incidental Benefits Exception

(Applies to *Compensation* Relationships)

- ▶ The exception specifically recognizes that "internet access, pagers, or two-way radios, used away from the campus **only to access** hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital Web-site or in hospital advertising, will meet the single **"on campus" requirement...**" (emphasis added)



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### Why Is Compliance So Hard?

- ▶ Tracking of benefit.
- ▶ Who is responsible for oversight?
- ▶ How do you allocate (focus is usually on value of benefit to receiving physician)?
- ▶ Does a "Will Work for Food" written agreement signed by the parties meet other exceptions?
- ▶ Unified gifts cannot be prorated.
- ▶ Non-monetary benefits are the most frequent financial arrangements between DHS entities and referring physicians.



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### Benefits Provided by St. All- Angels Align Hospital

- ▶ Dinners at restaurants 
- ▶ \$10,000 donation to charity golf outings with physician participation 
- ▶ Entertainment at sporting events, local theater, and symphony 

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### Benefits Provided by St. All- Angels Align Hospital

- ▶ Free lunches (with education, without education, with note thanking the physicians for their business) 
- ▶ Board retreat attended by three independent physicians and their spouses 
- ▶ Free meals to medical staff members in physician lounge 

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### Compliance Forms

- 1) Stark Audit Tool
- 2) Gifts/Benefits Tracking Form - Physicians
- 3) Physician Contract Checklist
- 4) Stark Production Checklist
- 5) Rent Tracking

<http://www.kriegdevault.com/info/stark-act>

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## **Case Study for the Healthcare Compliance Association Annual Institute**

### **Advanced Stark and Fair Market Value – A Progressive Case Study**

March 30 – April 4, 2014

#### **Phase I**

Mr. Will Doit is the Chief Executive Officer of St. All-Angels Align Hospital. Mr. Will Doit recently returned from a conference where it was emphasized that in order for hospitals to survive they need to collaborate and integrate with specialists. St. All-Angels Align Hospital is in the City of Runamuck, which has one other hospital known as Green Haven Medical Center. St. All-Angels Align Hospital and Green Haven Medical Center are of about the same size and most of the specialists in the City of Runamuck are members of the medical staffs of both hospitals.

Mr. Will Doit approaches Dr. Kurt Cutthroat, an orthopedic surgeon affiliated with a 10 surgeon physician group known as Ortho-4-All. Mr. Will Doit asks Dr. Kurt Cutthroat whether the orthopedic surgeons affiliated with Ortho-4-All would be willing to become employees of St. All-Angels Align Hospital. Dr. Kurt Cutthroat counsels with the other orthopedic surgeons affiliated with Ortho-4-All and because of the declining reimbursement for orthopedic services, the surgeons unanimously agreed to negotiate an employment arrangement with St. All-Angels Align Hospital.

Dr. Kurt Cutthroat drafts the following compensation terms as a proposal to St. All-Angels Align Hospital:

Each physician will be guaranteed a base salary of \$705,000, which is approximately at the 75<sup>th</sup> percentile, with an employment term of 5 years. Over the 5 year employment term, the compensation is to increase by 5% each year. In addition to the guaranteed base salary, I propose that St. All-Angels Align Hospital employ me to be the medical director over the orthopedic department for an additional \$150,000 per year recognizing that there currently is no medical director. I believe that my service as a medical director will bring “value” to St. All-Angels Align Hospital’s bottom line.

As part of the due diligence related to Dr. Kurt Cutthroat’s compensation proposal, Mr. Will Doit found out that, on average, each surgeon produced approximately 6,000 wRVUs, which is at the 25<sup>th</sup> percentile.

Mr. Will Doit turns to his Chief Compliance Officer, Cindy Wright, and General Counsel, Randy Gray, to assist with analyzing Dr. Kurt Cutthroat’s proposal.

## **Phase II**

St. All-Angels Align Hospital has a medical office building in a rural county approximately 30 miles away from its main facility in the City of Runamuck. Mr. Will Doit believes that if he can convince independent specialists to see patients in the rural clinic, such independent specialists will refer patients to St. All-Angels Align Hospital if hospital services are needed. Mr. Will Doit approaches several specialists who are interested in conducting a part-time clinic at the rural medical office building.

The vacant space in the medical office building consists of 1,000 square feet for which St. All-Angels Align Hospital is paying \$18 per square foot. The space is fully equipped with office furniture and medical equipment. Several of the specialists expressed an interest in renting the suite by the hour. Some of the specialists, however, do not believe that they need 1,000 square feet.

Mr. Will Doit turns to his Chief Compliance Officer, Cindy Wright, and his General Counsel, Randy Gray, to make the deal happen for as little rent as possible.

## **Phase III**

Cindy Wright recently attended a conference sponsored by the Health Care Compliance Association. One of the sessions Cindy Wright attended discussed the non-monetary compensation and medical staff incidental benefit exceptions under the Stark Law. Immediately after the session, Cindy Wright returned to her hotel room and contacted the Chief Financial Officer, Evelyn Free, to see whether St. All-Angels Align Hospital provides any gifts or benefits to referring physicians, and if so, whether someone was tracking the value of such gifts and benefits.

Upon returning from the conference, Cindy Wright met with Evelyn Free and learned that Mr. Will Doit was wining and dining several physicians within the City of Runamuck. Cindy Wright also learned that Mr. Will Doit was entertaining several physicians at sporting events, the local theater and at Runamuck's symphony. The hospital's intake coordinators provide frequent lunches at physician offices, often without any face time with the physicians, usually with a note to thank the physicians for their business. Three independent physicians serve on St. All-Angels Align Hospital's Board of Trustees and participated in a couple of board meetings paid for by the hospital at resort areas, which included their spouses. St. All-Angels Align Hospital also has a tradition of providing free meals to all members of its medical staff in its physician lounge. Lastly, Evelyn Free told Cindy Wright that Mr. Will Doit, on behalf of St. All-Angels Align Hospital, has donated money to several charity golf outings with an average sponsorship fee of \$10,000, where Mr. Will Doit included independent physicians on the foursome for the charity golf event. Cindy Wright calls Randy Gray to the meeting in order to formulate a plan.



**Auditing and Monitoring Provider Based Services:  
Is your reimbursement at risk?**

**Presented by: Debi Weatherford  
Executive Director, Internal Audit**

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**Agenda**

- Background
- OIG Initiatives
- Provider-Based Considerations
- Monitoring Techniques to Protect Status
- Auditing for Compliance with Regulatory Requirements
- Controls
- Questions/ Comments

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**Background**

- Provider-Based refers to services rendered in an integrated hospital outpatient clinic or location
- Provider-Based Status may result in higher reimbursement
- Patients will receive two bills:
  - Facility Charge
  - Professional or Physician Fee Charge

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### OIG Initiatives

HHS OIG Work Plan FY 2014:

- *Impact of provider-based status on Medicare billing*
- *Comparison of provider-based and free-standing clinics*

*....extent to which such facilities meet CMS's criteria*

*...provider-based status can result in additional Medicare payments and increase beneficiaries' coinsurance liabilities*

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### Provider-Based Considerations

- Emphasis on provider-based self attestations for all locations
- Written notice of co-insurance liability per 42 C.F.R. § 413.65(g)(7)
- Separate license/certificate required for each service or separate location
- Periodic review and update of documentation
- Hospital role in physician proper billing

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### Provider-Based Considerations - continued

- Sharing of same space – What happens when a Medicare patient of the freestanding clinic must be seen during the block of time when it is a provider-based clinic and the treating physician insists that the provider waive its facility charge?

*A site must not treat some Medicare patients as hospital outpatients and others as physician office patients.*

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**Monitoring Techniques to Protect Status**

- Annual review with utilization of Internal Control Questionnaire
- Criteria § 413.65(d) Checklist

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**Auditing for Compliance with Regulatory Requirements**

- Provider Based Rules Audit Protocol
- Audit Program and Work Plan
  - Provider Based Status
  - Billing of Physician Services with the Appropriate Site-Of-Service Indicator

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**Controls**

- ✓ Policy/Procedure
- ✓ Shared Folder with Documentary Evidence
- ✓ Physician Training and Education
- ✓ Monitoring for Compliance

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## § 413.65

which interest is computed begins on January 1, 1975, and the interest beginning January 1, 1975, would be at the rate of 11.625 percent per annum.

[51 FR 34793, Sept. 30, 1986, as amended at 51 FR 42238, Nov. 24, 1986; 53 FR 1628, Jan. 21, 1988; 57 FR 39830, Sept. 1, 1992; 59 FR 36713, July 19, 1994; 64 FR 41682, July 30, 1999; 65 FR 41211, July 3, 2000; 66 FR 41394, Aug. 7, 2001; 67 FR 56056, Aug. 30, 2002; 69 FR 49252, Aug. 11, 2004; 69 FR 66981, Nov. 15, 2004; 73 FR 30267, May 23, 2008]

### § 413.65 Requirements for a determination that a facility or an organization has provider-based status.

(a) *Scope and definitions.* (1) *Scope.* (i) This section applies to all facilities for which provider-based status is sought, including remote locations of hospitals, as defined in paragraph (a)(2) of this section and satellite facilities as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter, other than facilities described in paragraph (a)(1)(ii) of this section.

(ii) The determinations of provider-based status for payment purposes described in this section are not made as to whether the following facilities are provider-based:

(A) Ambulatory surgical centers (ASCs).

(B) Comprehensive outpatient rehabilitation facilities (CORFs).

(C) Home health agencies (HHAs).

(D) Skilled nursing facilities (SNFs) (determinations for SNFs are made in accordance with the criteria set forth in § 483.5 of this chapter).

(E) Hospices.

(F) Inpatient rehabilitation units that are excluded from the inpatient PPS for acute hospital services.

(G) Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services (as defined in section 1861(jj) of the Act), facilities that furnish only clinical diagnostic laboratory tests, other than those clinical diagnostic laboratories operating as parts of CAHs on or after October 1, 2010, or facilities that furnish only some combination of these services.

(H) Facilities, other than those operating as parts of CAHs, furnishing only physical, occupational, or speech therapy to ambulatory patients, through-

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out any period during which the annual financial cap amount on payment for coverage of physical, occupational, or speech therapy, as described in section 1833(g)(2) of the Act, is suspended by legislation.

(I) ESRD facilities (determinations for ESRD facilities are made under § 413.174 of this chapter).

(J) Departments of providers that perform functions necessary for the successful operation of the providers but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments).

(K) Ambulances.

(L) Rural health clinics (RHCs) affiliated with hospitals having 50 or more beds.

(2) *Definitions.* In this subpart E, unless the context indicates otherwise—

*Campus* means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by the CMS regional office, to be part of the provider's campus.

*Department of a provider* means a facility or organization that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A department of a provider comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A department of a provider may not by itself be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do not apply to a department as an independent entity. For purposes of this part, the term "department of a provider" does not include an RHC or, except as specified

in paragraph (n) of this section, an FQHC.

*Free-standing facility* means an entity that furnishes health care services to Medicare beneficiaries and that is not integrated with any other entity as a main provider, a department of a provider, remote location of a hospital, satellite facility, or a provider-based entity.

*Main provider* means a provider that either creates, or acquires ownership of, another entity to deliver additional health care services under its name, ownership, and financial and administrative control.

*Provider-based entity* means a provider of health care services, or an RHC as defined in § 405.2401(b) of this chapter, that is either created by, or acquired by, a main provider for the purpose of furnishing health care services of a different type from those of the main provider under the ownership and administrative and financial control of the main provider, in accordance with the provisions of this section. A provider-based entity comprises both the specific physical facility that serves as the site of services of a type for which payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. A provider-based entity may, by itself, be qualified to participate in Medicare as a provider under § 489.2 of this chapter, and the Medicare conditions of participation do apply to a provider-based entity as an independent entity.

*Provider-based status* means the relationship between a main provider and a provider-based entity or a department of a provider, remote location of a hospital, or satellite facility, that complies with the provisions of this section.

*Remote location of a hospital* means a facility or an organization that is either created by, or acquired by, a hospital that is a main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider, in accordance with the provisions of this section. A remote location of a hospital comprises both the specific physical facility that serves as the site of services

for which separate payment could be claimed under the Medicare or Medicaid program, and the personnel and equipment needed to deliver the services at that facility. The Medicare conditions of participation do not apply to a remote location of a hospital as an independent entity. For purposes of this part, the term “remote location of a hospital” does not include a satellite facility as defined in §§ 412.22(h)(1) and 412.25(e)(1) of this chapter.

(b) *Provider-based determinations.* (1) A facility or organization is not entitled to be treated as provider-based simply because it or the main provider believe it is provider-based.

(2) If a facility was treated as provider-based in relation to a hospital or CAH on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital’s first cost reporting period beginning on or after July 1, 2003. The requirements, limitations, and exclusions specified in paragraphs (d), (e), (f), (h), and (i) of this section will not apply to that hospital or CAH until the start of the hospital’s first cost reporting period beginning on or after July 1, 2003. For purposes of this paragraph (b)(2), a facility is considered as provider-based on October 1, 2000 if, on that date, it either had a written determination from CMS that it was provider-based, or was billing and being paid as a provider-based department or entity of the hospital.

(3)(i) Except as specified in paragraphs (b)(2) and (b)(5) of this section, if a potential main provider seeks a determination of provider-based status for a facility that is located on the campus of the potential main provider, the provider would be required to submit an attestation stating that the facility meets the criteria in paragraph (d) of this section and, if it is a hospital, also attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider seeking such a determination would also be required to maintain documentation of the basis for its attestations and to make that documentation available to CMS and to CMS contractors upon request. If

the facility is operated as a joint venture, the provider would also have to attest that it will comply with the requirements of paragraph (f) of this section.

(ii) If the facility is not located on the campus of the potential main provider, the provider seeking a determination would be required to submit an attestation stating that the facility meets the criteria in paragraphs (d) and (e) of this section, and if the facility is operated under a management contract, the requirements of paragraph (h) of this section. If the potential main provider is a hospital, the hospital also would be required to attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section. The provider would be required to supply documentation of the basis for its attestations to CMS at the time it submits its attestations.

(iii) Whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, as described in paragraph (b)(3)(i) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(iv) Whenever a provider submits an attestation of provider-based status for an off-campus facility or organization, as described in paragraph (b)(3)(ii) of this section, CMS will send the provider written acknowledgment of receipt of the attestation, review the attestation for completeness, consistency with the criteria in this section, consistency with the documentation submitted with the attestation and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility or organization is provider-based.

(4) A facility that is not located on the campus of a hospital and that is used as a site where physician services of the kind ordinarily furnished in phy-

sician offices are furnished is presumed as a free-standing facility, unless CMS determines the facility has provider-based status.

(5) A facility that has requested provider-based status in relation to a hospital or CAH on or after October 1, 2000 and before October 1, 2002 will be treated as provider-based in relation to the hospital or CAH from the first date on or after October 1, 2000 on which the facility was licensed (to the extent required by the State), staffed and equipped to treat patients until the date on which CMS determines that the facility does not qualify for provider-based status.

(c) *Reporting of material changes in relationships.* A main provider that has had one or more facilities or organizations considered provider-based also may report to CMS any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that would affect the provider-based status of the facility or organization.

(d) *Requirements applicable to all facilities or organizations.* Any facility or organization for which provider-based status is sought, whether located on or off the campus of a potential main provider, must meet all of the following requirements to be determined by CMS to have provider-based status:

(1) *Licensure.* The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If a State health facilities' cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State finds that a particular facility or organization is not part of a provider, CMS

will determine that the facility or organization does not have provider-based status.

(2) *Clinical services.* The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:

(i) Professional staff of the facility or organization have clinical privileges at the main provider.

(ii) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.

(iii) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

(iv) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.

(v) Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.

(vi) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

(3) *Financial integration.* The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as

evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

(4) *Public awareness.* The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.

(5) *Obligations of hospital outpatient departments and hospital-based entities.* In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph (g) of this section.

(e) *Additional requirements applicable to off-campus facilities or organizations.* Except as described in paragraphs (b)(2) and (b)(5) of this section, any facility or organization for which provider-based status is sought that is not located on the campus of a potential main provider must meet both the requirements in paragraph (d) of this section and all of the following additional requirements, in order to be determined by CMS to have provider-based status.

(1) *Operation under the ownership and control of the main provider.* The facility or organization seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:

(i) The business enterprise that constitutes the facility or organization is 100 percent owned by the main provider.

(ii) The main provider and the facility or organization seeking status as a

department of the main provider, a remote location of a hospital, or a satellite facility have the same governing body.

(iii) The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the main provider where it is based.

(iv) The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.

(2) *Administration and supervision.* The reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by compliance with all of the following requirements:

(i) The facility or organization is under the direct supervision of the main provider.

(ii) The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity—

(A) Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and

(B) Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.

(iii) The following administrative functions of the facility or organiza-

tion are integrated with those of the provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are—

(A) Contracted out under the same contract agreement; or

(B) Handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.

(3) *Location.* The facility or organization meets the requirements in paragraph (e)(3)(i), (e)(3)(ii), (e)(3)(iii), (e)(3)(iv), (e)(3)(v), or, in the case of an RHC, paragraph (e)(3)(vi) of this section, and the requirements in paragraph (e)(3)(vii) of this section.

(i) The facility or organization is located within a 35-mile radius of the campus of the hospital or CAH that is the potential main provider.

(ii) The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under § 412.106 of this chapter) greater than 11.75 percent or is described in § 412.106(c)(2) of this chapter implementing section 1886(d)(5)(F)(i)(II) of the Act and is—

(A) Owned or operated by a unit of State or local government;

(B) A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or

(C) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

(iii) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it

serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period—

(A) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider; or

(B) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider).

(iv) If the facility or organization is unable to meet the criteria in paragraph (e)(3)(iii)(A) or paragraph (e)(3)(iii)(B) of this section because it was not in operation during all of the 12-month period described in paragraph (e)(3)(iii) of this section, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in paragraph (e)(3)(iii) of this section, accounted for at least 75 percent of the patients served by the main provider.

(v) The facility or organization meets all of the following criteria:

(A) The facility or organization is seeking provider-based status with respect to a hospital that meets the criteria in § 412.23(d) for reimbursement under Medicare as a children's hospital;

(B) The facility or organization meets the criteria for identifying intensive care type units set forth in the Medicare reasonable cost reimbursement regulations under § 413.53(d).

(C) The facility or organization accepts only patients who are newborn infants who require intensive care on an inpatient basis.

(D) The hospital in which the facility or organization is physically located is in a rural area as defined in § 412.64(b)(1)(ii)(C) of this chapter.

(E) The facility or organization is located within a 100-mile radius of the

children's hospital that is the potential main provider.

(F) The facility or organization is located at least 35 miles from the nearest other neonatal intensive care unit.

(G) The facility or organization meets all other requirements for provider-based status under this section.

(vi) Both of the following criteria are met:

(A) The facility or organization is an RHC that is otherwise qualified as a provider-based entity of a hospital that has fewer than 50 beds, as determined under § 412.105(b) of this chapter; and

(B) The hospital with which the facility or organization has a provider-based relationship is located in a rural area, as defined in § 412.64(b)(1)(ii)(C) of this subchapter.

(vii) A facility or organization may qualify for provider-based status under this section only if the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, in adjacent States.

(f) *Provider-based status for joint ventures.* In order for a facility or organization operated as a joint venture to be considered provider-based, the facility or organization must—

(1) Be partially owned by at least one provider'

(2) Be located on the main campus of a provider who is a partial owner;

(3) Be provider-based to that one provider whose campus on which the facility or organization is located; and

(4) Also meet all the requirements applicable to all provider-based facilities and organizations in paragraph (d) of this section. For example, where a provider has jointly purchased or jointly created a facility under joint venture arrangements with one or more other providers, and the facility is not located on the campus of the provider or the campus of any other provider engaged in the joint venture arrangement, no party to the joint venture arrangement can claim the facility as provider-based.

(g) *Obligations of hospital outpatient departments and hospital-based entities.* To qualify for provider-based status in relation to a hospital, a facility or organization must comply with the following requirements:

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(1) The following departments must comply with the antidumping rules of §§ 489.20(l), (m), (q), and (r) and 489.24 of this chapter:

(i) Any facility or organization that is located on the main hospital campus and is treated by Medicare under this section as a department of the hospital; and

(ii) Any facility or organization that is located off the main hospital campus that is treated by Medicare under this section as a department of the hospital and is a dedicated emergency department, as defined in § 489.24(b) of this chapter.

(2) Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined under the rules of Part 414 of this chapter.

(3) Hospital outpatient departments must comply with all the terms of the hospital's provider agreement.

(4) Physicians who work in hospital outpatient departments or hospital-based entities are obligated to comply with the non-discrimination provisions in § 489.10(b) of this chapter.

(5) Hospital outpatient departments (other than RHCs) must treat all Medicare patients, for billing purposes, as hospital outpatients. The department must not treat some Medicare patients as hospital outpatients and others as physician office patients.

(6) In the case of a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based entity, payments for services in the hospital outpatient department or hospital-based entity are subject to the payment window provisions applicable to PPS hospitals and to hospitals and units excluded from PPS set forth at § 412.2(c)(5) of this chapter and at § 413.40(c)(2), respectively.

(7) When a Medicare beneficiary is treated in a hospital outpatient department that is not located on the main provider's campus, the treatment is not required to be provided by the antidumping rules in § 489.24 of this chapter, and the beneficiary will incur a coinsurance liability for an outpatient

visit to the hospital as well as for the physician service, the following requirements must be met:

(i) The hospital must provide written notice to the beneficiary, before the delivery of services, of—

(A) The amount of the beneficiary's potential financial liability; or

(B) If the exact type and extent of care needed are not known, an explanation that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based, an estimate based on typical or average charges for visits to the facility, and a statement that the patient's actual liability will depend upon the actual services furnished by the hospital.

(ii) The notice must be one that the beneficiary can read and understand.

(iii) If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, before the delivery of services, to the beneficiary's authorized representative.

(iv) In cases where a hospital outpatient department provides examination or treatment that is required to be provided by the antidumping rules of § 489.24 of this chapter, notice, as described in this paragraph (g)(7), must be given as soon as possible after the existence of an emergency has been ruled out or the emergency condition has been stabilized.

(8) Hospital outpatient departments must meet applicable hospital health and safety rules for Medicare-participating hospitals in part 482 of this chapter.

(h) *Management contracts.* A facility or organization that is not located on the campus of the potential main provider and otherwise meets the requirements of paragraphs (d) and (e) of this section, but is operated under management contracts, must also meet all of the following criteria:

(1) The main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management

staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at part 414 of this chapter. Other than staff that may be paid under such a Medicare fee schedule, the main provider may not utilize the services of “leased” employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) that are directly involved in the delivery of patient care.

(2) The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph (e)(2)(iii) of this section.

(3) The main provider has significant control over the operations of the facility or organization as determined under criteria in paragraph (e)(2)(ii) of this section.

(4) The management contract is held by the main provider itself, not by a parent organization that has control over both the main provider and the facility or organization.

(i) *Furnishing all services under arrangement.* A facility or organization may not qualify for provider-based status if all patient care services furnished at the facility or organization are furnished under arrangements.

(j) *Inappropriate treatment of a facility or organization as provider-based—(1) Determination and review.* If CMS learns that a provider has treated a facility or organization as provider-based and the provider did not request a determination of provider-based status from CMS under paragraph (b)(3) of this section and CMS determines that the facility or organization did not meet the requirements for provider-based status under paragraphs (d) through (i) of this section, as applicable (or, in any period before the effective date of these regulations, the provider-based requirements in effect under Medicare program regulations or instructions), CMS will—

(i) Issue notice to the provider in accordance with paragraph (j)(3) of this section, adjust the amount of future payments to the provider for services of the facility or organization in accordance with paragraph (j)(4) of this

section, and continue payments to the provider for services of the facility or organization only in accordance with paragraph (j)(5) of this section; and

(ii) Except as otherwise provided in paragraphs (b)(2), (b)(5), or (j)(2) of this section, recover the difference between the amount of payments that actually was made and the amount of payments that CMS estimates should have been made, in the absence of compliance with the provider-based requirements, to that provider for services at the facility or organization for all cost reporting periods subject to reopening in accordance with §§ 405.1885 and 405.1889 of this chapter.

(2) *Exception for good faith effort.* CMS will not recover any payments for any period before the beginning of the hospital’s first cost reporting period beginning on or after January 10, 2001, if, during all of that period—

(i) The requirements regarding licensure and public awareness in paragraphs (d)(1) and (d)(4) of this section were met;

(ii) All facility services were billed as if they had been furnished by a department of a provider, a remote location of a hospital, a satellite facility, or a provider-based entity of the main provider; and

(iii) All professional services of physicians and other practitioners were billed with the correct site-of-service indicator, as described in paragraph (g)(2) of this section.

(3) *Notice to provider.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will issue written notice to the provider that payments for past cost reporting periods may be reviewed and recovered as described in paragraph (j)(1)(ii) of this section, and that future payments for services in or of the facility or organization will be adjusted as described in paragraph (j)(4) of this section.

(4) *Adjustment of payments.* If CMS determines that a facility or organization was inappropriately treated as provider-based, CMS will adjust future payments to the provider or the facility or organization, or both, to estimate the amounts that would be paid for the same services furnished by a freestanding facility.

(5) *Continuation of payment.* (i) The notice of denial of provider-based status sent to the provider will ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, of whether the provider intends to seek a determination of provider-based status for the facility or organization under this section or whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a freestanding facility.

(ii) If the provider indicates that it will not be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will not be seeking to enroll, or if CMS does not receive a response within 30 days of the date the notice was issued, all payment under this paragraph (j)(5) will end as of the 30th day after the date of notice.

(iii) If the provider indicates that it will be seeking a determination for the facility or organization under this section or that the facility or organization or its practitioners will be seeking to meet enrollment and other requirements for billing for services in a freestanding facility, payment for services of the facility or organization will continue, at the adjusted amounts described in paragraph (j)(4) of this section, for as long as is required for all billing requirements to be met (but not longer than 6 months) if the provider or the facility or organization or its practitioners—

(A) Submits, as applicable, a complete request for a determination of provider-based status or a complete enrollment application and provide all other required information within 90 days after the date of notice; and

(B) Furnishes all other information needed by CMS to make a determination regarding provider-based status or process the enrollment application, as applicable, and verifies that other billing requirements are met.

(v) If the necessary applications or information are not provided, CMS will terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary appli-

cations or information have not been submitted.

(k) *Temporary treatment as provider-based.* If a provider submits a complete attestation of compliance with the requirements for provider-based status for a facility or organization that has not previously been found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section, the provider may bill and be paid for services of the facility or organization as provider-based from the date it submits the attestation and any required supporting documentation until the date that CMS determines that the facility or organization does not meet the provider-based rules. If CMS subsequently determines that the requirements for provider-based status are not met, CMS will recover the difference between the amount of payments that actually was made since the date the complete attestation of compliance with provider-based requirements was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements. For purposes of this paragraph (k), a complete attestation of compliance with provider-based requirements is one that includes all information needed to permit CMS to make a determination under paragraph (b)(3) of this section.

(1) *Correction of errors.* (1) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and the failure to qualify for provider-based status resulted from a material change in the relationship between the provider and the facility or organization that the provider did report to CMS under paragraph (c) of this section, treatment of the facility or organization as provider-based ceases with the date that CMS determines that the facility or organization no longer qualifies for provider-based status.

(2) If CMS determines that a facility or organization that had previously been determined to be provider-based under this section no longer qualifies for provider-based status, and if the failure to qualify for provider-based

status resulted from a material change in the relationship between the provider and the facility or organization that the provider did not report to CMS under paragraph (c) of this section, CMS will take the actions with respect to notice to the provider, adjustment of payments, and continuation of payment described in paragraphs (j)(3), (j)(4), and (j)(5) of this section, and will recover past payments to the provider to the extent described in paragraph (j)(1)(ii) of this section.

(m) *Status of Indian Health Service and Tribal facilities and organizations.* Facilities and organizations operated by the Indian Health Service or Tribes will be considered to be departments of hospitals operated by the Indian Health Service or Tribes if, on or before April 7, 2000, they furnished only services that were billed as if they had been furnished by a department of a hospital operated by the Indian Health Service or a Tribe and they are:

(1) Owned and operated by the Indian Health Service;

(2) Owned by the Tribe but leased from the Tribe by the IHS under the Indian Self-Determination Act (Pub. L. 93-638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes; or

(3) Owned by the Indian Health Service but leased and operated by the Tribe under the Indian Self-Determination Act (Pub. L. 93-638) in accordance with applicable regulations and policies of the Indian Health Service in consultation with Tribes.

(n) *FQHCs and "look alikes."* A facility that has, since April 7, 1995, furnished only services that were billed as if they had been furnished by a department of a provider will continue to be treated, for purposes of this section, as a department of the provider without regard to whether it complies with the criteria for provider-based status in this section, if the facility—

(1) Received a grant on or before April 7, 2000 under section 330 of the Public Health Service Act and continues to receive funding under such a grant, or is receiving funding from a grant made on or before April 7, 2000 under section 330 of the Public Health Service Act under a contract with the

recipient of such a grant, and continues to meet the requirements to receive a grant under section 330 of the Public Health Service Act; or

(2) Based on the recommendation of the Public Health Service, was determined by CMS on or before April 7, 2000 to meet the requirements for receiving a grant under section 330 of the Public Health Service Act, and continues to meet such requirements.

(o) *Effective date of provider-based status—(1) General rule.* Provider-based status for a facility or organization is effective on the earliest date all of the requirements of this part have been met.

(2) *Inappropriate treatment as provider-based or not reporting material change.* Effective for any period on or after October 1, 2002 (or, in the case of facilities or organizations described in paragraph (b)(2) of this section, for cost reporting periods starting on or after July 1, 2003), if a facility or organization is found by CMS to have been inappropriately treated as provider-based under paragraph (j) of this section for those periods, or previously was determined by CMS to be provider-based but no longer qualifies as provider-based because of a material change occurring during those periods that was not reported to CMS under paragraph (c) of this section, CMS will not treat the facility or organization as provider-based for payment purposes until CMS has determined, based on documentation submitted by the provider, that the facility or organization meets all requirements for provider-based status under this part

[65 FR 18538, Apr. 7, 2000, as amended at 65 FR 58920, Oct. 3, 2000; 66 FR 1599, Jan. 9, 2001; 66 FR 59920, Nov. 30, 2001; 67 FR 50114, Aug. 1, 2002; 68 FR 46070, Aug. 4, 2003; 68 FR 53261, Sept. 9, 2003; 70 FR 47487, Aug. 12, 2005; 74 FR 44000, Aug. 27, 2009]

#### § 413.70 Payment for services of a CAH.

(a) *Payment for inpatient services furnished by a CAH (other than services of distinct part units).* (1) Effective for cost reporting periods beginning on or after January 1, 2004, payment for inpatient services of a CAH, other than services of a distinct part unit of the CAH and other than the items included in the

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# Program Memorandum Intermediaries

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Department of Health &  
Human Services (DHHS)  
Centers for Medicare &  
Medicaid Services (CMS)

Transmittal A-03-030

Date: APRIL 18, 2003

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## CHANGE REQUEST 2411

### SUBJECT: Provider-based Status On or After October 1, 2002

Regulations in 42 CFR §413.65 describe the criteria and procedures for determining whether a facility or organization is provider-based. The Medicare Hospital Inpatient Prospective Payment System final rule published on August 1, 2002 (67 FR 50078) revised those regulations effective on October 1, 2002, for facilities or organizations that are not grandfathered as provider-based as described below and, in the case of grandfathered facilities, effective for main provider cost reporting periods beginning on or after July 1, 2003. This Program Memorandum (PM) provides information on the background of the provider-based regulations and notifies you of the actions you are to take to implement the revised regulations.

**NOTE:** This PM supersedes program instructions concerning provider-based status in §2446 of the Provider Reimbursement Manual, Part I (PRM-I) and §2004 of the State Operations Manual (SOM) that apply to any facility for periods before the regulations at 42 CFR §413.65 become applicable to it.

#### A. Background

##### 1. Current Regulations

Since the beginning of the Medicare program, some providers, which we refer to as “main providers,” have functioned as single entities while owning and operating multiple provider-based departments, locations, and facilities that were treated as part of the main provider for Medicare purposes. Having clear criteria for provider-based status is important because this designation can result in additional Medicare payments for services furnished at the provider-based facility, and may also increase the coinsurance liability of Medicare beneficiaries for those services.

In the April 7, 2000, **Federal Register** (65 FR 18504), we published a final rule specifying the criteria that must be met for a determination regarding provider-based status. The regulations at existing 42 CFR §413.65(b)(2) apply the same criteria to facilities on the main provider campus as to off-campus facilities, and state that before a main provider may bill for services of a facility as if the facility is provider-based, or before it includes costs of those services on its cost report, the facility must meet the criteria listed in the regulations. Those regulations were first effective for cost reporting periods beginning on or after January 10, 2001.

##### 2. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of December 2000

On December 21, 2000, the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA) of 2000 (Public Law 106-554) was enacted. Section 404 of BIPA contained provisions that significantly affected the provider-based regulations at §413.65. Under §404(a) of BIPA, any facilities or organizations that were “treated” as provider-based in relation to any provider on October 1, 2000, are to continue to be treated as such until October 1, 2002. “Facilities treated as provider-based” include those facilities with formal CMS determinations, as well as those facilities without formal CMS determinations that were being paid as provider-based as of October 1, 2000. As a result, facilities and organizations meeting the BIPA description were allowed to continue to be

treated as provider-based without meeting most of the criteria in the existing regulations until October 1, 2002. Those facilities and organizations affected under §404(a) of BIPA also were not required to submit an application for or obtain a provider-based status determination in order to continue receiving reimbursement as provider-based during this period.

### 3. Further Delay in Effective Date of Provider-Based Rules

Regulations implementing the BIPA §404 provisions were published in final on August 1, 2002. Under the August 1, 2002, revision to the provider-based regulations, if a facility was treated as provider-based in relation to a hospital or a critical access hospital (CAH) on October 1, 2000, it will continue to be considered provider-based in relation to that hospital or CAH until the start of the hospital's first cost reporting period beginning on or after July 1, 2003. (The new requirements are effective on October 1, 2002, with respect to provider-based status for facilities not in existence on October 1, 2000, or not treated as provider-based in relation to a hospital or CAH on that date.)

### 4. Criteria for Temporary Treatment as Provider-Based, Utilized Before Oct. 1, 2002

Section 404(c) of BIPA provides that a facility or organization that seeks a determination of provider-based status on or after October 1, 2000, and before October 1, 2002, shall be treated as having provider-based status for any period before a determination is made. Thus, recovery for overpayments will not be made retroactively once a request for a determination during that time period has been made. Once such a request has been submitted on or after October 1, 2000, and before October 1, 2002, CMS will treat the facility or organization as being provider-based from the date it began operating as provider-based until the effective date of a CMS determination that the facility or organization is not provider-based.

The provision concerning temporary treatment as provider-based in §404(c) of BIPA is effective only for requests filed on or after October 1, 2000 and before October 1, 2002.

## **B. Information on the Attestation Process Beginning on or After Oct. 1, 2002**

### 1. Is an attestation required?

Effective October 1, 2002, the mandatory requirement for provider-based determinations under §413.65(b) has been replaced with a voluntary attestation process. Providers are no longer required to apply for and receive a provider-based determination for their facilities prior to billing for services in those facilities as provider-based. However, under §413.65(b)(3), a provider may choose to obtain a determination of provider-based status by submitting an attestation stating that the facility meets the relevant provider-based requirements (depending on whether the facility is located on campus or off campus). Providers who wish to obtain such a determination of provider-based status for their facilities after October 1, 2002, should do so through the self-attestation process.

### 2. Should grandfathered facilities submit self-attestations?

As noted above, facilities treated as provider-based in relation to a provider on October 1, 2000, are not affected by the revised regulations until the main provider's first cost reporting period starting on or after July 1, 2003. In the case of these grandfathered facilities, any attestation regarding provider-based status will be considered only with respect to periods on or after that effective date.

### 3. What are the benefits of self-attesting?

Effective October 1, 2002, (or, for grandfathered facilities, effective for the potential main provider's first cost reporting period starting on or after July 1, 2003), an attestation of provider-based status, if approved, would result in a determination that a facility or organization is provider-based.

If CMS subsequently discovers that the facility for which an attestation has been made and approved in fact does not meet the provider-based rules, then CMS would not recover all past payments for periods subject to reopening, but instead would recover only the difference between the amount of payment that actually was made since the date the complete attestation for a provider-based determination was submitted and the amount of payments that CMS estimates should have been made in the absence of compliance with the provider-based requirements during that time period. For example, if a facility opens and begins billing as provider-based on October 1, 2002, and the

potential main provider submits an attestation on December 1, 2002, and the attestation is disapproved by CMS on February 1, 2003, then CMS will only recover the overpayments since December 1, 2002. In addition, at the time that CMS determines that a facility, that submitted a complete attestation, is actually not provider-based, payment would continue for up to 6 months but only at a reduced rate as described at §413.65(j)(5). However, if that main provider had not submitted an attestation and CMS determined that the facility is not provider-based, CMS would recover the overpayment for the period beginning October 1, 2002.

It could also benefit the provider to self-attest and obtain a determination because, under §413.65(l)(1), where a material change subsequently occurs in the relationship between the facility or organization and the main provider, and the main provider properly reports the material change to CMS, then treatment of a facility as provider-based would cease only with the date that CMS determines that the facility no longer qualifies for provider-based status. By contrast, a provider that does not self-attest at all, or does obtain a determination but fails to report a subsequent material change in its relationship with the facility, could face a recovery of the difference between provider-based and freestanding payment (i.e., the overpayment). For example, if a main provider opens a facility and begins billing as provider-based on October 1, 2002, but does not submit an attestation nor does the facility qualify as provider-based under § 413.65, and CMS discovers on February 1, 2003 that the main provider is billing inappropriately as provider-based, then CMS will recover the overpayments since October 1, 2002.

#### 4. Who is responsible for processing the attestations and making provider-based determinations?

The fiscal intermediaries (FIs) will receive and review the attestations. The providers should submit the original attestations (and documentation for off-campus facilities) to the FI, and submit an identical copy of the attestations (and documentation for off-campus facilities) to the regional office (RO) for the State in which the main provider is located. This will alert the ROs as to which providers are submitting attestations, and to expect a recommendation of approval or denial of provider-based status from the FIs for those providers.

However, all final determinations as to whether particular facilities or organizations are provider-based are to be made by the RO for the State in which the potential main provider is located. The FI for the potential main provider may make a recommendation to the RO as to whether the attestation should be accepted. The RO should either approve or disapprove the recommendation and notify the provider and the FI of its decision as to the status (provider-based or freestanding) of the facility or organization.

There are some providers who are serviced by FIs that are not under the same RO jurisdiction as the main provider. For example, a main provider may be physically located within the geographic jurisdiction of the Philadelphia RO, but the main provider may be serviced by a FI that is under the jurisdiction of the Dallas RO. In such cases, the RO for the State in which the main provider is located has jurisdiction over the provider-based determinations. Thus, for example, although a main provider in Pennsylvania may be serviced by an FI that is headquartered in Texas, the Philadelphia RO has jurisdiction over provider-based determinations made for the main provider located in Pennsylvania. Because the final decision as to whether the main provider's facilities are provider-based will be made by the RO for the State in which the main provider is located, the RO may need to coordinate the review process with multiple FIs, and another RO. Furthermore, although the "home" RO for the main provider has final jurisdiction for provider-based decisions, the RO with oversight of the servicing FI should be copied on and informed of all decisions the FI is asked to implement or otherwise is involved with.

#### 5. Is there a required form that must be used for attestations?

No, a provider may use a letter, memo, or any other format that contains the necessary information, although this PM contains an example of an acceptable format for the attestation.

#### 6. What should be included in the attestation?

Under §413.65(b)(3), a complete attestation is one that includes all information needed to permit CMS to make a determination. We have attached a sample attestation form that may, but is not required, to be used by the providers. At a minimum, an attestation should include:

- o The identity of the main provider and the facilities or organizations for which provider-based status is being sought,
- o An enumeration of each facility and a statement of its exact location (that is, its street address and whether it is on campus or off campus),
- o Supporting documentation for off-campus facilities for purposes of applying the provider-based status criteria in effect at the time the request or attestation is submitted,
- o The date on which the facility became provider-based to the main provider, and
- o Information on the person to contact should CMS or the intermediary have further questions.

Other required content for an attestation will depend on whether or not the facility is located on the main campus of the potential main provider. For purposes of the provider-based regulations, "campus" means the physical area immediately adjacent to the provider's main buildings, other areas and structures that are not strictly contiguous to the main buildings but are located within 250 yards of the main buildings, and any other areas determined on an individual case basis, by CMS, to be part of the provider's campus. Attestations for on-campus facilities must attest to meeting the items in paragraph C below. Attestations for off-campus facilities must attest to meeting and provide documentation for the items in paragraphs C and D below.

The following sections C and D list the requirements for attesting to provider-based status for on-campus and off-campus facilities, respectively, and specify ways in which the provider would document that the facility meets the particular requirement. At any time during the review of an attestation, either for on-campus or off-campus facilities, the RO or the FI may ask the provider for any documentation or information that they feel is necessary to make a determination.

### **C. Content of Attestations for on-campus facilities**

If a potential main provider seeks a determination of provider-based status for a facility that is located on the main campus of the potential main provider, the provider must submit an attestation containing the identifying information described in paragraph (B)(6) above, and stating that its facility meets each of the criteria in §413.65(d) listed below. If the potential main provider is a hospital, it must also attest that its facility will fulfill the obligations of hospital outpatient departments and hospital-based entities, as described in proposed §413.65(g). The provider must maintain documentation of the basis for its attestations and make that documentation available to CMS and to its FI upon request.

For attestations submitted for on-campus facilities, the FI should confirm that the facility is in fact on-campus. A map of the campus, use of mapping software such as Mapquest, or an onsite visit to the facility may be necessary to determine the facility's location.

**The criteria at §413.65(d) that are applicable to all facilities, including those on-campus, are:**

#### 1. Licensure

The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If a State health cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers in a State finds that a particular facility or organization is not part of a provider, CMS will determine that the facility or organization does not have provider-based status.

*Documentation maintained by the provider may include a copy of the State license, including the license number and the expiration date. Where applicable, the provider may need to maintain documentation of whether the State where the entity is located requires a separate license for the facility requesting provider-based status.*

## 2. Clinical Services

The clinical services of the facility or organization seeking provider-based status and the main provider are integrated as evidenced by the following:

(a) Professional staff of the facility or organization have clinical privileges at the main provider.

(b) The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.

(c) The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

(d) Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.

*Documentation maintained on (a)-(d) may include a list of all personnel working at the facility or organization showing their job titles and name of their employer, information as to whether professional staff of the facility have clinical privileges at the main provider, a description of the level of monitoring and oversight of the facility by the main provider as compared to oversight for another departments of the main provider, and a description of the responsibilities and relationships between the medical director of the facility, the chief medical officer of the main provider, and the medical staff committees at the main provider.*

(e) Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross-reference) of the main provider.

*The provider may maintain a copy or description of the policy utilized in record retrieval from both the main provider and the facility requesting provider-based status.*

(f) Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.

*For example, the provider could maintain information on how inpatient and outpatient services of the facility and the main provider are integrated, and examples of integration of services, including data on the frequency of referrals from inpatient to outpatient facilities of the provider, or vice versa.*

## 3. Financial Integration

The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.

*Documentation maintained by the provider could include a copy of the appropriate section of the main provider's chart of accounts or trial balance that would show the location of the facility's revenues and expenses.*

#### 4. Public Awareness

The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.

*As documentation, the provider may maintain examples that show that the facility is clearly identified as part of the main provider (i.e., a shared name, patient registration forms, letterhead, advertisements, signage, Web site). Advertisements that only show the facility to be part of or affiliated with the main provider's network or healthcare system are not sufficient.*

#### 5. Obligations of Hospital Outpatient Departments and Hospital-based Entities

In the case of a hospital outpatient department or a hospital-based entity, the facility or organization must fulfill the obligations of hospital outpatient departments and hospital-based entities as described in §413.65(g)(1) through (6) and (g)(8). The term "hospital," as used in connection with these obligations, includes a critical access hospital (CAH). These obligations include:

(a) Hospital outpatient departments located either on or off the campus of the hospital that is the main provider must comply with the antidumping rules in §§489.20 (l), (m), (q), and (r) and §489.24 of chapter IV of Title 42.

(b) Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) must be billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined.

(c) Hospital outpatient departments must comply with all the terms of the hospital's provider agreement.

(d) Physicians who work in hospital outpatient departments or hospital-based entities are obligated to comply with the non-discrimination provisions in §489.10(b) of chapter IV of Title 42.

(e) Hospital outpatient departments (other than RHCs) must treat all Medicare patients, for billing purposes, as hospital outpatients. The department must not treat some Medicare patients as hospital outpatients and others as physician office patients.

(f) In the case of a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based entity, payments for services in the hospital outpatient department or hospital-based entity are subject to the payment window provisions applicable to PPS hospitals and to hospitals and units excluded from PPS set forth at §412.2(c)(5) of this chapter and at §413.40(c)(2), respectively.

**NOTE:** The payment window provisions do not apply to critical access hospitals (CAHs).

(g) Hospital outpatient departments must meet applicable hospital health and safety rules for Medicare-participating hospitals in part 482 of this chapter.

*Documentation maintained by the provider to document compliance with some of these requirements might include a copy of the EMTALA policy in place at the facility.*

#### 6. Provider-based Status for Joint Ventures

In order for a facility or organization operating as a joint venture to be considered provider-based, the facility or organization must:

- (a) Be partially owned by at least one provider;
- (b) Be located on the main campus of a provider who is a partial owner;
- (c) Be provider-based to the main provider on whose campus the facility or organization is located; and
- (d) Also meet all the requirements applicable to all provider-based facilities and organizations in §413.65(d).

For example, where a provider has jointly purchased or jointly created a facility under joint venture arrangements with one or more other providers, and the facility is not located on the campus of the provider or the campus of any other provider engaged in the joint venture arrangement, no party to the joint venture arrangement can claim the facility as provider-based. In other words, if Hospital A and Hospital B form a joint venture, but the joint venture facility is not located on the campus of either hospital, then neither Hospital A nor B may claim the facility as provider-based. Additionally, the facility operated as a joint venture must be provider-based only to the provider whose campus on which the facility is located, regardless of whether that provider is the majority owner. For example, if Hospital A owns 60 percent of Facility C, and Hospital B owns 40 percent of Facility C, but Facility C is located on the campus of Hospital B, Facility C may only be provider-based to Hospital B.

The facility does not have to advertise as a joint venture, but as a facility that is provider-based to the main provider. Accordingly, the services in the facility would be billed using the provider number of the provider whose campus on which the facility is located. (The facility cannot, of course, be provider-based with respect to both hospitals.)

#### **D. Content of Attestations for Off-campus Facilities**

If the facility is not located on the main campus of the potential main provider, the provider that wishes to obtain a determination of provider-based status must submit an attestation containing the identifying information described in paragraph B.6 and state that its facility meets each of the criteria in paragraph C.1 through C.4 (corresponding to regulations at §413.65(d)) as well as the additional requirements listed below (corresponding to regulations at §413.65(e)). If the facility is operated as a joint venture or under a management contract, the potential main provider must also attest to compliance with the requirements in paragraph C.6 and D.5 (corresponding to §§413.65(f) and 413.65(h)), as applicable. As explained below, if the potential main provider is a hospital, the hospital also must attest that it will fulfill the obligations of hospital outpatient departments and hospital-based entities described in paragraph C.5 and item 4 of this paragraph (corresponding to §413.65(g)).

The provider seeking such a determination must submit documentation of the basis for its attestations to CMS at the time it submits its attestation.

**The *additional* requirements applicable specifically to off-campus facilities or organizations are as follows:**

##### **1. Operation Under the Ownership and Control of the Main Provider**

The facility or organization seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:

- (a) The business enterprise that constitutes the facility or organization is 100 percent owned by the provider.
- (b) The main provider and the facility or organization seeking status as a department of the provider, a remote location of a hospital, or a satellite facility have the same governing body.
- (c) The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status must be subject to common bylaws and operating decisions of the governing body of the main provider where it is based.

(d) The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.

*As documentation for this requirement, the provider may need to furnish documents such as the articles of incorporation and the bylaws for both the main provider and the facility. The provider also may want to describe who has final approval for administrative decisions, contracts with outside parties, personnel policies, and medical staff appointments for the facility.*

## 2. Administration and Supervision

The reporting relationship between the facility or organization seeking provider-based status and the main provider must have the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by compliance with all of the following requirements:

(a) The facility or organization is under the direct supervision of the main provider.

*Documentation furnished by the provider may include a list of key administrative staff (position/titles only) at the main provider and the facility that reflects a reporting relationship.*

(b) The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity:

(i) Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and

*Documentation for this requirement may include an organizational chart that includes the main provider and the facility requesting provider-based status.*

(ii) Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.

*As documentation, the provider may include a written description of the facility director's reporting requirements and accountability procedures for day to day operations.*

(c) The following administrative functions of the facility or organization are integrated with those of the provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are—

(i) Contracted out under the same contract agreement; or

(ii) Handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.

*Documentation furnished by the provider may include a list of the various administrative functions (e.g., billing services, laundry, payroll) at the facility that are integrated with the main provider. Additionally, the provider may include copies of any contracts for administrative functions that are completed under arrangements for the main provider and/or facility.*

### 3. Location

The facility or organization is located within a 35-mile radius of the campus of the provider that is the potential main provider, except when the requirements in paragraph C.3.a, C.3.b, or C.3.c (corresponding to §§413.65(e)(3)(i), (e)(3)(ii), and (e)(3)(iii)) are met:

(a) The facility or organization is owned and operated by a provider that has a disproportionate share adjustment (as determined under §412.106 of chapter IV of Title 42) greater than 11.75 percent or is described in §412.106(c)(2) of chapter IV of Title 42 implementing §1886(e)(5)(F)(i)(II) of the Act and is:

(i) Owned or operated by a unit of State or local government;  
(ii) A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or

(iii) A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

(b) The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period:

(i) At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider;

(ii) At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider); or

(iii) If the facility or organization is unable to meet the criteria in paragraph (e)(3)(ii)(A) or paragraph (e)(3)(ii)(B) because it was not in operation during all of the 12-month period described in paragraph (e)(3)(ii), the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in paragraph (e)(3)(ii), accounted for at least 75 percent of the patients served by the main provider.

*Note that the 75/75 test under § 413.65(e)(3)(ii)(A) and § 413.65(e)(3)(ii)(B) may be demonstrated with any mix of inpatients and/or outpatients of the main provider.*

Providers may submit Excel spreadsheets or other computer files with listings of all patients treated at the hospital and at the facility within the most recent 12-month period. The listing should include the patient's name, medical record number, date(s) of visit, date(s) of discharge, address, city, and zip code. To demonstrate compliance with §413.65(e)(3)(ii)(A), after including the total number of patients from both the facility and the provider, the provider should list each zip code, and the number of patients from that zip code that were treated at the hospital, and the number of patients from that same zip code that were treated at the facility. Alternatively, to demonstrate compliance with §413.65(e)(3)(ii)(B), the provider may submit admissions data that would indicate the reasons the patients served by the facility came to receive treatment at the provider.

(c) A facility or organization may qualify for provider-based status under this section only if the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, in adjacent States.

(d) An RHC that is otherwise qualified as a provider-based entity of a hospital that is located in a rural area, as defined in §412.62(f)(1)(iii) of chapter IV of Title 42, and has fewer than 50 beds, as determined under §412.105(b) of chapter IV of Title 42, is not subject to the criteria in paragraphs (D)(3)(a) and (b) of this PM (corresponding to §413.65(e)(3)(i) through (e)(3)(iii)).

*To demonstrate that a facility is located within a 35-mile radius of the main provider, maps or an online service such as Mapquest may be used. (Note, however, that under this policy, the 35-mile*

*radius is measured by actual straight-line distance between the provider and the facility, not road miles).*

#### 4. Obligations of Hospital Outpatient Departments and Hospital-Based Entities

The obligations for on campus facilities or organizations apply to those off campus, with the following additional obligations:

(a) When a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity (other than an RHC) that is not located on the main provider's campus, and the treatment is not required to be provided by the antidumping rules in §489.24 of chapter IV of Title 42, the hospital must provide written notice to the beneficiary, before the delivery of services, of the amount of the beneficiary's potential financial liability (that is, that the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, and of the amount of that liability).

(i) The notice must be one that the beneficiary can read and understand.

(ii) If the exact type and extent of care needed is not known, the hospital may furnish a written notice to the patient that explains that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based.

(iii) The hospital may furnish an estimate based on typical or average charges for visits to the facility, while stating that the patient's actual liability will depend upon the actual services furnished by the hospital.

(iv) If the beneficiary is unconscious, under great duress, or for any other reason unable to read a written notice and understand and act on his or her own rights, the notice must be provided, before the delivery of services, to the beneficiary's authorized representative.

(v) In cases where a hospital outpatient department provides examination or treatment that is required to be provided by the antidumping rules of §489.24 of chapter IV of Title 42, notice, as described in this paragraph (g)(7), must be given as soon as possible after the existence of an emergency has been ruled out or the emergency condition has been stabilized.

*For example, information providers may supply as documentation could include a copy of the form they give to patients and a copy of their policies regarding distribution of the form. Providers may also supply a copy of their policy on EMTALA compliance.*

*Note that an Advance Beneficiary Notification (ABN) for non-covered services does not meet the requirement of providing written notice of beneficiary liability. Also, notice is not required if the facility furnishes only services for which the beneficiary will not incur any deductible or coinsurance liability, or services for which the beneficiary liability is the same in both the provider-based and freestanding settings (e.g., screening mammography).*

#### 5. Management Contracts

A facility or organization that is not located on the campus of the potential main provider and otherwise meets the requirements of sections C and D of this document, but is operated under management contracts, must also meet all of the following criteria:

(a) The main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at part 414 of chapter IV of Title 42. Other than staff that may be paid under such a Medicare fee schedule, the main provider may not utilize the services of "leased" employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) that are directly involved in the delivery of patient care.

(b) The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph D.2.c (corresponding to §413.65(e)(2)(iii)).

(c) The main provider has significant control over the operations of the facility or organization as determined under criteria in paragraph D.2.b (corresponding to §413.65(e)(2)(ii)).

(d) The management contract is held by the main provider itself, not by a parent organization that has control over both the main provider and the facility or organization.

Main providers are not required to employ other support staff, such as maintenance or security personnel, who are not directly involved in providing patient care, nor are licensed professional caregivers such as physicians, physician assistants, or certified registered nurse anesthetists required to become provider employees. As noted above, other than staff that may be paid under a Medicare fee schedule, the main provider may not utilize the services of “leased” employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing arrangement) that are directly involved in the delivery of patient care.

*Providers could include as documentation a copy of any relevant management contracts for the facility.*

## **E. Additional Issues to Consider for Attestations**

1. Does a main provider have to submit a separate attestation for each of its facilities and services, on campus and off campus?

The provider-based rules do not apply to specific services; rather, these rules are site-specific. That is, each individual department or entity in its entirety must be a subordinate and integrated part of the main provider. For example, a provider may have several outpatient departments, some located on campus and some located off campus, yet each department as a whole must meet the applicable rules for provider-based status. However, a main provider would not need to submit a separate application for each one of its facilities for which a provider-based determination is sought. A facility or organization may also be viewed as constituting a separate cost center in a main provider’s general ledger. A provider may attest in a single application package that each one of its facilities (or cost centers) for which it intends to bill for services as if the facility is provider-based meets the applicable provider-based rules under §13.65. For those facilities that are located on campus, no documentation is required to be submitted with the attestation. Documentation must be submitted for those facilities located off campus. However, we are requiring that as part of its attestation, the main provider enumerate each facility and state its exact location (that is, its street address and whether it is on campus or off campus).

For purposes of provider-based determinations, a facility may be an entire building, two or more buildings, or defined areas within a building. For example, a hospital may lease space in a building that includes numerous physicians’ offices, a DME supplier, and some other non-medical offices, in addition to housing the hospital’s radiology department and an outpatient clinic. Provider-based status would only apply, however, to the radiology department and the outpatient clinic. Because the provider-based rules are site-specific, the provider would attest to the provider-based status of the radiology department and the outpatient clinic. That is, the provider would attest that each department or entity within that multi-suite building to which the provider-based rules apply, meets the provider-based rules. The provider would *not* attest that the entire building is provider-based, but only that those specific offices or suites where hospital services are provided are provider-based. A provider may need to submit floor plans of such a building in order to document that a department or entity is provider-based.

2. Effective Date of Determinations of Provider-Based Status

Generally, a determination of provider-based status cannot be effective before the earliest date on which an attestation regarding provider-based status has been made and all requirements of 42 CFR Part 413 have been met. See issue #3 below for an exception to this rule.

3. For grandfathered facilities, may a main provider submit an attestation prior to the cost reporting period beginning on or after July 1, 2003 in which the provider-based rules will apply?

Even though the provider-based criteria in §§413.65(d) and (e) do not apply to grandfathered facilities until main provider cost reporting periods beginning on or after July 1, 2003, providers with grandfathered facilities may file an attestation prior to the July 1, 2003 date to attest to

compliance for the main provider's first cost reporting period beginning on or after July 1, 2003. For example, if a main provider with a June 30 fiscal year end has facilities that are grandfathered until June 30, 2003, then, although the main provider may submit the attestation for those facilities prior to July 1, 2003, the provider-based determination made based on that attestation cannot be effective for any period prior to July 1, 2003. Accordingly, the FI has the discretion, but is not required, to review the attestation prior to July 1, 2003. Even if the attestation is reviewed before July 1, 2003, it would not be effective until July 1, 2003. If it is reviewed after July 1, 2003, and if the facility is found to meet the provider-based rules back to July 1, 2003, then CMS can make the determination apply as of July 1, 2003.

4. For new facilities, may a main provider submit an attestation prior to the date that the facility opens?

The FI has the discretion to decide whether attestations submitted for facilities that have not yet opened will be accepted and reviewed. However, the effective date of a determination of provider-based status for a facility that has not yet opened cannot be a date before the facility opens.

5. CMS Action on Attestations and Timeframe

The regulations at §413.65(b)(3)(iii) state that whenever a provider submits an attestation of provider-based status for an on-campus facility or organization, CMS will send the provider written acknowledgement of receipt of the attestation, review the attestation for completeness, consistency with the criteria in §413.65, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility is provider-based. Unless CMS has reason to believe that the attestation submitted for the on-campus facility is incomplete or inconsistent with the applicable provider-based requirements, CMS may make a provider-based determination on the basis of the attestation, and need not request and review documentation from the provider in support of the attestation. Incomplete attestations should be handled as described in paragraph E.6 below.

In §413.65(b)(3)(iv), we clarified that whenever a provider submits an attestation of provider-based status for an off-campus facility or organization, CMS will send the provider written acknowledgement of receipt of the attestation, review the attestation for completeness, consistency with the criteria in §413.65, consistency with the documentation submitted with the attestation, and consistency with information in the possession of CMS at the time the attestation is received, and make a determination as to whether the facility is provider-based.

6. Relation to Enrollment Approvals

In some cases, a provider may request an enrollment change, such as adding a new practice location for an outpatient clinic that wishes to bill under the provider number of an existing hospital, but may or may not submit an attestation of provider-based status for that practice location. When issuing an approval of an enrollment change of this kind, please inform the provider that such an approval is effective for enrollment purposes only and does not constitute a determination that the facility meets the requirements for provider-based status in 42 CFR §413.65.

7. What actions will be taken if an attestation is incomplete?

If an attestation is found to be incomplete, the provider should be notified in writing of the specific information or documentation needed to complete the attestation, and be given 30 days to submit the missing information or documentation. Depending on the extent of the omissions, the FI may either proceed with its review of the attestation or suspend review until the necessary supplementary information or documentation is received. If the needed material is not received within 30 days, the attestation should be disapproved, and recovery of any overpayments will be made from the date of the disapproval back to the date on which the provider submitted the attestation.

8. What actions will be taken if the attestation (i.e., determination of provider-based status) is denied?

As stated in the response to the previous question #6, in accordance with §413.65(k), recovery of overpayments will be made from the date of the disapproval of the attestation back to the date on

which the provider submitted the attestation. In addition, the RO should issue a notice of denial of provider-based status to the provider explaining that the provider has the following 4 options:

(1) The provider may notify CMS in writing within 30 days of the date the notice is issued that the provider intends to make the changes needed for the facility or organization to comply with the provider-based rules and that the provider intends to seek a determination of provider-based status for its facility or organization. If the provider indicates that it will be seeking a provider-based determination for the facility or organization, then CMS will continue to pay for services provided at the facility or organization at a rate estimated for services furnished by a freestanding facility. CMS will continue to pay at this rate for as long as is required for the facility or organization to comply with the provider-based rules, (but not for longer than 6 months), if the provider submits a complete request (not an attestation) for a provider-based determination and all other required information within 90 days after the date of the notice of denial of provider-based status. If the necessary application or information is not provided, CMS will terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.

(2) The provider may notify CMS in writing within 30 days of the date the notice is issued that the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a free-standing facility. If the provider indicates that the facility or organization, or its practitioners, will be seeking to meet enrollment and other requirements for billing for services in a free-standing facility, then CMS will continue to pay for services provided at the facility or organization at a rate estimated for services furnished by a freestanding facility. CMS will continue to pay at this rate for as long as is required for the facility or organization to enroll as a freestanding facility, (but not for longer than 6 months), if the facility or organization, or its practitioners, submit a complete enrollment application and furnish all other information needed by CMS to process the enrollment application and verify that other billing requirements are met within 90 days after the date of notice of the denial of provider-based status. If the necessary enrollments or information is not provided, CMS will terminate all payment to the provider, facility, or organization as of the date CMS issues notice that necessary applications or information have not been submitted.

(3) The provider may choose not to notify CMS within 30 days of the date the notice is issued of whether it intends to pursue provider-based status under item (1) above, or freestanding status under item (2) above. If CMS does not receive a response as described in item (1) or item (2) within 30 days of the date the notice is issued, all payment will end as of the 30th day after the date of the notice.

Regardless of whether or how it responds to the notice in items (1) through (3) above, the provider may choose to appeal its denial of provider-based status within 60 days from the date of the notice of denial. Adverse determinations regarding provider-based status may be appealed under the administrative appeals procedures set forth in 42 CFR Part 498. Any notice to the provider of an adverse determination must contain a paragraph informing the provider of its right to appeal under those procedures. The following language may be used to inform the provider of its appeal rights:

#### Initial Determination Request for Reconsideration

If you are dissatisfied with this determination, you may request reconsideration by filing a written reconsideration request within sixty (60) days from the date on which you receive this letter. Your request must state the issues or findings of fact with which you disagree and the reasons for disagreement. Your reconsideration rights are set forth in the regulations at 42 CFR §498.22. Please address your request for reconsideration to:

(Insert address of appropriate CMS RO ARA.)

#### Denial of a Reconsideration Request

If you disagree with this first level appeals determination, you or your legal representative may request a hearing before an Administrative Law Judge (ALJ) of the Department of Health and Human Services, Departmental Appeals Board. Procedures governing this process are set out in the regulations at 42 CFR §498.40 et

seq. A written request for a hearing must be filed within sixty (60) days from the date on which you receive your first level appeal results. The request should be made to:

Departmental Appeals Board  
Civil Remedies Division  
Room 637-D  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Washington, D.C. 20201  
Attention: Jacqueline Williams

Forward a copy of your request for an ALJ hearing to:

(Insert address of appropriate CMS RO ARA.)

and

(Insert address of appropriate RO General Counsel.)

A request for a hearing must identify the specific issues and findings of fact and conclusions of law with which you disagree, and specify the basis for contending that the findings and conclusions are incorrect.

9. Is an attestation required before a provider begins billing for services of a facility or organization?

Regardless of whether they are grandfathered under BIPA, providers are not obligated to submit attestations or applications for provider-based status before they begin billing as provider-based. A provider would only be considered to be billing inappropriately if the facility actually did not meet the relevant provider-based rules. However, if a provider does not submit a complete attestation acceptable to CMS of provider-based status, and CMS subsequently determines that the provider is billing inappropriately, the provider would be subject to recovery of overpayments under §413.65(j)(ii) for services at that facility(ies) for all prior cost reporting periods subject to reopening in accordance with §§405.1885 and 405.1889.

10. Does a main provider need to “re-attest” after a certain period of time?

Just as providers are no longer explicitly required to submit an initial attestation, there is also no explicit requirement for hospitals to re-attest that their facilities continue to meet the provider-based requirements. However, §413.65(c) provides information on reporting of material changes in provider-based relationships. Under §413.65(l), if CMS determines that a facility that had previously been determined to be provider-based no longer qualifies for provider-based status, and the failure to qualify for provider-based status results from a material change in the relationship between the main provider and the facility that the main provider reported to CMS, treatment of the facility as provider-based would cease with the date that CMS determines that the facility no longer qualifies for provider-based status. Conversely, if a main provider did not report a material change to CMS, the main provider will be subject to recovery of overpayments as described under §413.65(j)(1)(ii).

11. How should applications for provider-based status that were submitted prior to October 1, 2002 be handled?

As stated above in part A of this PM, §404(c) of BIPA states that facilities for which a request for determination of provider-based status was submitted on or after October 1, 2000 and before October 1, 2002, are treated as having provider-based status for any period before a determination is made. This applies even to those facilities that have submitted applications for a determination during that time period but CMS has *not* yet determined those facilities to be provider-based.

After September 30, 2002, providers no longer submit applications to obtain provider-based determinations under §404(c) of BIPA. Instead, providers wishing to obtain provider-based determinations regarding specific facilities must submit attestations as described above. For those

applications that were submitted on or after October 1, 2000 and before October 1, 2002 for which a determination regarding provider-based status is still pending, rather than have the providers submit attestations, the FI will apply the regulations in effect on and after October 1, 2002, or July 1, 2003, if applicable, when reviewing the providers' applications for provider-based status. If an application does not contain all the documentation necessary for a determination to be made, the FI may request that the provider submit the additional documentation. Any *determinations* made on such applications can be effective as early as the earliest date that the facility or organization is found to meet the provider-based rules, but not before October 1, 2002. In addition, for periods prior to October 1, 2002, (but not before October 1, 2000), because §404(c) of BIPA states that a facility or organization that seeks a determination of provider-based status on or after October 1, 2000, and before October 1, 2002, shall be treated as having provider-based status for any period *before a determination is* made, CMS will treat the facility as provider-based from the date the application was submitted until the date that CMS makes a provider-based determination. (This is in addition to provider-based status deemed under §404(a) of BIPA.)

## **F. Provider Education**

You must inform the affected provider community of the information outlined in this memorandum within 2 weeks of its receipt by posting portions of this PM relevant to the provider community on your Web site. You should use your list-serv to send notification to providers that important information about the provider-based determination process and requirements is available on your Web site.

Attachment

**The *effective date* of this PM is October 1, 2002.**

**The *implementation date* of this PM is May 1, 2003.**

**This PM may be discarded April 30, 2004.**

**Funding is available through the regular budget process for costs required for implementation.**

**If you have any questions, contact Tzvi Hefter at (410) 786-4487.**

## SAMPLE ATTESTATION FORMAT

The following is an example of an acceptable format for an attestation of provider-based compliance.

Please note that provider-based determinations in relation to hospitals are not made for the following facilities: ambulatory surgical centers (ASCs), comprehensive outpatient rehabilitation facilities (CORFs), home health agencies (HHAs), skilled nursing facilities (SNFs), hospices, inpatient rehabilitation units that are excluded from the inpatient prospective payment system for acute hospital services, independent diagnostic testing facilities furnishing only services paid under a fee schedule (subject to §413.65(a)(1)(ii)(G)), facilities other than those operating as parts of CAHs that furnish only physical, occupational, or speech therapy to ambulatory patients (subject to § 413.65(a)(1)(ii)(H)), ESRD facilities, departments of providers that perform functions necessary for the successful operation of the providers but do not furnish services of a type for which separate payment could be claimed under Medicare or Medicaid (for example, laundry or medical records departments), ambulances.

(**Note:** As of the date of release of this Program Memorandum, legislation has not been enacted to further extend the moratorium on applying the \$1,500 annual cap on physical therapy, occupational therapy, and speech therapy services of providers and suppliers other than hospitals).

### Provider-Based Status Attestation Statement

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Main provider's Medicare Provider Number: \_\_\_\_\_

Main provider's name: \_\_\_\_\_

Main provider's address: \_\_\_\_\_

Application Contact name and Phone Number \_\_\_\_\_

Facility/Organization's name: \_\_\_\_\_

Facility/Organization's **exact** address: \_\_\_\_\_

(Include bldg. no., suite/room no., etc.)

Facility/Organization's Medicare Provider Number, if there is one: \_\_\_\_\_

Is the facility/organization part of a multi-campus hospital? \_\_\_\_\_

Is the facility a Federally Qualified Health Center (FQHC)? If so, and if the FQHC meets the criteria at section 413.65(n), it need not attest to its provider-based status. The provider-based rules do not apply to other FQHCs that do not meet the criteria at section 413.65(n), and an attestation should not be submitted.

The facility/organization became provider-based with the main provider on the following date:

\_\_\_\_\_  
 (Please indicate if this attestation is adding deleting, or changing previous information—if yes, please make certain to include the effective date.)

Indicate whether the facility/organization is "on campus" or "off campus" (per § 413.65(a)(2)) with the main provider:

1. \_\_\_\_\_ **On campus** of the main provider (located within 250 yards from the main provider building)

OR

2. \_\_\_\_\_ **Off campus** of the main provider (located 250 yards or greater from the main provider building, but subject to § 413.65(e)(3))

**I certify that I have carefully read the attached sections of the Federal provider-based regulations, before signing this attestation, and that the facility/organization complies with the following requirements to be provider-based to the main provider (initial ONE selection only):**

1. \_\_\_\_ The facility/organization is “**on campus**” per 42 C.F.R. §413.65(a)(2) and is in compliance with the following provider-based requirements (shown in the following attached pages) in §413.65(d) and §413.65(g), other than those in §413.65(g)(7). If the facility/organization is operated as a joint venture, I certify that the requirements under §413.65(f) have been met. I am aware of, and will comply with, the requirement to maintain documentation of the basis for these attestations (for each regulatory requirement) and to make that documentation available to the Centers for Medicare & Medicaid Services (CMS) and to CMS contractors upon request.

OR

2. \_\_\_\_ The facility/organization is “**off campus**” per 42 C.F.R. §413.65(a)(2) and is in compliance with the following provider-based requirements (shown in the following attached pages) in §413.65(d) and §413.65(e) and §413.65(g). If the facility/organization is operated under a management contract/agreement, I certify that the requirements of §413.65(h) have been met. Furthermore, I am submitting along with this attestation to the Centers for Medicare & Medicaid Services (CMS), the documentation showing the basis for these attestations (for each regulatory requirement).

**Please complete the following for on campus AND off campus facilities and organizations:**

**I attest that the facility/organization complies with the following requirements to be provider-based to the main provider (please indicate Yes or No for each requirement):**

1. \_\_\_\_ The department of the provider, the remote location of a hospital, or the satellite facility and the main provider are operated under the same license, except in areas where the State requires a separate license for the department of the provider, the remote location of a hospital, or the satellite facility, or in States where State law does not permit licensure of the provider and the prospective department of the provider, the remote location of a hospital, or the satellite facility under a single license. If the provider and facility/organization are located in a state having a health facilities’ cost review commission or other agency that has authority to regulate the rates charged by hospitals or other providers, the commission or agency has not found that the facility/organization is not part of the provider.
2. \_\_\_\_ The clinical services of the facility or organization seeking provider-based status and the main provider are integrated.
  - 2a. \_\_\_\_ Professional staff of the facility or organization have clinical privileges at the main provider.
  - 2b. \_\_\_\_ The main provider maintains the same monitoring and oversight of the facility or organization as it does for any other department of the provider.
  - 2c. \_\_\_\_ The medical director of the facility or organization seeking provider-based status maintains a reporting relationship with the chief medical officer or other similar official of the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the medical director of a department of the main provider and the chief medical officer or other similar official of the main provider, and is under the same type of supervision and accountability as any other director, medical or otherwise, of the main provider.

- 2d. \_\_\_ Medical staff committees or other professional committees at the main provider are responsible for medical activities in the facility or organization, including quality assurance, utilization review, and the coordination and integration of services, to the extent practicable, between the facility or organization seeking provider-based status and the main provider.
- 2e. \_\_\_ Medical records for patients treated in the facility or organization are integrated into a unified retrieval system (or cross reference) of the main provider.
- 2f. \_\_\_ Inpatient and outpatient services of the facility or organization and the main provider are integrated, and patients treated at the facility or organization who require further care have full access to all services of the main provider and are referred where appropriate to the corresponding inpatient or outpatient department or service of the main provider.
3. \_\_\_ The financial operations of the facility or organization are fully integrated within the financial system of the main provider, as evidenced by shared income and expenses between the main provider and the facility or organization. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance.
4. \_\_\_ The facility or organization seeking status as a department of a provider, a remote location of a hospital, or a satellite facility is held out to the public and other payers as part of the main provider. When patients enter the provider-based facility or organization, they are aware that they are entering the main provider and are billed accordingly.
5. \_\_\_ In the case of a hospital outpatient department or a hospital-based entity **(if the facility is not a hospital outpatient department or a hospital-based entity, please record "NA" for "not applicable" and skip to requirements under number 6)**, the facility or organization fulfills the obligation of:
- 5a. \_\_\_ Hospital outpatient departments located either on or off the campus of the hospital that is the main provider comply with the anti-dumping rules in §§489.20(l), (m), (q), and (r) and §489.24 of chapter IV of Title 42.
- 5b. \_\_\_ Physician services furnished in hospital outpatient departments or hospital-based entities (other than RHCs) are billed with the correct site-of-service so that appropriate physician and practitioner payment amounts can be determined under the rules of Part 414 of chapter IV of Title 42.
- 5c. \_\_\_ Hospital outpatient departments comply with all the terms of the hospital's provider agreement.
- 5d. \_\_\_ Physicians who work in hospital outpatient departments or hospital-based entities comply with the non-discrimination provisions in §489.10(b) of chapter IV of Title 42.
- 5e. \_\_\_ Hospital outpatient departments (other than RHCs) treat all Medicare patients, for billing purposes, as hospital outpatients. The departments do not treat some Medicare patients as hospital outpatients and others as physician office patients.

5f. \_\_\_\_ In the case of a patient admitted to the hospital as an inpatient after receiving treatment in the hospital outpatient department or hospital-based entity, payments for services in the hospital outpatient department or hospital-based entity are subject to the payment window provisions applicable to PPS hospitals and to hospitals and units excluded from PPS set forth at §412.2(c)(5) of chapter IV of Title 42 and at § 413.40(c)(2) of chapter IV of Title 42, respectively. **(Note: If the potential main provider is a CAH, enter "NA" for this item).**

5g. \_\_\_\_ **(Note: This requirement only applies to off campus facilities).** When a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity (other than an RHC) that is not located on the main provider's campus, and the treatment is not required to be provided by the antidumping rules in §489.24 of chapter IV of Title 42, the hospital provides written notice to the beneficiary, before the delivery of services, of the amount of the beneficiary's potential financial liability (that is, that the beneficiary will incur a coinsurance liability for an outpatient visit to the hospital as well as for the physician service, and of the amount of that liability).

(1)\_\_\_\_ The notice is on that the beneficiary can read and understand.

(2)\_\_\_\_ If the exact type and extent of care needed is not known, the hospital furnishes a written notice to the patient that explains that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based.

(3)\_\_\_\_ The hospital furnishes an estimate based on typical or average charges for visits to the facility, but states that the patient's actual liability will depend upon the actual services furnished by the hospital.

(4)\_\_\_\_ If the beneficiary is unconscious, under great duress, or for any other reason is unable to read a written notice and understand and act on his or her own rights, the notice is provided before the delivery of services, to the beneficiary's authorized representative.

(5)\_\_\_\_ In cases where a hospital outpatient department provides examination or treatment that is required to be provided by the antidumping rules at § 489.24 of chapter IV of Title 42, the notice is given as soon as possible after the existence of an emergency condition has been ruled out or the emergency condition has been stabilized.

5h. \_\_\_\_ Hospital outpatient departments meet applicable hospital health and safety rules for Medicare-participating hospitals in part 482 of this chapter.

**For off campus facilities, please complete the following:**

**In addition to the above requirements (numbers 1-5h), I attest that the facility/organization complies with the following requirements to be provider-based to the main provider as an off campus facility (please indicate Yes or No for each requirement):**

6. \_\_\_\_ The facility or organization seeking provider-based status is operated under the ownership and control of the main provider, as evidenced by the following:

6a. \_\_\_\_ The business enterprise that constitutes the facility or organization is 100 percent owned by the provider.

- 6b. \_\_\_\_ The main provider and the facility or organization seeking status as a department of the provider, a remote location of a hospital, or a satellite facility have the same governing body.
- 6c. \_\_\_\_ The facility or organization is operated under the same organizational documents as the main provider. For example, the facility or organization seeking provider-based status is subject to common bylaws and operating decisions of the governing body of the provider where it is based.
- 6d. \_\_\_\_ The main provider has final responsibility for administrative decisions, final approval for contracts with outside parties, final approval for personnel actions, final responsibility for personnel policies (such as fringe benefits or code of conduct), and final approval for medical staff appointments in the facility or organization.
7. \_\_\_\_ The reporting relationship between the facility or organization seeking provider-based status and the main provider has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and one of its existing departments, as evidenced by compliance with all of the following requirements:
- 7a. \_\_\_\_ The facility or organization is under the direct supervision of the main provider.
- 7b. \_\_\_\_ The facility or organization is operated under the same monitoring and oversight by the provider as any other department of the provider, and is operated just as any other department of the provider with regard to supervision and accountability. The facility or organization director or individual responsible for daily operations at the entity--
- (1) \_\_\_\_ Maintains a reporting relationship with a manager at the main provider that has the same frequency, intensity, and level of accountability that exists in the relationship between the main provider and its existing departments; and
- (2) \_\_\_\_ Is accountable to the governing body of the main provider, in the same manner as any department head of the provider.
- 7c. \_\_\_\_ The following administrative functions of the facility or organization are integrated with those of the provider where the facility or organization is based: billing services, records, human resources, payroll, employee benefit package, salary structure, and purchasing services. Either the same employees or group of employees handle these administrative functions for the facility or organization and the main provider, or the administrative functions for both the facility or organization and the entity are (1) contracted out under the same contract agreement; or (2) handled under different contract agreements, with the contract of the facility or organization being managed by the main provider.
8. \_\_\_\_ The facility or organization is located within a 35-mile radius of the campus of the potential main provider, except when the requirements in paragraph 8a of this section are met (please check below in the appropriate location if you qualify for the exemption):
- 8a. \_\_\_\_ The facility or organization is owned and operated by a hospital or CAH that has a disproportionate share adjustment (as determined under §412.106 of chapter IV of Title 42) greater than 11.75 percent or is described in §412.106(c)(2) of chapter IV of Title 42 implementing section 1886(e)(5)(F)(i)(II) of the Act and is:
- (1) \_\_\_\_ Owned or operated by a unit of State or local government;

- (2) \_\_\_\_ A public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government; or
- (3) \_\_\_\_ A private hospital that has a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services for low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan).

8b. \_\_\_\_ The facility or organization demonstrates a high level of integration with the main provider by showing that it meets all of the other provider-based criteria and demonstrates that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the attestation for provider-based status is filed with CMS, and for each subsequent 12-month period:

- (1) \_\_\_\_ At least 75 percent of the patients served by the facility or organization reside in the same zip code areas as at least 75 percent of the patients served by the main provider;
- (2) \_\_\_\_ At least 75 percent of the patients served by the facility or organization who required the type of care furnished by the main provider received that care from that provider (for example, at least 75 percent of the patients of an RHC seeking provider-based status received inpatient hospital services from the hospital that is the main provider); or
- (3) \_\_\_\_ If the facility or organization is unable to meet the criteria in (1) or (2) directly above because it was not in operation during all of the 12-month period described paragraph 8b, the facility or organization is located in a zip code area included among those that, during all of the 12-month period described in paragraph 8b, accounted for at least 75 percent of the patients served by the main provider.

8c. \_\_\_\_ If the facility or organization is attempting to qualify for provider-based status under this section, then the facility or organization and the main provider are located in the same State or, when consistent with the laws of both States, in adjacent States.

**Note:** An RHC that is otherwise qualified as a provider-based entity of a hospital that is located in a rural area as defined in § 412.62(f)(1)(iii) of chapter IV of Title 42, and has fewer than 50 beds as determined under §412.105(b) of chapter IV of Title 42, is not subject to the criteria in 8a and 8b above.

9. \_\_\_\_ The facility or organization that is not located on the campus of the potential main provider and otherwise meets the requirements of 1-8 above, but is operated under management contract, meets all of the following criteria (**please respond to 9a - 9d if the facility is operated under a management contract; otherwise record "NA" for "not applicable"**):

9a. \_\_\_\_ The main provider (or an organization that also employs the staff of the main provider and that is not the management company) employs the staff of the facility or organization who are directly involved in the delivery of patient care, except for management staff and staff who furnish patient care services of a type that would be paid for by Medicare under a fee schedule established by regulations at Part 414 of chapter IV of Title 42. Other than staff that may be paid under such a Medicare fee schedule, the main provider does not utilize the services of "leased"

employees (that is, personnel who are actually employed by the management company but provide services for the provider under a staff leasing or similar agreement) that are directly involved in the delivery of patient care.

- 9b. \_\_\_\_ The administrative functions of the facility or organization are integrated with those of the main provider, as determined under criteria in paragraph 7c above.
- 9c. \_\_\_\_ The main provider has significant control over the operations of the facility or organization as determined under criteria in paragraph 7b above.
- 9d. \_\_\_\_ The management contract is held by the main provider itself, not by a parent organization that has control over both the main provider and the facility or organization.

**For facilities/organizations operated as joint ventures requesting provider-based determinations: In addition to the above requirements (numbers 1-5h for on campus facilities), I attest that the facility/organization complies with the following requirements to be provider-based to the main provider:**

10. \_\_\_\_ The facility or organization being attested to as provider-based is a joint venture that fulfills the following requirements:
- 10a. \_\_\_\_ The facility is partially owned by at least one provider;
- 10b. \_\_\_\_ The facility is located on the main campus of a provider who is a partial owner;
- 10c. \_\_\_\_ The facility is provider-based to that one provider whose campus on which the facility organization is located; and
- 10d. \_\_\_\_ The facility or organization meets all the requirements applicable to all provider-based facilities and organizations in paragraphs 1-5 of this attestation.

**\* I certify that the responses in this attestation and information in the documents are accurate, complete, and current as of this date. I acknowledge that the regulations must be continually adhered to. Any material change in the relationship between the facility/organization and the main provider, such as a change of ownership or entry into a new or different management contract, may be reported to CMS. (NOTE: ORIGINAL ink signature must be submitted)**

Signed: \_\_\_\_\_  
(Signature of Officer or Administrator or authorized person)

\_\_\_\_\_  
(PRINT Name of signature)

Title : \_\_\_\_\_  
(Title of authorized person acting on behalf of the provider)

\_\_\_\_\_  
(Direct telephone number)

Date : \_\_\_\_\_

**\* Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious or fraudulent statement or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than \$10,000 or imprisoned not more than five years or both. (18 U.S.C. § 1001).**

## CRITERIA §413.65(d)

### Applicable to all facilities ON or OFF-Campus

Please check the appropriate box to indicate the requirement has been met (see §42 CFR 413.65 for a detailed description of requirements):

- |  | Yes                      | No                       |
|--|--------------------------|--------------------------|
| 1. <b>Licensure</b> - Entity is operated under the same license as the main provider (where permitted by state law). | <input type="checkbox"/> | <input type="checkbox"/> |

Note: only applies to a department of the provider, a remote location of a hospital or a satellite facility.

*Please provide a copy of the facilities business license and JACHO accreditation. If the state in which the facility and main provider are located requires separate licenses, please provide support for verification.*

**2. Clinical Services** [see 42 CFR §413.65(2)]

- |   | <b>Yes</b>               | <b>No</b>                |
|---|--------------------------|--------------------------|
| a. Professional staff of the facility or organization have clinical privileges at the main provider.  | <input type="checkbox"/> | <input type="checkbox"/> |
| b. The main provider maintains the same monitoring and oversights of the facility as it does for any other department of the hospital.                                    | <input type="checkbox"/> | <input type="checkbox"/> |
| c. The medical director of the facility maintains a reporting relationship with an officer of the main provider similar to that of other departments within the hospital. | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Medical staff and other professional committees at the main provider are responsible for medical activities in the facility.   | <input type="checkbox"/> | <input type="checkbox"/> |

***Submit a list of all key personnel working at the facility showing their job titles and name of their employer, information as to whether professional staff of the facility have clinical privileges at the main provider, a description of the level of monitoring and oversight of the facility by the main provider as compared to oversight for another other departments of the main provider, and a description of the responsibilities and relationships between the medical director of the facility, the chief medical officer of the main provider, and the medical staff committees at the main provider.***

- |   | <b>Yes</b>               | <b>No</b>                |
|---|--------------------------|--------------------------|
| e. Medical records for patients in the facility are integrated into a unified retrieval system (or cross reference) of the main provider. | <input type="checkbox"/> | <input type="checkbox"/> |

***Submit a copy or description of the policy utilized in record retrieval from both the main provider and the provider based facility.***

- |   |                          |                          |
|---|--------------------------|--------------------------|
| f. Inpatient and outpatient services of the facility and the main provider are integrated, and patients treated at the facility who require further care have full access to all services of the main provider. | <input type="checkbox"/> | <input type="checkbox"/> |
|---|--------------------------|--------------------------|

***Submit information on how inpatient and outpatient services of the facility and the main provider are integrated, and examples of integration of services, including data on the frequency of referrals from inpatient to outpatient facilities, or vice versa.***

- |   | <b>Yes</b>               | <b>No</b>                |
|---|--------------------------|--------------------------|
| <b>3. Financial Integration</b> – financial operations are fully integrated within the financial systems of the main provider, as evidenced by shared income and expenses between the main provider and facility. The costs of a facility or organization that is a hospital department are reported in a cost center of the provider, costs of a provider-based facility or organization other than a hospital department are reported in the appropriate cost center or cost centers of the main provider, and the financial status of any provider-based facility or organization is incorporated and readily identified in the main provider's trial balance. | <input type="checkbox"/> | <input type="checkbox"/> |

*Please provide a copy of the appropriate section of the main provider's chart of accounts or trial balance that shows the location of the revenues and expenses.*

4. **Public Awareness** – the facility is held out to the public and other payers as part of the main provider. When patients enter the provider based facility, they are aware they are entering the main provider and are billed accordingly.

**Yes**

**No**

Note: only applies to a department of a provider, a remote location of a hospital or a satellite facility.

*Attach examples that show that the entity is clearly identified as part of the main provider (i.e. patient registration forms, letterhead, advertisements, signage, etc.). Advertisements that show the facility to be part of or affiliated with the main provider's healthcare system only, are not acceptable. They must be affiliated with the hospital. We must also take a photo of the outside signage that show this facility is part of the hospital.*

*Example: XYZ Clinic- a division of Piedmont Hospital*

## Obligations of Hospital Outpatient Departments & Hospital-Based Entities

Please check appropriate box to indicate obligation has been met as described in 42 CFR 413.65(g)(1) through (6) and (g)(8). If necessary, refer to PM A-03-030 for more details on this step.

|   | Yes                      | No                       |
|---|--------------------------|--------------------------|
| a. <b>Patient Anti-Dumping Rules-</b> Facility complies with criteria listed in 42 CFR 489.20 and 489.24  | <input type="checkbox"/> | <input type="checkbox"/> |
| b. <b>Site-of-Service-</b> Physicians providing services in the facility use the correct site-of-service-code on CMS-1500 claim form.<br>Note: not applicable for RHC                       | <input type="checkbox"/> | <input type="checkbox"/> |
| c. <b>Provider Agreement-</b> Facility complies with terms of Medicare provider agreement.  | <input type="checkbox"/> | <input type="checkbox"/> |
| d. <b>Non-Discrimination Provisions -</b> Physicians working in the facility comply with the non-discrimination provisions of 42 CFR 489.1(b).  | <input type="checkbox"/> | <input type="checkbox"/> |
| e. <b>Consistent Treatment as Outpatient-</b> Facility treats all Medicare patients as hospital outpatients for billing purposes.<br><b>Note: not applicable to provider-based entities</b> | <input type="checkbox"/> | <input type="checkbox"/> |
| f. <b>3-Day Payment Window-</b> Facility complies with all applicable Medicare payment window provisions.<br>(Note: The payment window provisions do not apply to CAHs)                     | <input type="checkbox"/> | <input type="checkbox"/> |
| g. <b>Health and Safety Rules-</b> Facility meets the applicable hospital health and safety rules for Medicare participating hospitals in Part 482 of the Medicare regulations.             | <input type="checkbox"/> | <input type="checkbox"/> |

*Attach documentation, such as the EMTALA, to verify compliance with these requirements.*

## Joint Ventures

The facility or organization operated as a joint venture is:

- |   | Yes                      | No                       |
|---|--------------------------|--------------------------|
| a. Partially owned by at least one provider   | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Located on the main campus of a provider who is partial owner  | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Provider-based to that one provider whose campus on which the facility or organization is located            | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Also meets all the requirements applicable to all provider-based facilities and organizations in §413.65(d). | <input type="checkbox"/> | <input type="checkbox"/> |

**IF CONSIDERED OFF-CAMPUS : If any responses are “No” the entity does not qualify as a Provider-Based facility.**

**ADDITIONAL OFF-CAMPUS REQUIREMENTS  
(CFR 413.65(e))**

- | <b>1. Ownership and Control:</b>   | <b>Yes</b>               | <b>No</b>                |
|--|--------------------------|--------------------------|
| a. The facility is 100% owned by the provider.   | <input type="checkbox"/> | <input type="checkbox"/> |
| b. The facility is operated under the same governing body.   | <input type="checkbox"/> | <input type="checkbox"/> |
| c. The facility is subject to common bylaws and operating decisions of the governing body of the provider where it is based.   | <input type="checkbox"/> | <input type="checkbox"/> |
| d. The main provider has final responsibility for administrative decisions, approval for contracts with outside parties, approval for personnel actions and policies, and approval for medical staff appointments in the facility. | <input type="checkbox"/> | <input type="checkbox"/> |

***Submit the articles of incorporation and bylaws for both the main provider and facility. Also, please describe who has final approval for administrative decisions, contracts with outside parties, personnel policies, and medical staff appointments for the facility.***

**2. Administration and Supervision:**

**Yes No**

a. The facility is under direct supervision of the main provider.

*Provide a list of key administrative staff (position/titles only) at the main provider and the entity requesting provider-based status that have a reporting relationship.*

b. The facility is operated under the same monitoring and oversight by the provider as any other department of the provider with regard to supervision and accountability, as evidenced by the following:

(i) Facility director maintains a reporting relationship with a manager at the main provider.

*Provide a copy of the organization's departmental and personnel organizational chart. The chart must include the main provider and the entity requesting provider based status and show which department of the main provider the entity is included.*

(ii) Facility director is accountable to the governing body of the main provider.

*Provide a written description of the entities director's reporting requirements and accountability procedures for day to day operations.*

c. The following administrative functions of the facility are integrated with those of the main provider:

|                             | <b>Yes</b>               | <b>No</b>                |
|-----------------------------|--------------------------|--------------------------|
| 1. Billing Services         | <input type="checkbox"/> | <input type="checkbox"/> |
| 2. Records                  | <input type="checkbox"/> | <input type="checkbox"/> |
| 3. Human Resources          | <input type="checkbox"/> | <input type="checkbox"/> |
| 4. Payroll                  | <input type="checkbox"/> | <input type="checkbox"/> |
| 5. Employee Benefit Package | <input type="checkbox"/> | <input type="checkbox"/> |
| 6. Salary Structure         | <input type="checkbox"/> | <input type="checkbox"/> |
| 7. Purchasing Services      | <input type="checkbox"/> | <input type="checkbox"/> |

The above services are:

- |   | <b>Yes</b>               | <b>No</b>                |
|---|--------------------------|--------------------------|
| i. Contracted out under the same contract agreement   | <input type="checkbox"/> | <input type="checkbox"/> |
| ii. Handled under different contact agreements, with the contract of the facility or organization being managed by the main provider. | <input type="checkbox"/> | <input type="checkbox"/> |

***Submit a list of various administrative functions at the facility that are integrated with the main provider. Also, include copies of any contracts for administrative functions that are completed under arrangements for the main provider and/or facility.***

**3. Location**

**Yes    No**

- a. The facility is located within 35 miles radius of the main provider

**Note:** A Rural Health Clinic (RHC) that is otherwise qualified as a provider-based entity of a hospital that is located in a rural area as defined in § 412.62(f)(1)(iii) of Chapter IV of Title 42, and has fewer than 50 beds as determined under § 412.105(b) of Chapter IV of Title 42, is not subject to additional off-campus requirements.

**If the response is “Yes” skip questions b, c & d and answer question e below. If the answer is “No” complete the following section.**

- b. At least 75% of the patients served by the entity reside in the same zip code areas as at least 75% of the patients served by the main provider.
- c. At least 75% of the patients served by the facility who require the type of care furnished by the main provider received that care from that provider, **OR**
- d. The entity is not able to meet the criteria in 2 or 3 because it was not in operation during all of the 12 month period previously described, the facility is located in a zip code area included among those that, during all of the 12 month period described previously, accounted for at least 75% of the patient population served by the main provider.

***Please submit records showing that during the 12 month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12 month period that meet the above criteria.***

- e. If the entity is not located in the same State as the main Provider, is the entity consistent with the laws of both states.

***If “Yes”, please provide supporting documentation.***

#### 4. Additional Obligations of Hospital Outpatient Departments & Hospital-Based Entities

Applicable for Provider-Based entities that are not located on campus and are providing treatment that is not required to be provided by the anti-dumping rules in section 489.24 of chapter IV of Title 42. **The hospital must provide written notice to the beneficiary before the delivery of services noting the amount of potential financial liability to the beneficiary.** The notice meet the following guidelines:

- |   | Yes                      | No                       |
|---|--------------------------|--------------------------|
| a. Beneficiary can read and understand  | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Explain that the beneficiary will incur a coinsurance liability to the hospital that he or she would not incur if the facility were not provider-based.  | <input type="checkbox"/> | <input type="checkbox"/> |
| c. State that the patient's actual liability will vary if the amount is estimated.  | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Be presented to the beneficiary's authorized representative before delivery of services if the beneficiary is unconscious.   | <input type="checkbox"/> | <input type="checkbox"/> |
| e. Be given as soon as possible after the existence of an emergency has been ruled out if the hospital outpatient department provides examination or treatment that is required to be provided by the anti-dumping rules. | <input type="checkbox"/> | <input type="checkbox"/> |

*Please submit a copy of the notice given to patients.*

**Note: The Advance Beneficiary Notice (ABN) forms are not acceptable.**

**5. Management Contracts**

- |   | <b>Yes</b>               | <b>No</b>                |
|---|--------------------------|--------------------------|
| a. The entity is operated under a management contract | <input type="checkbox"/> | <input type="checkbox"/> |

**If answered “Yes”, complete question b. & c. below.**

- |   |                          |                          |
|---|--------------------------|--------------------------|
| b. The administrative functions for both the facility and main provider are contracted out under the same contract agreement.   | <input type="checkbox"/> | <input type="checkbox"/> |
| c. The administrative functions for both the facility and main provider are handled under different contract agreements, with the contract of the facility being managed by the main provider | <input type="checkbox"/> | <input type="checkbox"/> |

*Please submit a copy of the management contract.*

**If the answer was no, the entity does not meet the requirements to be considered Provider-Based.**

## PROVIDER ATTESTATION

**I certify that the responses in this attestation and information in the documents are accurate, complete, and current as of this date. I acknowledge that the regulations must be continually followed. Any material change in the relationship between the facility/organization and the main provider, such as a change of ownership or entry into a new or different management contract, may be reported to CMS.**

**Print Name:** \_\_\_\_\_

**Signature:** \_\_\_\_\_  
(Signature of Officer or Administrator or authorized person)

**Title:** \_\_\_\_\_  
(Title of authorized person acting on behalf of the provider)

**Phone number:** \_\_\_\_\_  
(Direct telephone number)

**Date:** \_\_\_\_\_

**Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by an trick, scheme or device a material fact, makes any false, fictitious or fraudulent statement or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry, shall be fined not more than \$10,000 or imprisoned not more than five years or both. (18 U.S.C. Section 1001).**

# PROVIDER BASED RULES AUDIT PROTOCOL

This simple audit is useful for hospital-based entities, departments and remote locations. The provider-based rules are not applicable to ASCs, HHAs, CORFs, SNFs, labs and ESRD facilities.

## 1. Operating Under the Same License

Do the entities operate under the same license (unless otherwise required by the state)?

Yes \_\_\_\_\_ No \_\_\_\_\_

## 2. Financial Integration\*\*

Is there shared income and expenses between the entities? Yes \_\_\_\_\_ No \_\_\_\_\_

Are the costs of the provider-based entity reported in a cost center of the main provider?

Yes \_\_\_\_\_ No \_\_\_\_\_

Is the provider-based entity easily identifiable in the main provider's trial balance?

Yes \_\_\_\_\_ No \_\_\_\_\_

## 3. Clinical Integration\*\*

Do the entities have an integrated medical staff? Yes \_\_\_\_\_ No \_\_\_\_\_

Do the entities have integrated medical records? Yes \_\_\_\_\_ No \_\_\_\_\_

Is quality monitoring the same? Yes \_\_\_\_\_ No \_\_\_\_\_

Do patients at the provider-based facility have access to the main provider services?

Yes \_\_\_\_\_ No \_\_\_\_\_

## 4. Public Awareness\*\*

Is the main provider name included on:

|                    |           |          |
|--------------------|-----------|----------|
| Outside signage    | Yes _____ | No _____ |
| Advertising        | Yes _____ | No _____ |
| Patient Bills      | Yes _____ | No _____ |
| Registration Forms | Yes _____ | No _____ |
| Medical Records    | Yes _____ | No _____ |

**\*\*Not meeting a few of the examples cited by CMS wouldn't necessary mean that the entity is not provider-based. However, going forward, it would be prudent to consider why examples and not met and then meet as many as possible so payment to the main provider will not be questioned.**

**Additional Rules For Off-Campus Providers (located 250 yards from main buildings)**

1. Ownership

Is the provider-based entity 100% owned by the main provider (if not, must be located on main campus of the provider that bills for its services)? Yes \_\_\_\_\_ No \_\_\_\_\_

2. Control\*\*

Do the entities have the same governing body? Yes \_\_\_\_\_ No \_\_\_\_\_

Do the entities have common bylaws? Yes \_\_\_\_\_ No \_\_\_\_\_

Does the main provider's governing body have final approval over administrative decisions, contracts and personnel policies? Yes \_\_\_\_\_ No \_\_\_\_\_

2. Administration and Supervision\*\*

Is the provider-based entity is under the same monitoring and oversight as any other department of the main provider? Yes \_\_\_\_\_ No \_\_\_\_\_

Does the provider-based director maintain a reporting relationship to the main provider and accountability to the governing body just like any other department? Yes \_\_\_\_\_ No \_\_\_\_\_

Do the entities share, contract out together or have the main provider manage the provider-based entities:

|                           |           |          |
|---------------------------|-----------|----------|
| Billing services          | Yes _____ | No _____ |
| Records                   | Yes _____ | No _____ |
| Human resources           | Yes _____ | No _____ |
| Payroll                   | Yes _____ | No _____ |
| Employee salary structure | Yes _____ | No _____ |
| Employee benefit package  | Yes _____ | No _____ |
| Purchasing services       | Yes _____ | No _____ |

**\*\*Not meeting a few of the examples cited by CMS wouldn't necessary mean that the entity is not provider-based. However, going forward, it would be prudent to consider why examples and not met and then meet as many as possible so payment to the main provider will not be questioned.**

3. Location

a. Does the main provider have a disproportionate share adjustment of greater than 11.75%, and is it owned or operated by: (a) a unit of state/local government; (2) a public or non-profit corporation granted governmental power; or (3) a private entity with a state/local contract that includes operating the off-campus clinic?

Yes \_\_\_\_\_ No \_\_\_\_\_

b. Is the main provider a children's hospital that: (1) has intensive care units that accept newborn infants; (2) is in a rural area at least 35 miles from other neonatal intensive care units; and (3) is located within a 100-miles of the hospital-based clinic?

Yes \_\_\_\_\_ No \_\_\_\_\_

c. Is the provider-based clinic a rural health clinic and does the main hospital have fewer than 50 beds and is it located in a rural area? Yes \_\_\_\_\_ No \_\_\_\_\_

IF NONE OF THE ABOVE:

During a 12-month period are 75% of the provider-based entities patients from the same zip code as 75% of the main provider's patients? Yes \_\_\_\_\_ No \_\_\_\_\_

During a 12-month period did 75% of the provider-based entities patients that needed inpatient care receive it from the main provider? Yes \_\_\_\_\_ No \_\_\_\_\_

If the provider-based entity was not in operation for 12 months, is it in the same zip code area as at least 75% of the patients served by the main provider?

Yes \_\_\_\_\_ No \_\_\_\_\_

**\*\*Not meeting a few of the examples cited by CMS wouldn't necessary mean that the entity is not provider-based. However, going forward, it would be prudent to consider why examples and not met and then meet as many as possible so payment to the main provider will not be questioned.**



## Off Campus Medicare Outpatient Coinsurance Notice

To our Medicare patients:

Medicare regulations require us to provide you with a notice of your potential financial liability for the hospital service(s) you will receive.

We are required to advise you that because the service(s) is/are furnished by a department of the hospital, you will incur a coinsurance liability to the hospital that you would otherwise not incur if the services were furnished in an entity that is not hospital-based. At this time, we can provide you with the following information on the estimated amount of your coinsurance liability.

- † Your coinsurance liability for the hospital service(s) is **estimated** to be \$\_\_\_\_\_, based on our current information about scheduled services.
- † Since we do not know the exact type and extent of services that you may need, we are unable to provide you with an estimate of your liability. However, the typical charge incurred by a beneficiary based on all visits to this department or facility normally ranges from \$\_\_\_\_\_ to \$\_\_\_\_\_.

---

The actual amount of your coinsurance liability to the hospital may be different from any estimate that is provided above. Actual coinsurance liability will be based on the services that you receive and also subject to final determination by the Medicare program.

If you are enrolled in a state medical assistance program such as Medicaid or Medi-Cal, your coinsurance liability may be reduced or eliminated by law.

Your coinsurance liability for hospital services is separate from the Medicare coinsurance liability that you may owe for any physician or professional services provided to you in conjunction with hospital services.

---

I have read the foregoing and understand that I will incur a liability to the hospital for Medicare coinsurance as permitted by law.

---

Signature of patient or authorized representative

Date

## Audit Program and Work Plan Provider Based Services Audit

| Risk  | How Could Something Go Wrong?   | Potential Consequence |  | Examples of Typical Controls<br>P = Preventive; D = Detective | Audit Steps   | Est. Hours | W/P |
|---|---|-----------------------|--|---|---|------------|-----|
| <b>Conduct necessary planning and background research.</b>  |   |                       |  |   |   |            |     |
|   | Objective - Evaluate regulatory compliance to provider based status for the hospital.<br><br>The scope of this audit included:<br><ul style="list-style-type: none"> <li>Review provider-based status for compliance with federal, state and local laws and</li> <li>Evaluate controls over hospital facilities doing business off the hospital's main campus.</li> </ul> |                       |  |   | <ol style="list-style-type: none"> <li>1 Research topic to gain an initial understanding of area/department to be reviewed.               <ol style="list-style-type: none"> <li>a. Request organization chart for area being reviewed.</li> <li>b. Examine policies and procedures for area being reviewed.</li> </ol> </li> <li>2 Review prior work conducted for this area.</li> <li>3 Verify key contacts for the area.</li> <li>4 Review and revise ICQ as required.</li> <li>5 Review and revise audit program as required</li> <li>6 Prepare draft of audit objectives.</li> <li>7 Meet with audit management to discuss project.</li> <li>8 Alert area of the audit - by phone or email</li> <li>10 Contact area and arrange entrance meeting.</li> <li>11 Send audit announcement letter</li> <li>12 Conduct entrance meeting to "kick off" project.</li> <li>13 Finalize audit objectives and scope based on information gathered to date.</li> </ol> | 18         |     |
| <b>I. Controls are in place to ensure attestations are completed for all off campus provider based locations.</b>         |   |                       |  |   |   |            |     |
|   | Controls are not in place to ensure attestations are completed for each off campus location.  |                       |  |   |   | 40         |     |
| A   |   |                       |  |   | <ol style="list-style-type: none"> <li>1 Obtain a listing of all locations billing as provider based.</li> </ol>  |            |     |
|   |   |                       |  |   | <ol style="list-style-type: none"> <li>2 Obtain and review a copy of the CMS attestation for each location.<br/><br/>Obtain and review the confirmation letter from CMS or the appropriate Government Benefit Administrator (GBA).<br/><br/>Resolve any discrepancies.</li> </ol>   |            |     |
| <b>II. Policies and procedures are in place regarding provider based status requirements for all healthcare entities.</b> |   |                       |  |   |   |            |     |
|   | Controls are not in place to ensure all entities are aware of and are following healthacre policies and procedures regarding provider based status.   |                       |  |   | Obtain a copy of the policy regarding Provider Based Services and any other entity specific policy referencing guidelines for provider based services.  | 40         |     |

## Audit Program and Work Plan Provider Based Services Audit

| Risk   | How Could Something Go Wrong? | Potential Consequence |  |  |  | Examples of Typical Controls<br>P = Preventive; D = Detective | Audit Steps  | Est. Hours | W/P |
|--|-------------------------------|-----------------------|--|--|--|---|--|------------|-----|
|  |                               |                       |  |  |  |   |  |            |     |
| A  |                               |                       |  |  |  |   | 1 Review policies and procedures for the minimum topics: <ul style="list-style-type: none"> <li>• Attestation requirements</li> <li>• Communication channels</li> <li>• Approvals</li> <li>• Monitoring</li> </ul>   |            |     |
| B  |                               |                       |  |  |  |   | 2 For the provider based location, review sample documentation for the following to support compliance with CFR 413.65 regulations: <ul style="list-style-type: none"> <li>• Licensure</li> <li>• Clinical staff intergration</li> <li>• Financial integration</li> <li>• Public awareness/signage</li> <li>• Hospital/ Physician Billing</li> <li>• EMTALA</li> <li>• Medicare Patient Notifications of Co-Insurance</li> </ul> |            |     |
| <b>Perform administrative steps to complete the project.</b> |                               |                       |  |  |  |   |  |            |     |
| A  | Exceptions                    |                       |  |  |  |   | 1 As issues become apparent, prepare an Exceptions form that documents the issue/root cause/action plan/education/monitoring/accountable leader/implementation date  | 8          |     |
|  |                               |                       |  |  |  |   | 2 Review all exceptions with audit management and the contact. Obtain audit management's documented approval.  |            |     |
| B  | Exit Meeting                  |                       |  |  |  |   | 1 Have an exit meeting with area as may be appropriate.  | 2          |     |
| C  | Report Preparation            |                       |  |  |  |   | 1 Prepare draft report.  | 22         |     |
|  |                               |                       |  |  |  |   | 2 Verify the draft report matches key work papers that support issue/root cause/action plan/education/monitoring/accountable leader/implementation date.   |            |     |
|  |                               |                       |  |  |  |   | 3 Have report draft proof read by another auditor.   |            |     |
|  |                               |                       |  |  |  |   | 4 Meet with audit management to get approval of draft report.  |            |     |
|  |                               |                       |  |  |  |   | 5 Send draft report to contact (and others as needed) for responses/ edits etc.  |            |     |
|  |                               |                       |  |  |  |   | 6 Prepare final report.  |            |     |
|  |                               |                       |  |  |  |   | 7 Obtain audit management approval to issue the final report.  |            |     |
| <b>Total Hours</b>   |                               |                       |  |  |  |   |  | <b>130</b> |     |

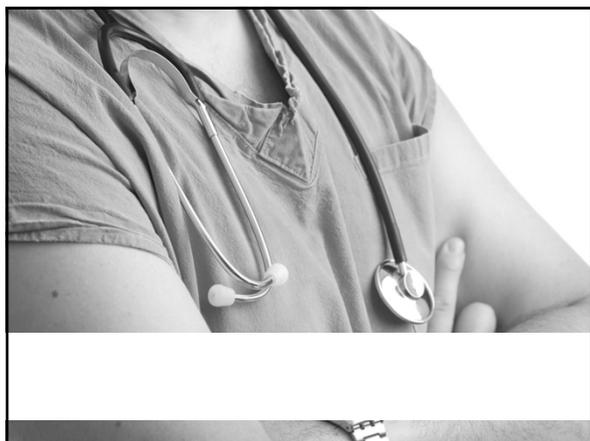
**Provider Based Services  
Internal Control Questionnaire**

| Provider Based Services |  | Yes | No | Comments |
|-------------------------|--|-----|----|----------|
| 1                       | Do the entities operate under the same license (unless otherwise required by the state)?   |     |    |          |
| 2                       | Is there shared income and expenses between the entities?  |     |    |          |
| 3                       | Are the costs of the provider-based entity reported in a cost center of the main provider?   |     |    |          |
| 4                       | Is the provider-based entity easily identifiable in the main provider's trial balance?   |     |    |          |
| 5                       | Do the entities have an integrated medical staff?  |     |    |          |
| 6                       | Do the entities have integrated medical records?   |     |    |          |
| 7                       | Is quality monitoring the same?  |     |    |          |
| 8                       | Do patients at the provider-based facility have access to the main provider services?  |     |    |          |
| 9                       | Is the main provider name included on:<br>Outside signage?   |     |    |          |
|                         | Advertising?   |     |    |          |
|                         | Patient Bills?   |     |    |          |
|                         | Registration Forms?  |     |    |          |
|                         | Medical Records?   |     |    |          |
| 10                      | Is the provider-based entity 100% owned by the main provider (if not, must be located on main campus of the provider that bills for its services)?               |     |    |          |
| 11                      | Do the entities have the same governing body?  |     |    |          |
| 12                      | Do the entities have common bylaws?  |     |    |          |
| 13                      | Does the main provider's governing body have final approval over administrative decisions, contracts and personnel policies?                                     |     |    |          |
| 14                      | Is the provider-based entity under the same monitoring and oversight as any other department of the main provider?   |     |    |          |
| 15                      | Does the provider-based director maintain a reporting relationship to the main provider and accountability to the governing body just like any other department? |     |    |          |
| 16                      | Do the entities share, contract out together or have the main provider manage the provider-based entities:   |     |    |          |
|                         | Billing services?  |     |    |          |
|                         | Records?   |     |    |          |
|                         | Human resources?   |     |    |          |
|                         | Payroll?   |     |    |          |
|                         | Employee salary structure?   |     |    |          |
|                         | Employee benefit package?  |     |    |          |
| Purchasing services?    |  |     |    |          |

| Provider Based Services |   | Yes | No | Comments |
|-------------------------|---|-----|----|----------|
| 17                      | Is the facility located within a 35 mile radius of the campus of the provider?  |     |    |          |
| 18                      | Does the main provider have a disproportionate share adjustment of greater than 11.75%, and is it owned or operated by: (a) a unit of state/local government; (2) a public or non-profit corporation granted governmental power; or (3) a private entity with a state/local contract that includes operating the off-campus clinic? |     |    |          |
| 19                      | Is the provider-based clinic a rural health clinic and does the main hospital have fewer than 50 beds and is it located in a rural area?  |     |    |          |
| 20                      | During a 12-month period are 75% of the provider-based entities patients from the same zip code as 75% of the main provider's patients?   |     |    |          |
| 21                      | During a 12-month period did 75% of the provider-based entities patients that needed inpatient care receive it from the main provider?  |     |    |          |
| 22                      | If the provider-based entity was not in operation for 12 months, is it in the same zip code area as at least 75% of the patients served by the main provider?   |     |    |          |

Preparer's Signature/Title

Date



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### Agenda

- CMS CoP § 482.12(a)(2)— Hospital, 416.50(a)(3)— Ambulatory Surgical Center, 484.10(b)—Home Health Agencies, 494.180 End Stage Renal DiseaseFacilities
- 1 Organizational Policy
- 2 Dissection of a Patient Grievance
- 3 Resolving Patient Grievances while Maintaining Compliance
- 4 Integrating Compliance with Quality
- 5 Quality Improvement resulting from Compliance with Complaint Resolution
- 6 Grievance Reports to Quality Committee/Board of Directors
- 7



M. Tomlinson, CHC

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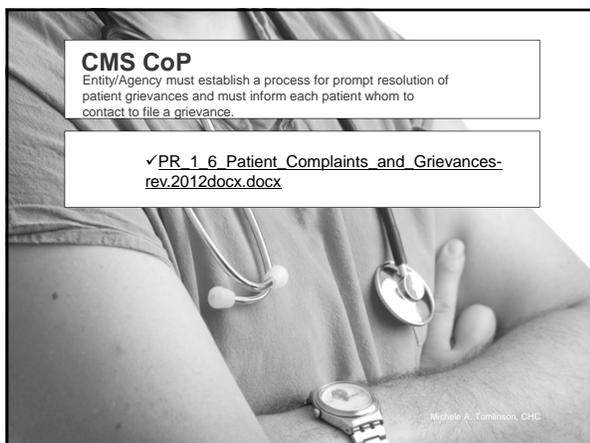
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### CMS CoP

Entity/Agency must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.

[✓PR\\_1\\_6\\_Patient\\_Complaints\\_and\\_Grievances-rev.2012docx.docx](#)



Michele A. Tomlinson, CHC

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## Dissection of Patient Grievances

Case Study 1

Patient contacts your Billing Dept. to protest the bill of an inpatient hospital stay where they suffered an IV infiltration that contributed to additional treatment and a prolonged hospital stay.

**What Quality Issues can be identified that may also be a Compliance Issue?**

2

Expectant mother on way to another Labor & Delivery Center presents to your facility because she "thinks she may be in labor". It is determined that she is in the initial stages of labor but is not experiencing any great level of discomfort; and therefore insists on leaving to go to her planned place of delivery. Staff has explained the need to be transported by ambulance but the patient and family perceive this as unnecessary and demand to speak with the patient advocate.

**What Compliance Concerns exist with this situation and what must your patient advocate consider when attempting to resolve this matter?**

Michele A. Tomlinson, CHC

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## Compliance with Regulatory Agencies



Case Study 3

An investigation is commenced by the State Department of Health based on a complaint that has been filed with them in regard to an adverse drug event that occurred at your facility. The patient indicates that they have filed a complaint directly with the facility, who has not satisfactorily resolved the matter. This event resulted in the patient requiring ICU services and becoming ventilator dependent for a period of time. The patient was told that he was inadvertently given a like and similar name medication that caused this event.

The DOH is requesting all investigative documents of the event; including all reports submitted by the patient and responded to by the entity.

**What are your Quality/Compliance Concerns in responding to this investigation?**

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## Resolving Patient Grievances while Maintaining Compliance

Potential Violation of MMSEA 111

1 Write off or forgiveness of patient financial responsibility may be perceived as a risk mitigation strategy, which is not permitted.

1 Medical Record documentation must accurately reflect the series of events. The record must be coded accordingly to reflect HAC.

Potential Violation of EMTALA

2 From the point of onset of labor, a patient is deemed unstable; and therefore, must be either stabilized/delivered at the receiving entity, transferred via ambulance to Labor & Delivery Center of choice OR sign out AMA.

Potential Violation of CMS CoP

3 Documentation of complaint, investigation and response to patient that includes the venues to voice their concern if they remain unresolved or unsatisfied. Evidence of Quality Improvement involvement and any corrective measures implemented as a result of incident identified in complaint.

Michele A. Tomlinson, CHC

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|   |   |  |
|---|---|--|
| <ul style="list-style-type: none"> <li>•Data compiled can illustrate trends on medical units, departments or areas of operations.</li> <li>•Resolutions can support continuing Quality Improvement measures.</li> <li>•Reports are required during The Joint Commission Surveys.</li> </ul> | <ul style="list-style-type: none"> <li>•Provide to Quality Committee or Committee for Quality/Performance Improvement</li> <li>•Provide to various Clinical Units to establish compliance/improvement goals</li> <li>•Provide to Organization's Board of Trustees</li> <li>•Provide to Organization's Risk Management to improve Patient Safety.</li> </ul> | <p><b>Are Mandatory in order to be in Compliance with CMS CoP.</b></p> |
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### Templates

Policy + Process = Compliance

- ✓ 1 Patient Rights Policy—Patient Complaints and Grievances
- ✓ 2 Complaint/Complaint Report Form
- ✓ 3 Patient/Personal Representative Initial Response
- ✓ 4 Patient/Personal Representative Formal/Final Response
- ✓ 5 Complaint/Grievance Tracking System

This is an example text. Go ahead and replace it



Michele A. Tomlinson, CHC

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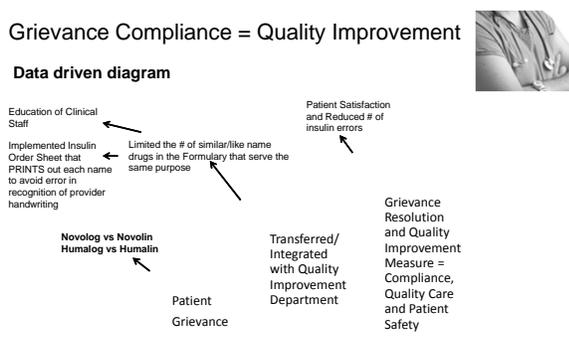
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### Grievance Compliance = Quality Improvement

**Data driven diagram**



Education of Clinical Staff

Implemented Insulin Order Sheet that PRINTS out each name to avoid error in recognition of provider handwriting

Limited the # of similar/like name drugs in the Formulary that serve the same purpose

Novolog vs Novolin  
Humalog vs Humalin

Patient Grievance

Transferred/Integrated with Quality Improvement Department

Patient Satisfaction and Reduced # of insulin errors

Grievance Resolution and Quality Improvement Measure = Compliance, Quality Care and Patient Safety

Michele A. Tomlinson, CHC

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Questions????



- Are YOU Tuning into what YOUR Patients are saying about YOUR Organization?

Michele A. Tomlinson, CHC

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Michele A. Tomlinson, CHC  
St. Mary's Healthcare  
Amsterdam, NY 12010  
518-770-7528  
[tomlinsonm@smha.org](mailto:tomlinsonm@smha.org)

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|   |                           |   |
|---|---------------------------|---|
|  <p><b>ST. MARY'S Organizational Policy Manual</b></p> | <b>Policy # PR 1.6</b>    |   |
|   | <b>Title:</b>             | <b>Patient Complaints and Grievances</b>  |
|   | <b>Replaces Policy:</b>   |   |
|   | <b>Policy Originator:</b> | Claims Mgmt. & Corporate Responsibility Coordinator   |
|   | <b>Concurrence:</b>       | <b>SMH Board of Directors</b><br><b>VP of Mission Integration</b><br><b>Director of Corporate Compliance &amp; Claims Mgmt.</b><br><b>Director of Patient Safety/Risk Mgmt.</b> |
| <b>Chapter Patient Rights/ Organizational Ethics</b>  | <b>Effective Date:</b>    | December 1994   |
|   | <b>Revised Date:</b>      | July 1997, September 2008, January 2012, October 2012   |
|   | <b>Approval:</b>          |   |
|   | <b>Date:</b>              |   |

## I. Policy Statement:

St. Mary's Healthcare will establish policies and procedures for the submission and management of patients' written or verbal complaints and grievances, which will be clearly communicated to its patients.

## II. Purpose:

To ensure optimum complaint/grievance management consistent with a person-centered holistic culture that is an expression of the mission of St. Mary's Healthcare.

## III. Policy

Consistent with our commitment to person-centered healthcare, all Patients, their Representatives and their Families have the right to voice complaints/grievances regarding the care received, without concern for reprisal, and to have those complaints/grievances reviewed, mediated and whenever possible resolved. Complaints/Grievances are viewed by St. Mary's Healthcare Leadership as opportunities for performance improvement, as well as, an occasion to assess current practice.

## IV. Procedure

1. All patients (and families when appropriate) are provided information about their right to voice complaints/grievances at the time of admission. Hospitalized patients are visited by staff and/or Volunteer Patient Representatives who review these rights and procedures.
2. Any Patient Representative, Volunteer, or Healthcare Employee may receive a complaint from a patient, family member or visitor. Any patient needs and/or concerns which can be addressed immediately by staff present are handled in order to ensure the patient's comfort and satisfaction. Grievances and system-issues must be recorded on the formal SMH complaint document and then are to be referred, either directly or indirectly, to the Office of Corporate Responsibility or its designee.
3. The Healthcare organization's governing body approves the effective operation of the grievance process, as illustrated in this policy and delegates the responsibility of reviewing and resolving grievances to the Corporate Responsibility Department.

4. The Office of Corporate Responsibility reviews and evaluates the formal complaint/grievance document to assure that those grievances involving situations or practices that place the patient in immediate danger or are in regard to Quality of Care or premature discharge, receive immediate and appropriate referral to the Director of Risk Management & Patient Safety, Quality Management Services or Utilization Review, respectively.
5. The Office of Corporate Responsibility will open a file, documenting the grievance in the Patient Relations System (PRS), alert the appropriate Department Head or Vice President, and then acknowledge the grievance to the complainant within 3 working days of its receipt. The Department Head/Vice President will:
  - Investigate the complaint/grievance within 72 hours.
  - Report a response to the Office of Corporate Responsibility.
  - Work with the Office of Corporate Responsibility to draft a response to the complainant.
6. The Office of Corporate Responsibility will finalize and close the PRS file and provide a written formal response to the complainant in a language and manner that the complainant understands within 14 working days of its receipt or provide an interim report if more time is needed to complete the investigation; but in all events, formally respond no later than 30 working days from initial receipt of the grievance.
7. Complainants who wish to file a report of a complaint/grievance about St. Mary's Healthcare or any other Health Care Organization may submit complaints directly to The Joint Commission as follows:
  - E-Mail: [complaint@jointcommission.org](mailto:complaint@jointcommission.org)
  - Fax: Office of Quality Monitoring 630-792-5636
  - Mail: Office of Quality Monitoring  
The Joint Commission  
One Renaissance Boulevard  
Oakbrook Terrace, IL60181
8. Complainants who wish to file a report of a grievance/complaint about St. Mary's Healthcare or any other Health Care Organization may submit complaints directly to the New York State Department of Health (NYSDOH). The NYSDOH complaint process is as follows: "If you have a concern, problem or complaint related to any aspect of care during your Hospital or Nursing Home stay, speak to your doctor, nurse or Healthcare staff member. If the problem cannot be resolved by the Healthcare staff, you may contact the New York State Department of Health by mail or by phone.  
You may call the toll-free number at 1-800-804-5447 or you may file a complaint in writing and send it to:

New York State Department of Health  
Centralized Hospital Intake Program  
433 River Street, 6<sup>th</sup> floor  
Troy, NY12180

Questions or Comments: [www.hospinfo@health.state.ny.us](mailto:www.hospinfo@health.state.ny.us)"

OR

If your grievance/complaint is related to Mental Health Services,  
New York State Department of Mental Health

Central NY Field Office  
545 Cedar St.  
Syracuse NY 13210-2319

1 (315) 426-3930  
Fax: 1 (315) 426-3950

## V. Definitions

### A. Complaint:

1. A current concern or post-Healthcare communication regarding patient care or service expressed by the patient, their representative or family member that requires a response and can, or could have been resolved at the point of service by the staff present. (“Staff present” includes any Healthcare staff present at the time of incident giving rise to the complaint or who can quickly be at the patient’s location to resolve the complaint. “Staff present” may include physicians, nurses, administrative staff, nursing supervisors, Volunteer Patient Representatives, or other staff); and
2. A billing issue that does not include patient quality of care issues or involve Medicare beneficiary complaints related to rights and limitations.

### B. Grievance:

1. Formal, written or verbal notice of complaint that is filed, independently or as an attachment to a SMH Patient Satisfaction Survey, by a patient, their representative or family member, when a patient issue cannot be promptly resolved by staff present; and
2. Notices of complaint that involve patient abuse, neglect, patient harm, or Healthcare compliance with Centers for Medicare and Medicaid Services (CMS) Conditions of Participation or Medicare beneficiary complaints related to rights and limitations. Staff will report all allegations of abuse, neglect, patient harm or compliance-related matters in accordance with other applicable St. Mary Healthcare policies.
3. A privacy issue or an issue involving use or disclosure of protected health information that does not include patient quality of care issues. **These are governed under law, as well as SMH HIPAA Policy.**

### C. Complainant:

1. A person who is entitled to make a complaint/grievance on his/her own behalf or on behalf of another. i.e. patient, patient representative or patient’s family member.

## VI. Appendix

Appendix A—Complaints Process Flowchart

Appendix B—SMH Patient Complaint Document

## VII. References

Centers for Medicare and Medicaid Services. 42 CFR, Part 482 Medicare and Medicaid Programs; Hospital Conditions of Participation Patients’ Rights; Interim Final Rule.

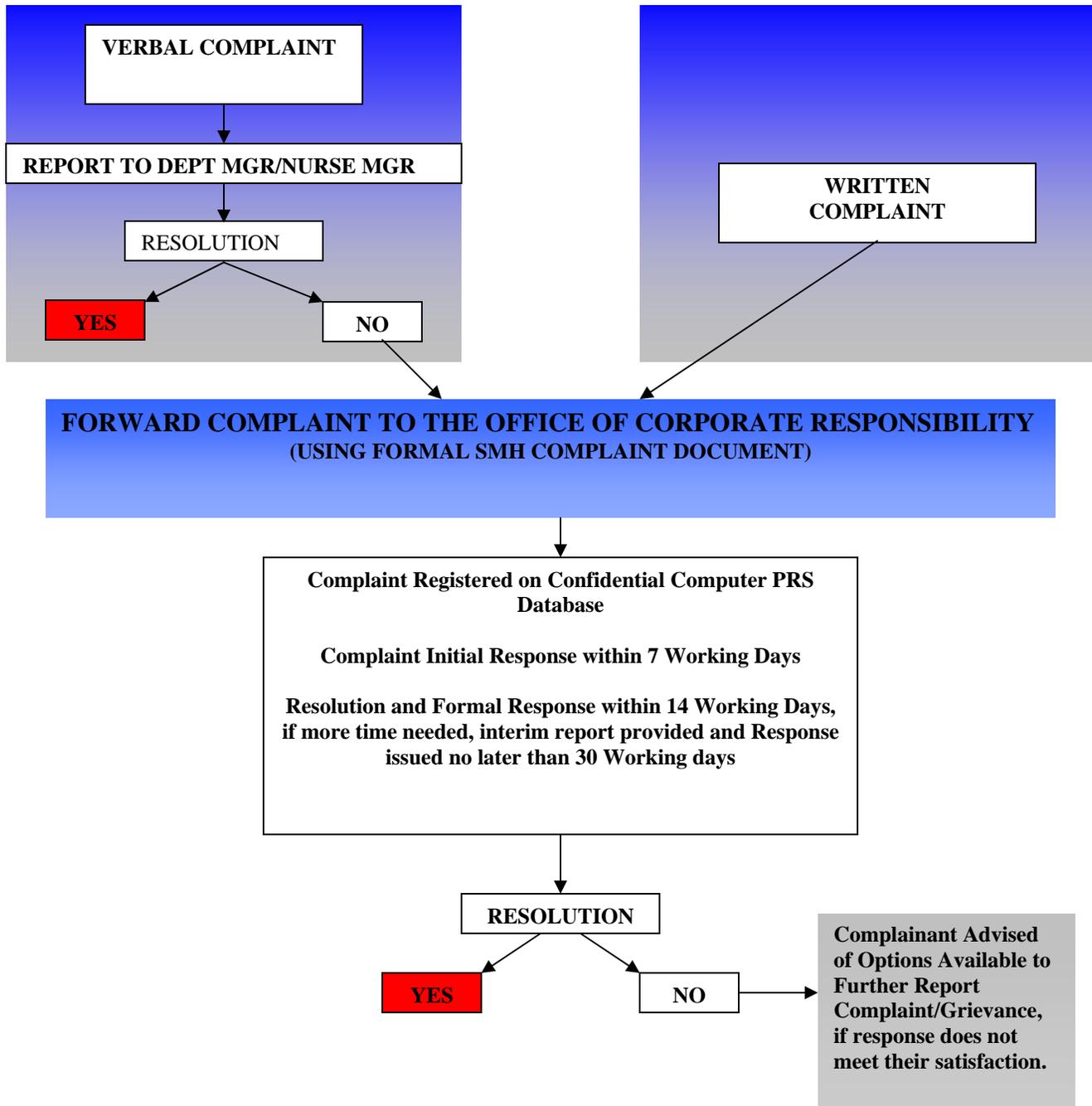
<http://www.cms.hhs.gov/transmittals/downloads/R17SOM.pdf>

The Joint Commission. [www.jointcommission.org](http://www.jointcommission.org)

New York State Department of Health. [www.health.state.ny.us](http://www.health.state.ny.us)

|  |                       |   |
|--|-----------------------|---|
| <b>Complaints &amp; Grievance Policy</b> | <b>Policy Number</b>  | PR 1.6                                  |
|  | <b>Effective Date</b> | December 1994                           |
|  | <b>Revision Date</b>  | July 1997, September 2008, January 2012 |
|  | <b>Approval</b>       |   |

**Appendix A—Complaints/Grievance Process**



|  |                       |  |
|--|-----------------------|--|
| <b>Complaints &amp; Grievance Policy</b> | <b>Policy Number</b>  | PR 1.6                                     |
|  | <b>Effective Date</b> | December 1994                              |
|  | <b>Revision Date</b>  | July 1997, September 2008,<br>January 2012 |
|  | <b>Approval</b>       |  |

**Appendix B—SMH Formal Complaint Document**

|                                    |  |
|------------------------------------|--|
| <b>Complainant:</b><br>Name: _____ | <b>Patient:</b> (If different from complainant)<br>Name: _____ |
| Address: _____                     | Address: _____   |
| City: _____                        | City: _____  |
| Phone: _____                       | Phone: _____   |

**Relationship to patient:**

Does this complaint relate to SMH Privacy or Security Practices? Yes  
Please complete this form and then submit to:  
Michele A. Tomlinson, Claims Mgmt/Corp. Resp. Coordinator  
St. Mary's Hospital  
Amsterdam, NY12010

Provide the following detail, if possible: Date, Time, and Description of complaint, grievance, or violation. Individuals involved and proposed resolution. (Use an additional sheet of paper if necessary)

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***For Hospital use only***

Register No: \_\_\_\_\_ Date: \_\_\_\_\_

Referred to: \_\_\_\_\_

Investigation date:  
Began: \_\_\_\_\_ Completed: \_\_\_\_\_

**Resolution or action on this complaint (Include all actions taken to investigate and resolve)**

| Date | Action Taken | By whom (Name & Title) |
|------|--------------|------------------------|
|      |              |                        |
|      |              |                        |
|      |              |                        |

**Response:** Date \_\_\_\_\_ Method:  Written  Oral

Original: Corporate Responsibility/Claims Mgmt. Coordinator

CC: Department Head/Manager Vice-President

KMP 03/03 MAT Rev 08/06



February 17, 2014

Complainant Name

Address 1

Address 2

City, State ZIP

Dear Mr./Mrs./Ms. \_\_\_\_\_,

We are in receipt of your recently expressed concern of the care and services provided to you by St. Mary's Healthcare of Amsterdam, NY.

It is our policy for all of our patients, their representatives and their families to have the right, without concern for reprisal, to voice complaints or grievances regarding the care received, and to have those complaints or grievances reviewed, mediated and whenever possible resolved. The leadership of St. Mary's Healthcare views these as opportunities to improve our performance, as well as, occasions to assess current practice.

We have begun our process to manage your complaint or grievance and will formally respond with the results of our investigation within fourteen (14) working days of its receipt or provide you with an interim report, at that point, if additional time is needed to finalize our process.

We thank you for this additional opportunity to serve you, and we are pleased to share the enclosed contact information with you in regard to this matter.

Sincerely,

Michele A. Tomlinson, CHC  
Director of Corporate Compliance & Claims Mgmt.

enc.

February 17, 2014

Complainant Name  
Address 1  
Address 2  
City, State ZIP

Dear Mr./Mrs./Ms. \_\_\_\_\_,

We are in receipt of your recently expressed concern of the care and services provided to your \_\_\_\_\_ by St. Mary's Hospital of Amsterdam, NY.

It is our policy for all of our patients, their representatives and their families to have the right, without concern for reprisal, to voice complaints or grievances regarding the care received, and to have those complaints or grievances reviewed, mediated and whenever possible resolved. The leadership of St. Mary's Hospital views these as opportunities to improve our performance, as well as, occasions to assess current practice.

We have begun our process to manage your complaint or grievance and will formally respond with the results of our investigation within fourteen (14) working days of its receipt or provide you with an interim report, at that point, if additional time is needed to finalize our process. In order to respond directly to you, we will need the attached authorization, completed by the patient, in order to release the patient's protected health information, as is required by HIPAA law. You may return this to us as soon as you are able to have it completed.

We thank you for this additional opportunity to serve you, and we are pleased to share the enclosed contact information with you in regard to this matter.

Sincerely,

Michele A. Tomlinson, CHC  
Director of Corporate Compliance & Claims Mgmt.  
enc.

February 17, 2014

Complainant Name  
Address 1  
Address 2  
City, State ZIP

Dear Complainant,

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We are hopeful that this response meets with your satisfaction and sincerely appreciate your interest in St. Mary's Hospital. It is through these communications that we continue to work toward improved processes and excellence in healthcare. If it does not satisfactorily address or resolve your complaint or grievance, you may file additional reports as follows:

- E-Mail: [complaint@jointcommission.org](mailto:complaint@jointcommission.org)
- Fax: Office of Quality Monitoring 630-792-5636
- Mail: Office of Quality Monitoring  
The Joint Commission  
One Renaissance Boulevard  
Oakbrook Terrace, IL 60181

You may call the toll-free number at 1-800-804-5447 or you may file a complaint in writing and send it to:  
New York State Department of Health  
Centralized Hospital Intake Program  
433 River Street, 6<sup>th</sup> floor  
Troy, NY 12180

Questions or Comments: [www.hospinfo@health.state.ny.us](mailto:www.hospinfo@health.state.ny.us)

Sincerely,

Michele A. Tomlinson, CHC  
Director of Corporate Compliance & Claims Mgmt.

February 17, 2014

Complainant Name  
Address 1  
Address 2  
City, State ZIP

Dear Complainant,

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We are hopeful that this response meets with your satisfaction and sincerely appreciate your interest in St. Mary's Hospital. It is through these communications that we continue to work toward improved processes and excellence in healthcare. If it does not satisfactorily address or resolve your complaint or grievance, you may file additional reports as follows:

- E-Mail: [complaint@jointcommission.org](mailto:complaint@jointcommission.org)
- Fax: Office of Quality Monitoring 630-792-5636
- Mail: Office of Quality Monitoring  
The Joint Commission  
One Renaissance Boulevard  
Oakbrook Terrace, IL 60181

You may call the toll-free number at 1-800-804-5447 or you may file a complaint in writing and send it to:  
New York State Department of Health  
Centralized Hospital Intake Program  
433 River Street, 6<sup>th</sup> floor  
Troy, NY 12180

Questions or Comments: [www.hospinfo@health.state.ny.us](http://www.hospinfo@health.state.ny.us)

You may contact the following, if your complaint or grievance is related to care rendered by our Mental Health services:

New York State Department of Mental Health  
Central NY Field Office  
545 Cedar St.  
Syracuse NY 13210-2319  
(315) 426-3930  
Fax: (315) 426-3950

Sincerely,

Michele A. Tomlinson, CHC  
Director of Corporate Compliance & Claims Mgmt.



-  Area of Concern by Department v3  
[Run](#)  
639 Reports Ran
-  Complaint Turnaround Report By Department V2  
[Run](#)  
56 Reports Ran
-  Complaint Turnaround Report v2  
[Run](#)  
72 Reports Ran
-  Event Turnaround Report V1  
[Run](#)  
204 Reports Ran
-  EventType\_FacilityTotals  
[Run](#)  
71 Reports Ran
-  Open Complaint by Department v3  
[Run](#)  
99 Reports Ran
-  Open Complaint by Facility v2  
[Run](#)  
46 Reports Ran
-  Open Complaint by Main Issue v2  
[Run](#)  
44 Reports Ran
-  Patient Relations Details by Date v3  
[Run](#)  
2691 Reports Ran
-  Physician Event Details by Facility v2  
[Run](#)  
169 Reports Ran
-  Top 10 Complaints by Facility YrQtr  
[Run](#)  
115 Reports Ran
-  Total Number of Complaints by Facility v2  
[Run](#)  
139 Reports Ran
-  Total Number of Events by Main Issue v2  
[Run](#)  
508 Reports Ran
-  Total Number of Events by Type v3  
[Run](#)  
292 Reports Ran

## Area of Concern by Department 2014

For activity that have a Date of Notification of 01/01/2014 through 01/31/2014

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### St Marys - Amsterdam

|                                       | Complaint | Grievance | Total     |
|---------------------------------------|-----------|-----------|-----------|
| SMA Ambulatory Care-6720              | 0         | 1         | 1         |
| SMA AMH Medical Imaging               | 1         | 0         | 1         |
| SMA Discharge Planning-8350           | 0         | 1         | 1         |
| SMA Emergency Department-6710         | 0         | 2         | 2         |
| SMA Gloversville Family Health Center | 1         | 0         | 1         |
| SMA Hospitalist Service               | 0         | 1         | 1         |
| SMA Intensive Case Management-6948    | 0         | 1         | 1         |
| SMA Maria Hall-6012                   | 0         | 1         | 1         |
| SMA St Theresa Hall-6010              | 1         | 0         | 1         |
| <b>Total</b>                          | <b>3</b>  | <b>7</b>  | <b>10</b> |

## Area of Concern by Department 2014

For activity that have a Date of Notification of 01/01/2014 through 01/31/2014

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**Report Totals**

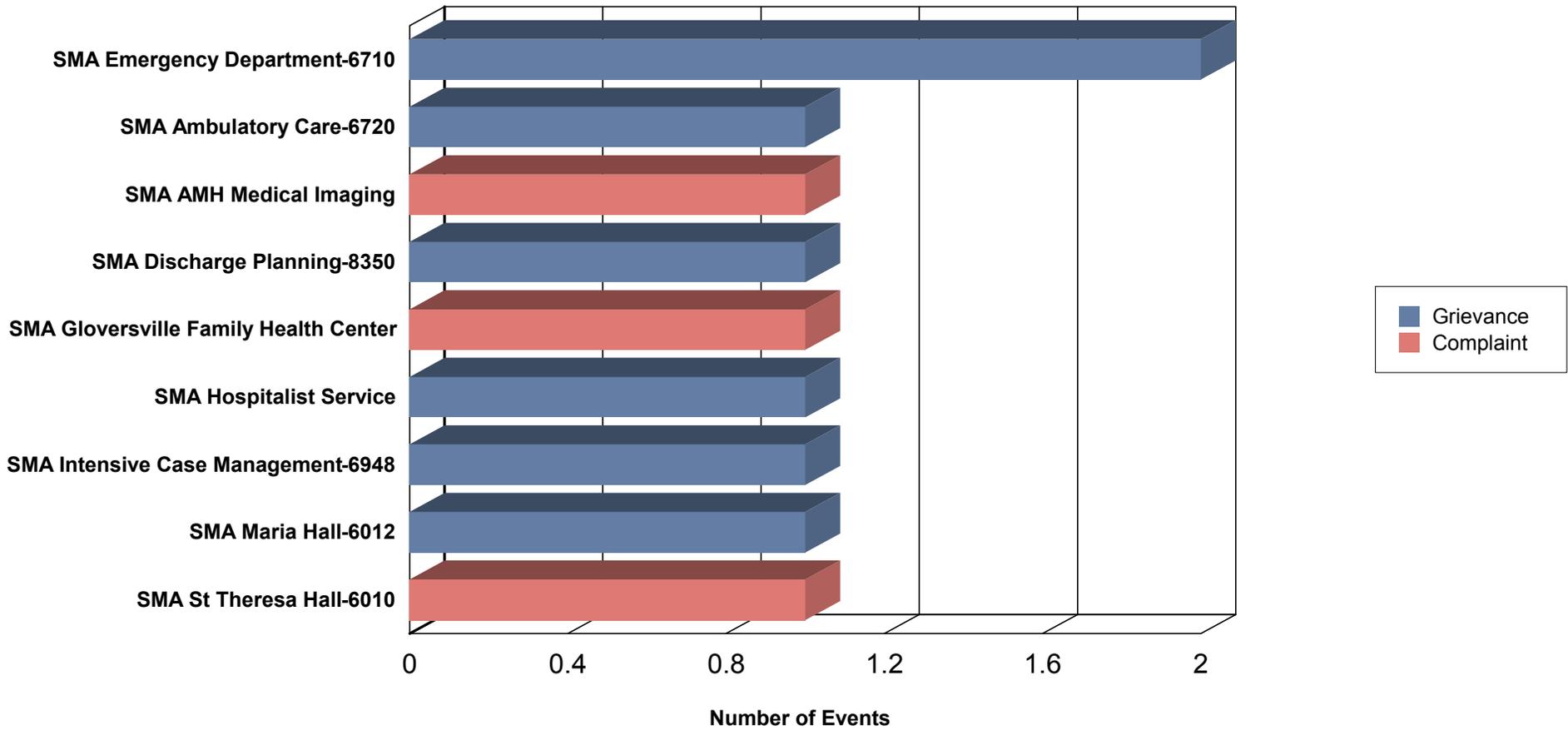
|                                       | Complaint | Grievance | Total     |
|---------------------------------------|-----------|-----------|-----------|
| SMA Ambulatory Care-6720              | 0         | 1         | 1         |
| SMA AMH Medical Imaging               | 1         | 0         | 1         |
| SMA Discharge Planning-8350           | 0         | 1         | 1         |
| SMA Emergency Department-6710         | 0         | 2         | 2         |
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### Area of Concern by Department 2014

For activity that have a Date of Notification of 01/01/2014 through 01/31/2014

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Top 10 Departments with Issues for Selected Facilities



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\* Only Departments with patient relations activity for the specified date range are listed.

# Code of Federal Regulations

## Title 42 - Public Health

Volume: 5 Date: 2011-10-01 Original Date: 2011-10-01 Title: Section 482.13 - Condition of participation: Patient's rights. Context: Title 42 - Public Health. CHAPTER IV - CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED). SUBCHAPTER G - STANDARDS AND CERTIFICATION. PART 482 - CONDITIONS OF PARTICIPATION FOR HOSPITALS. Subpart B - Administration.

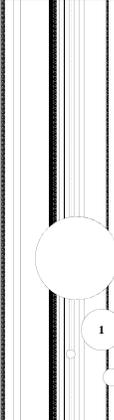
§ 482.13 Condition of participation: Patient's rights. A hospital must protect and promote each patient's rights. (a) *Standard: Notice of rights*—(1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible. (2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum: (i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital. (ii) The grievance process must specify time frames for review of the grievance and the provision of a response. (iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion. (b) *Standard: Exercise of rights*. (1) The patient has the right to participate in the development and implementation of his or her plan of care. (2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. (3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates). (4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital. (c) *Standard: Privacy and safety*. (1) The patient has the right to personal privacy. (2) The patient has the right to receive care in a safe setting. (3) The patient has the right to be free from all forms of abuse or harassment. (d) *Standard: Confidentiality of patient records*. (1) The patient has the right to the confidentiality of his or her clinical records. (2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits. (e) *Standard: Restraint or seclusion*. All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time. (1) *Definitions*. (i) A *restraint* is— (A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or (B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. (C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). (ii) *Seclusion* is the involuntary confinement of a patient alone in a room or area from

which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior. (2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm. (3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm. (4) The use of restraint or seclusion must be— (i) In accordance with a written modification to the patient's plan of care; and (ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law. (5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law. (6) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN). (7) The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion. (8) Unless superseded by State law that is more restrictive— (i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older; (B) 2 hours for children and adolescents 9 to 17 years of age; or (C) 1 hour for children under 9 years of age; and (ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient. (iii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy. (9) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order. (10) The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy. (11) Physician and other licensed independent practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion. (12) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention— (i) By a— (A) Physician or other licensed independent practitioner; or (B) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section. (ii) To evaluate— (A) The patient's immediate situation; (B) The patient's reaction to the intervention; (C) The patient's medical and behavioral condition; and (D) The need to continue or terminate the restraint or seclusion. (13) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of this section. (14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) as soon as possible after the completion of the 1-hour face-to-face evaluation. (15) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored— (i) Face-to-face by an assigned, trained staff member; or (ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient. (16) When restraint or seclusion is used, there must be documentation in the patient's medical record of the following: (i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior; (ii) A description of the patient's behavior and the intervention used; (iii) Alternatives or other less restrictive interventions attempted (as applicable); (iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and (v) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention. (f) *Standard: Restraint or seclusion: Staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff. (1) *Training intervals.* Staff must be trained

and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion— (i) Before performing any of the actions specified in this paragraph; (ii) As part of orientation; and (iii) Subsequently on a periodic basis consistent with hospital policy. (2) *Training content.* The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following: (i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion. (ii) The use of nonphysical intervention skills. (iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition. (iv) The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia); (v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary. (vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation. (vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification. (3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors. (4) *Training documentation.* The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed. (g) *Standard: Death reporting requirements:* Hospitals must report deaths associated with the use of seclusion or restraint. (1) The hospital must report the following information to CMS: (i) Each death that occurs while a patient is in restraint or seclusion. (ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion. (iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation. (2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. (3) Staff must document in the patient's medical record the date and time the death was reported to CMS. (h) *Standard: Patient visitation rights.* A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements: (1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section. (2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time. (3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability. (4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

[71 FR 71426, Dec. 8, 2006, as amended at 75 FR 70844, Nov. 19, 2010]



**THE RIDDLE OF DATA-DRIVEN COMPLIANCE PROGRAM**

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Regina Gurvich, MBA CHC  
*Chief Compliance Officer, AdvantageCare Physicians*

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- o Establishing internal data-mining program by connecting the dots of data, revenue cycle indicators, and FWA-prevention program
- o Discussion of methods and tools working with large amounts of data
- o Aberrant utilization – a case study in understanding the data and implications

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**CONCEPT**

- o Collection, extraction, warehousing, analysis, and statistics
- o Automatic or semi-automatic analysis of large quantities of data to extract previously unknown patterns such as groups of data records (cluster analysis), unusual records (anomaly detection) and dependencies (association rule mining)
- o Translating data generated through healthcare transaction through analysis by transitional methods
- o Testing hypothesis

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APPLICATION

- o Population health initiatives
- o MLR (Medical Loss Ratio) analysis
- o Medical utilization trends
- o Quality improvement initiatives
- o Revenue cycle trending
- o ERM (Enterprise Risk Management) – identifying, vulnerabilities and mitigating organizational risk and now
- o **Compliance**

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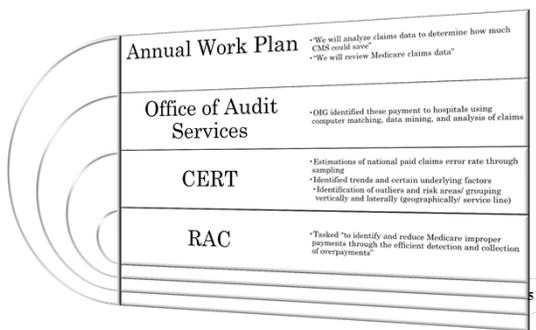
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DATA MINING @ OIG



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DATA-MINING PAYS OFF

- o FY 2012 recoveries topped \$4.2 billion (FY2011 - \$4.1 billion)
- o Highest average ROI - \$1 to \$7.90
- o "The strike force teams use advanced data analysis techniques to identify high-billing levels in healthcare fraud....that interagency teams can target..." (HEAT)
- o ACA funding to foster expansion of application

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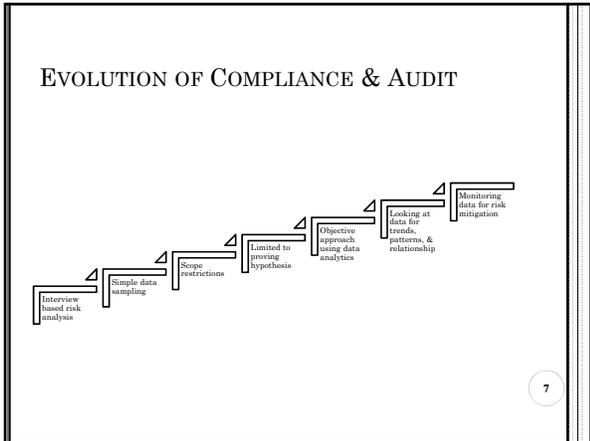
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### SUBJECTIVE VS. OBJECTIVE APPROACH

- Preselected audit target vs. benchmark
- Sample selection vs. target issue
- Results limited to individual cases vs. patterns of identified risk

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### YOU AND YOUR AUDIT PLAN: OBJECTIVE OR SUBJECTIVE?

Common approach based on combination of

- Risk assessment interviews with leadership
- Survey of key employees
- OIG Annual Work Plan
- OMIG Annual Work Plan
- Federal and State audit initiatives
- Emerging topics
- Past issues, audit experience, known vulnerabilities

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**OBJECTIVE OR SUBJECTIVE**

| Subject  | Subjective | Objective | Both |
|--|------------|-----------|------|
| Risk assessment interviews with leadership           | X          |           |      |
| Survey of key employees                              | X          |           |      |
| OIG Annual Work Plan                                 |            | X         |      |
| OMIG Annual Work Plan                                |            | X         |      |
| Federal and State audit initiatives                  |            |           | X    |
| Emerging topics                                      |            |           | X    |
| Past issues, audit experience, known vulnerabilities |            |           | X    |

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**PERCEPTION OF RISK VS. ACTUAL RISK**

- o Validation of the 'right' risks through data
- o Actual risks to be included on the Audit Work Plan
- o Addressing perceived/ reported risk
  - Underlying cause subjective or mis-interpreted objective issue?
  - Validation through data analysis
  - Correlations with original assertion of risk
- o Predictive modeling for risk

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**WHAT RISKS MAKES THE 'AUDIT PLAN' CUT?**

***Internal/ corporate***

- o Perceived risks
- o Validated vulnerabilities

***External/ regulatory oversight***

- o Validation of risk and scope
- o Filter based on criteria
  - Scope
  - Frequency
  - Tangible effect (Risk in term potential \$\$ loss/ fines)
- o Monitoring vs. data-mining vs. formal audit

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### INVESTIGATIONS & DATA-MINING

- o Setting appropriate hypothesis and expectations
- o Defining data sampling and setting the universe under review
- o Drawing appropriate conclusions
- o *The Goldie Locks approach*

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### COMMUNICATING “DATA-MINING” THROUGH DASHBOARD

- o Establishing benchmarks
  - Regulatory driven
  - “Best in business”
  - Peer review
    - o Within organization
    - o External (Medicare, MGMA, AMGA, etc.)
- o Top compliance risks trended over time
- o Auditing vs. monitoring
- o Ad hoc reporting capabilities

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### COST CENTER DILEMMA

- o Required, mandated, established...fully paid for
- o “Indemnity policy”
- o Expenses, repayments, non-revenue producing

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### COST-AVOIDANCE AS REVENUE

- o Data-mining brings efficiency to annual audit plan by segregating and weighing risks
- o Data-mining in right-sizing your team
- o Timely response to identified trends
- o Expand the value of data-mining by including revenue cycle data
- o The reach of consequence to potential operational improvements

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### BURDEN OF EFFECTIVE DATA-MINING

In building your data-driven audit plan, keep in mind that:

- o Efficiency of identification of vulnerabilities places burden of action, monitoring, and mitigation
- o Complete data set quantifies overpayments due
- o Indicates potential for extrapolation

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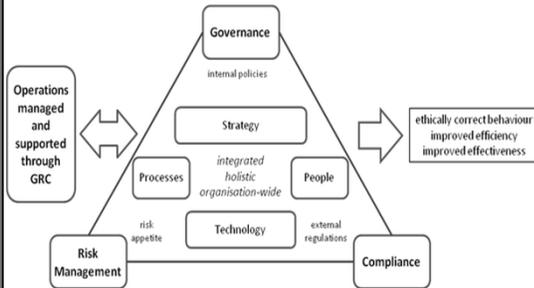
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### DATA-MINING AND GRC FRAMEWORK



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\* Chart created by CreativeCommons.org

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CONTACT

**Regina Gurvich,**  
Chief Compliance Officer  
**AdvantageCare Physicians**  
Phone: 646-447-4365  
Email: [gurvichr@acpny.com](mailto:gurvichr@acpny.com)

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**Recent Trends in RAC and MAC Appeals**  
*HCCA Compliance Institute*  
 San Diego, California  
 March 30 – April 2, 2014

Tracy M. Field, M.S., J.D.  
 Deonys de Cardenas, R.N., J.D.  
 Womble Carlyle Sandridge & Rice, LLP  
 271 17<sup>th</sup> Street, NW – Suite 2400, Atlanta, GA 30363  
 (404) 872-7000




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**AGENDA**

- The Audit and Appeal Environment
- Two-Midnight Rule and Implementation
- Compliance Considerations
  - Medical Necessity and False Claims Act
  - Assessing Accuracy?




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**MEDICARE AUDITS**  
***Now What?***

Perspective:

- By challenging denials, CMS changed the rules!
- Compliance challenge: How assess accuracy?
- Business reasons for rebilling Part B
  - 2 year backlog – and growing!




CALIFORNIA DELAWARE GEORGIA MARYLAND NORTH CAROLINA SOUTH CAROLINA VIRGINIA WASHINGTON, D.C. 3

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**BACKGROUND**  
**The Audit and Appeal Process**

Office of Medicare Hearings and Appeals  
 (OMHA) Forum: February 12, 2014

- Backlog of 500,000 cases – and counting!
- Moratorium on docketing new appeals until workload addressed per ALJ
  - Hearings being scheduled



WOMBLE  
 CARLYLE  
 INNOVATORS AT LAW<sup>SM</sup>

CALIFORNIA DELAWARE GEORGIA MARYLAND NORTH CAROLINA SOUTH CAROLINA VIRGINIA WASHINGTON, D.C. 4

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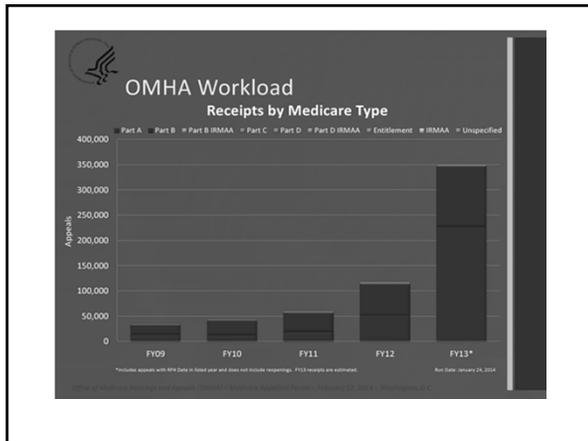
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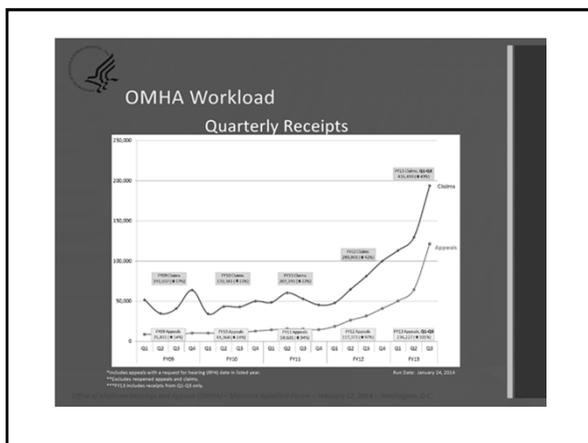
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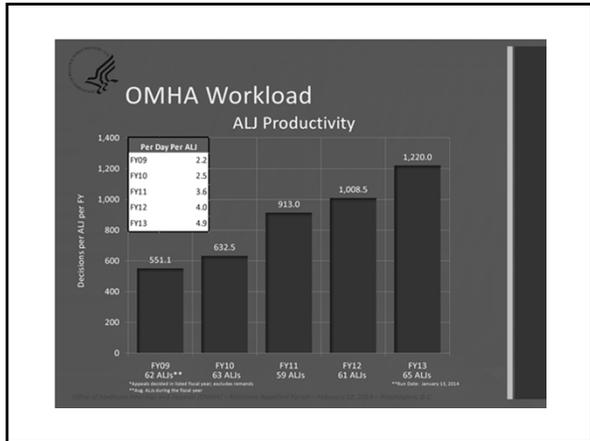
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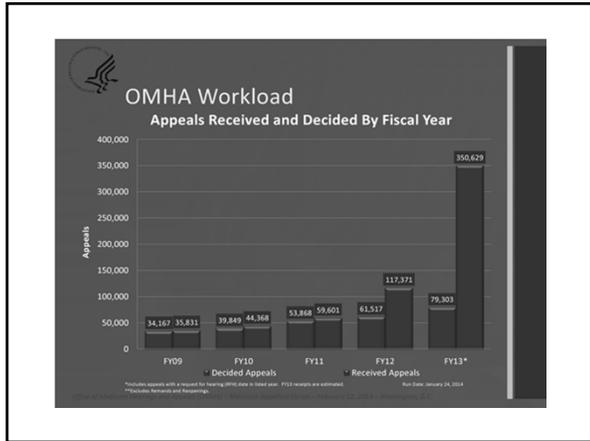
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**BACKGROUND**  
**OMHA February 2014 Forum**

- Backlog
  - Budget increase: 18+% (after sequester)
  - Statistical sampling?
    - OMHA statistician
    - Appropriate for fact-specific cases?
  - Mediation/Alternative Dispute Resolution
  - **New regulations**




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**BACKGROUND**  
**OMHA February 2014 Forum**

- No longer need to submit medical records?
- Group cases – but individually file!
- Electronic filing?
  - Send files via tracking methods, and don't expect an acknowledgment!
  - Miami pilot
  - 2 year development from award




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**BACKGROUND**  
**OMHA February 2014 Forum**

- Backlog
  - Increase in Escalation to DAB-MAC
    - NO Hearing at DAB-MAC
    - Access to federal court sooner – but...
  - OMHA stated testimony makes difference - yet
  - OMHA suggested may not want to request hearing?




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**BACKGROUND**  
**OMHA February 2014 Forum**

- Legal Considerations
  - Medicare Modernization Act (MMA) and BIPA deadlines not being met
  - For medical necessity cases, what standard of review applies?
  - Confusion on local coverage effective dates
  - *Jimmo* Case: Important for rehab, other uses?




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**BACKGROUND**  
**OMHA February 2014 Forum**

- Compliance Considerations
  - Part A/B Claims: 97% of appeals
  - **Redetermination** reversal rate to fully favorable:
    - **30% per OMHA**




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**BACKGROUND**  
**OMHA February 2014 Forum**

For OMHA Outcomes of Cases Decided at ALJ

- **37% Fully Favorable – 4% Partially Favorable**
- 30% Unfavorable
- 1% Remand
- 27% Dismissed

Impact on Compliance activities....




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**HOSPITAL ADMISSIONS: MEDICAL NECESSITY**  
**The 2 Midnight Rule**

Two-Midnight Rule

- Issued August 2, 2013: CMS-1599-F
- Intent: Improve payment integrity and provide clarity regarding inpatient status orders
- Previous “Standard”
  - Medicare Benefit Policy Manual, Pub. No. 100-02, Ch. 1, § 10




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**BACKGROUND**  
***The 2 Midnight Rule***

Two-Midnight Rule

- Physician expectation that patient requires a stay crossing at least 2 midnights; and
- Physician admits the patient to hospital based on that expectation
- Published in Federal Register:  
*< 90 day implementation*



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**BACKGROUND**  
***The 2 Midnight Rule***

Implementation Challenges

- Short "lead time"
- Coordination with adopting new electronic medical records?
- Who can enter patient "status"?
  - Automatic if in outpatient lab?
  - Prompts to have order signed pre-discharge?



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**INITIAL REVIEWS**  
***Probe Audits***

MAC Audits: January 2014

- MAC prepayment reviews: "probe and educate"

Recovery Audits:

- Delayed until November 2014



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**PROBE AUDITS**  
***Occurrence Span Code 72***

- Started December 1, 2013
- Voluntary
- Procedure for Application
  - Contiguous outpatient hospital services preceding inpatient admission can be reported on inpatient claim
  - Condition Code 44 still exists



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**INITIAL REVIEWS**  
***Probe Audits***

Presumptions that Hospital Stays Less than 2  
Midnights are Not Medically Necessary

- **Presumption** does not mean wrong!!
- Legal challenges to denials
- Strategy to avoid audits
  - Some opted for no one-day stays
  - Rebill under Part B?



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**IMPLEMENTATION**  
***Training***

Who? Training...

- Physicians
- Physician Extenders
- Case Management
- Utilization Management Committee
- Registered Nurses?



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**IMPLEMENTATION**  
***Elements***

*What?* Need the Inpatient Order

- Physician Certification and Documentation
  - Authentication
  - Reason for Inpatient Services (Elements)
  - Document Expectation Length of Stay
  - Post-Hospital Care
- Recertification



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**IMPLEMENTATION**  
***Elements***

*What?* Medical Necessity

- Medical History, Co-morbidities
- Severity of Clinical Presentation
- Medical Stability of the Patient
- Risk of Adverse Events



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**IMPLEMENTATION**  
***Elements***

*What?* Medical Necessity (*cont...*)

- Current Medical Needs
- Diagnostic Testing/Monitoring
- Plan of Care/Treatment Requiring Inpatient Setting

Answer “because” (hasn’t changed)



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**IMPLEMENTATION**  
***Electronic v. Paper?***

Where? How? Form Not Mandatory, but:

- Electronic record
- Paper record with form
- Paper record progress note



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**IMPLEMENTATION**  
***Operational Challenges***

- Changing the Culture
  - Case Managers
  - Physician's practice of medicine
- Admit: Document "inpatient"
- Authenticate prior to discharge
  - Certification: Still complex medical judgment
- No retroactive admissions! No social stays!
- No contingent orders!



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**OPERATIONAL CONSIDERATIONS**  
***Implementation***

Unforeseen or Unusual Circumstances

- Must document:
  - Against medical advice
  - Patient expires
  - Transfers
  - Hospice
  - Improves sooner than expected



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**COMPLIANCE ISSUES**  
*Internal Reviews*

Compliance Internal Reviews

- Audit tool
- Robust utilization management committee
- Re-educate!



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**FALSE CLAIMS ACT**  
*Medical Necessity Litigation*

- WakeMed
- Physician Cases
- Other Medical Necessity Cases:
  - Shands – settlement
  - Health Management Associates
  - Halifax
    - Privilege issues to consider



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**WAKEMED**  
*The Media Reports and Lessons Learned*

**December 9, 2012**

WakeMed to pay \$8M to settle investigation

- Criminal charges: Making material false statements
- Medicare billed for inpatient admissions for patients discharged same day
  - No physician order or order “overwritten”



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**WAKEMED**  
***The Legal Process***

**Deferred Prosecution Agreement (DPA)**

- DOJ tool since 1999
- File Criminal Information: Admission of Facts
- Deferral Avoids “Arthur Andersen Effect”
- Judge: Convict and Defer Sentencing...
- Debarment!



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**WAKEMED**  
***The Investigation***

- 2007 Program Safety Contractor Audit
- Data mining of claims
- For NC, WakeMed with highest Zero-Day stay billings for Oct. 1, 2003 – Sep. 30, 2006
- On-site interviews at WakeMed – conflicting information
  - *Tip: On site with auditors!*



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**FALSE CLAIMS ACT**  
***Medical Necessity Litigation***

Maryland St. Joseph’s Medical Center: \$4.9M settlement for unnecessary hospital admissions 2007-09

- Related prosecution of cardiologist for medically unnecessary admissions under fraud theory



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**FALSE CLAIMS ACT**  
***Medical Necessity Litigation***

Other observations:

- Contractors as whistleblowers:  
Reported concerns to compliance, but issues not addressed
- Data Mining
- More sophisticated whistleblowers
- Whistleblowers “going all the way”



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**FALSE CLAIMS ACT**  
***Medical Necessity Litigation***

Health Management Associates (HMA)

- Employed physician as whistleblower – first to JC, not validated
- Allegations of free office space, medically unnecessary admissions from ED
- CEO named individually as well as HMA



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**FALSE CLAIMS ACT**  
***Privilege Issues***

Halifax Hospital:

- Whistleblower suit: unlawful compensation of physicians violating Stark, AKS – \$200M
- Government intervened: Discovery of regulatory compliance, communication with legal
- Court: Business advice, not protected with in-house counsel



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**FALSE CLAIMS ACT**  
***Privilege Issues***

Halifax Hospital:

- **No presumption of privilege with in-house counsel communications**
- Business advice, not protected with in-house counsel when routine communications with compliance
- Lawyer was on email, to be “kept in loop”



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**OTHER FCA ISSUES**  
***Medical Necessity***

Halifax Hospital:

- Allegations that neurosurgeons paid in excess of Fair Market Value
- Allegations that spinal fusion surgeries that were not medically necessary were performed

*Stay tuned...*



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**MEDICARE AUDITS**  
***Medical Necessity***

Compliance Concerns

- Monitor trends
- Other business
- Considerations may dictate rebilling
- Disagreement is not a False Claim!



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**MEDICARE APPEALS**  
***The Two Midnight Rule***

Admission Order and Certification as Condition of Payment

- Certification: PRIOR to Discharge
  - Authenticated order
  - Documentation of reason for inpatient admission, estimated time of hospital stay
  - Physician judgment!



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**MEDICARE APPEALS**  
***Jimmo v. Sebelius***

Rehabilitation Providers/Suppliers:

- Change Request 8458, MedLearn on standard for rehab/care

Affirms “Longstanding” Policy:

- *Beneficiary need for care, not improvement dictates coverage*



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**REFERENCES**

[www.hhs.gov/omha](http://www.hhs.gov/omha)

- Per OMHA: Updates after 15<sup>th</sup> of each month on adjudication timelines, processes
- OMHA Adjudication Manual Pending



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**QUESTIONS?**

Tracy M. Field, M.S., J.D.  
Deonys de Cárdenas, R.N., J.D.

[tfield@wscr.com](mailto:tfield@wscr.com)  
(404) 962-7539  
[ddecardenas@wscr.com](mailto:ddecardenas@wscr.com)  
(404) 879-2473

Womble Carlyle Sandridge & Rice, LLP  
271 17<sup>th</sup> Street, N.W.  
Suite 2400  
Atlanta, Georgia 30363



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*Effective Compliance Presentations:  
Use of Art, Literature and the Media*

*Juliann Tenney, JD, CHRC  
Director, Research Compliance Program  
Research Compliance, Privacy and Conflict of Interest  
University of North Carolina at Chapel Hill*

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*Presentation Objectives*

*Interactive examination of successful incorporation of art, literature and the media into compliance presentations*

*Examples*

- *Books*
- *Films*
- *Magazines*
- *Media: cartoons, news, "features" and documentaries, photography, radio (!)*

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*Sometimes compliance professionals must work with colleagues who have trouble understanding them (and may never understand them)*

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*Establish "Tone"*

*Consider*

- *Identify your audience (internal, external, level of sophistication)*
- *Audience may be compliance contrarians – think about our "language"*
- *Challenge is to develop interest and empathy with compliance goals*  
*Provide a new lens through which compliance perceived*
- *Provide activities or tools that encourage engagement*
- *Open your eyes to potential of stories and analogies to deliver your message*

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*Books – Oprah is on to something*

*Note rich bibliographies*

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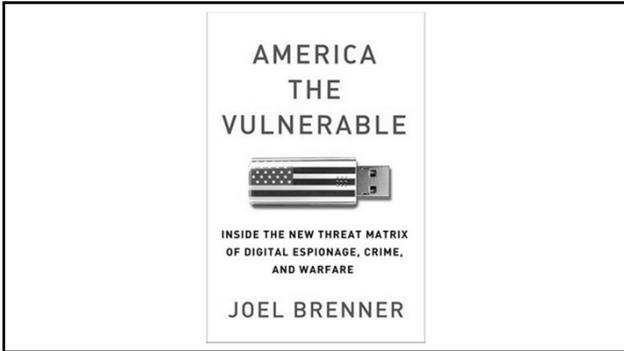
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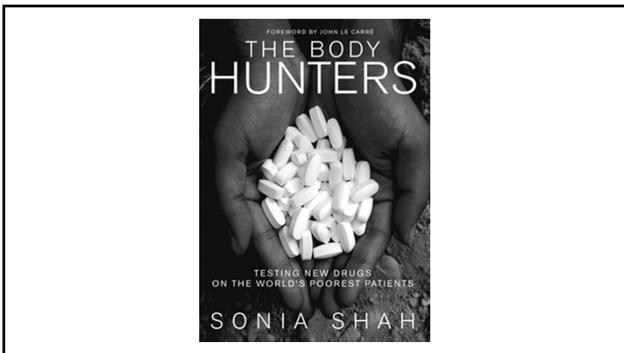
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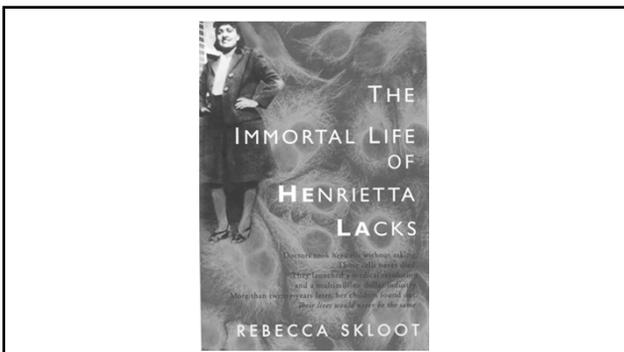
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*Films – Let's go to the movies!*

- The Constant Gardener*
- Extraordinary Measures*
- Miss Evers' Boys*
- Project X – Animal*
- Lorenzo's Oil*

*More ...*

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*Magazines – They are everywhere*

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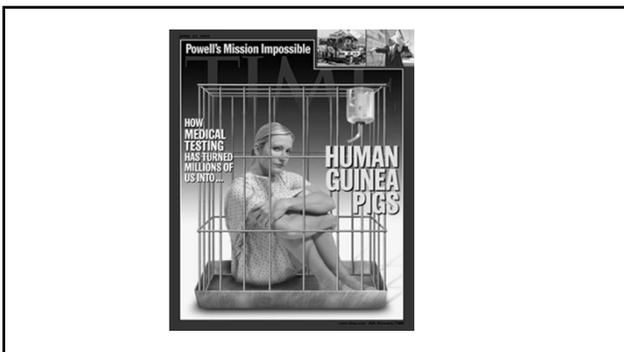
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*Analogies – Relating compliance to something familiar*

*Words – Compliance is ...*

*Real stories to which compliance concepts can be applied*

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*Who is this fellow?*

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*Media: Cartoons, news, "features" and documentaries, photography*

*Fair Use Doctrine*

*Not for profit*

*Minimal extraction*

*Note source, date*

*Much is in the public domain*

*When in doubt, ask for permission*

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*Radio*

*How to Spatchcock Your Compliance Program*

*Inspired by NPR*

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*Thank you!*

*Juliann (Juli) Tenney, JD  
Institutional Research Compliance and HIPAA Privacy Officer  
Director, Institutional Research Compliance Program  
The University of North Carolina at Chapel Hill  
CVS Plaza Building, Suite 501  
137 East Franklin Street  
Chapel Hill, NC 27516  
Mailing Address:  
Campus Box 9103  
Chapel Hill, NC 27599-9103  
E-mail: [juliann.tenney@unc.edu](mailto:juliann.tenney@unc.edu)*

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## The OIG Report: Audits are Here!

*Presented by:*  
**Kris Mastrangelo, President & CEO**  
Harmony Healthcare International,  
(HHI)

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### About Kris

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**Kris Mastrangelo, OTR/L, LNHA, MBA**

Kris Mastrangelo, President and CEO, owns and operates Harmony Healthcare International, (HHI) an industry leader in Long Term Care consulting.

- 14,000 Medical records reviewed per year
- Core Business Patient Centered

 Follow Me! @KrisMastrangelo

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### OIG Audits

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## How We Got Here

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Wall Street Journal, November 12, 2012

- Thomas Burton, November 2012
  - “More intensive services were done than actually performed”
  - “Patients could not benefit from it”
  - “Cutting fraud” Obama

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Wall Street Journal

- Sample 499 claims by 245 (stays) nursing facilities
  - 1 home reached a settlement agreement on allegations of fraudulent billing for “medically unnecessary” therapy
  - “More therapy during the period on which bills were based”
  - “Look-Back Period”

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OIG Report:  
Claims in 2009

- 25% billed all claims in error 1.5 billion
- 26% claims not supported in the medical record
- 542 million in over payment
- “Majority” error “upcoded”\*
- Many Ultra High

\* Original RUG was a higher paying RUG than the revised RUG

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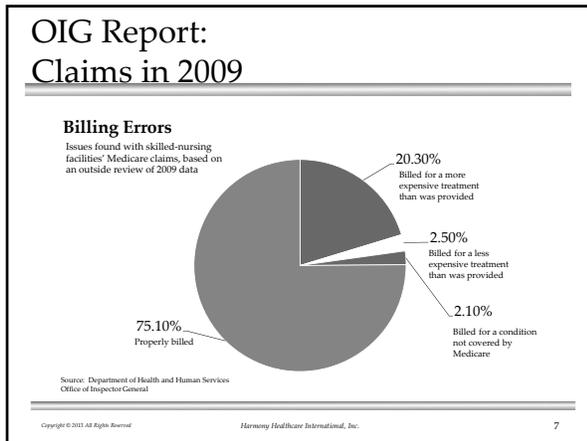
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- ### OIG Report: Claims in 2009
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- Remaining, "downcoded"\*
    - Did not meet Medicare coverage requirements
  - 47% claims, misreported information on the MDS
  - "SNF's commonly misreported therapy"
- \* If the original RUG was a lower paying RUG than the revised RUG
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- ### OIG Report: Claims in 2009
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- MedPac noted that the payment system "encourages SNF's to furnish therapy, even when it is of little or no benefit"
  - 2006→2008 SNF's increasingly billed for higher paying categories even though beneficiary characteristics remained largely unchanged
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**OIG Report:  
Claims in 2009**

- 3 RN Nurses reviewed the claims along with the PT/OT/ST
- Analysis
  - Upcoded
  - Downcoded
  - Both considered errors

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**OIG Report:  
Claims in 2009**

- Paid **\$1.5 billion** for these claims. This represents 5.6 percent of the \$26.9 billion paid to SNFs in 2009
- See Table 1 for the percentage of SNF claims that were in error and Appendix D for the confidence intervals

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**OIG Report:  
Claims in 2009**

**Table 1: Percentage of SNF Claims That Were in Error - 2009**

| Type of Error                      | Percentage of SNF Claims |
|------------------------------------|--------------------------|
| Inaccurate RUGs                    | 22.8%                    |
| Upcoded                            | 20.3%                    |
| Downcoded                          | 2.5%                     |
| Did Not Meet Coverage Requirements | 2.1%                     |
| Total Error Rate                   | 24.9%                    |

Source: OIG analysis of medical record review results, 2012

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OIG Report:  
Claims in 2009

- SNFs billed **inaccurate RUGs** in **23 percent of claims**. Most of these claims were upcoded; far fewer were downcoded
- Claims with inaccurate RUGs amounted to a net **\$1.2 billion** in inappropriate Medicare payments

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OIG Report:  
Claims in 2009

- Notably, **20 percent** of claims billed by SNFs had **higher paying RUGs** than were appropriate
- In these cases, the SNFs upcoded the RUGs on the claims. For approximately **half** of these claims, SNFs billed for **Ultra High Therapy RUGs** when they should have billed for lower levels of therapy or nontherapy RUGs

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OIG Report:  
Claims in 2009

- For **57 percent** of the **upcoded claims**, SNFs reported providing more therapy on the MDS than was indicated in the medical record

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OIG Report:  
Claims in 2009

- For a quarter of the upcoded claims, reviewers determined that the amount of therapy indicated in the beneficiaries' medical records was not reasonable and necessary

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OIG Report:  
Claims in 2009

- For example, in one case, the SNF provided the highest level of therapy to the beneficiary even though the medical record indicated that the **physician refused to sign the order for therapy**
- In another example, the SNF provided an excessive amount of therapy to the beneficiary given her condition

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OIG Report:  
Claims in 2009

- In another example, the SNF report on the MDS that **speech therapy** was provided even though the record contained an **evaluation** of the beneficiary concluding that no speech therapy was needed and that speech therapy had not been provided

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### OIG Report: Claims in 2009

- **Two percent** of SNF claims did not meet Medicare coverage requirements
  - For some of these claims, beneficiaries were not eligible for SNF care, either because they did not need skilled nursing or therapy on a daily basis or because there were no physician orders for these services

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### OIG Report: Claims in 2009

- SNFs **misreported** information on the **MDS** for **47 percent** of claims.
  - SNFs reported inaccurate information, which was not supported or consistent with the medical record, on a **least one MDS item** for 47 percent of claims
  - For **30 percent of claims**, SNFs misreported the **amount of therapy** that the beneficiaries received or needed

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### OIG Report: Claims in 2009

| MDS Category<br>With Misreported Information                   | Percentage of Claims |
|--|----------------------|
| Therapy (i.e., physical, occupational, speech)                 | 30.3%                |
| Special Care (e.g., intravenous medication, tracheostomy care) | 16.8%                |
| Activities of Daily Living (e.g., bed mobility, eating)        | 6.5%                 |
| Oral/Nutritional Status (e.g., parenteral feeding)             | 4.8%                 |
| Skin Conditions and Treatments (e.g., ulcers, wound dressings) | 2.4%                 |

Source: OIG analysis of medical record review results, 2012  
Note: The rows do not sum to 47 percent because some claims had more than one problem

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## Look Back Period

- In addition, reviewers found several instances in which SNFs provided **more therapy** during the **look-back** period than they did during periods that did not determine payment rates

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## Therapy Minutes

- In one example, the SNF provided **90 to 110 minutes** of therapy a day to the beneficiary during the **look-back** period; however, **after that period**, the SNF provided only about **half that amount** of therapy to the beneficiary

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## Therapy Minutes

- In another example, the SNF provided **50 to 55 minutes** of therapy a day to the beneficiary during the **look-back period**. It lowered the amount to **30 to 40 minutes** a day during the **rest of the coverage** period but then raised it back to 50 to 55 minutes during the next look-back period.

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## MDS

- For **17 percent** of claims, SNFs **misreported** whether the beneficiaries received **special care**. The inaccuracies came primarily from one MDS item in this category – **intravenous medication**. At the time of our review, SNFs were allowed to report intravenous medication if the beneficiary received it in the hospital prior to or during the SNF stay.

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## MDS

- For these claims, the **medical records** either **did not indicate** that intravenous medication was provided during the hospital or SNF stay or clearly contradicted that these services were provided

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## MDS

- For **7 percent of claims**, SNFs misreported the amount of **assistance** beneficiaries needed with **activities of daily living** (e.g., bed mobility, transfers, eating, and toilet use)
- SNFs also misreported MDS items related to **oral and nutritional** status and items related to skin conditions and treatments

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## Skin

- SNFs did not always report the correct **number of stage of skin ulcers** or they reported the presence of burns or open lesions inaccurately. They also did not always correctly report skin treatments, such as surgical wound care or ulcer care.

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## OIG Recommendations

- Increase and **expand reviews** of SNF claims
  - CMS should instruct its contractors to conduct more medical reviews of SNF claims

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## OIG Recommendations

- Use its **Fraud Prevention System** to Identify SNFs that are Billing for Higher Paying RUGs
  - CMS should use its Fraud Prevention System to identify and target these SNFs

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### OIG Recommendations

- **Monitor Compliance with the New Therapy Assessments**
  - As of October 2011, SNFs must complete a **“change of therapy”** assessment when the amount of therapy provided no longer reflects the RUG and an **“end of therapy”** assessment when therapy is discontinued for 3 days

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### OIG Recommendations

- CMS should instruct its MACs and RACs to closely monitor SNFs utilization of these assessments through **analyses of claims data**. Such analyses will identify SNFs that are using the assessments infrequently or not at all.

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### OIG Recommendations

- **Change the Current Method for Determining How Much Therapy is Needed to Ensure Appropriate Payments**

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## OIG Recommendations

- CMS should instruct the MACs to provide **education** to all SNFs, as well as specific training to selected SNFs, to improve the accuracy of their MDS reporting

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## OIG Recommendations

- **Follow up** on the SNFs That Billed in Error
  - In a separate memorandum, we will refer to CMS for appropriate action the SNFs with claims in our sample that had inaccurate RUGs or that did not meet coverage requirements

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## Appendix D: Sample Sizes, Point Estimates, and 95 Percent Confidence Intervals for Estimates Presented in the Report

| Characteristic  | Sample Size | Point Estimate | 95 Percent Confidence Interval |
|---|-------------|----------------|--------------------------------|
| SNF claims in error in 2009   | 499         | 24.3%          | 19.0%-29.6%                    |
| SNF claims with inaccurate RUGs   | 499         | 22.8%          | 18.0%-28.2%                    |
| SNF claims with higher paying RUGs than were appropriate (up-coded)   | 499         | 20.3%          | 15.0%-25.6%                    |
| Up-coded SNF claims that had an Ultra High RUG  | 101         | 48.2%          | 34.9%-61.7%                    |
| Up-coded SNF claims in which SNFs reported providing more therapy on the MDS than was indicated on the medical record | 101         | 56.8%          | 42.8%-70.2%                    |
| Up-coded SNF claims in which reviewers determined that the amount of therapy was not reasonable and necessary         | 101         | 25.6%          | 14.0%-39.4%                    |
| SNF claims with lower paying RUGs than were appropriate (down-coded)  | 499         | 2.5%           | 1.3%-4.5%                      |
| SNF claims that did not meet Medicare coverage requirements   | 499         | 2.1%           | 0.7%-4.7%                      |
| Total inappropriate Medicare payments for SNF claims  | 499         | \$1.5 billion  | \$988 million-\$2.0 billion    |
| Inappropriate Medicare payments in proportion to total payments to SNFs in 2009                                       | 499         | 5.6%           | 3.7%-7.9%                      |
| Medicare payments for SNF claims with inaccurate RUGs   | 499         | \$1.2 billion  | \$790 million-\$1.6 billion    |
| SNF claims that had inaccurate information on the MDS   | 487         | 47.3%          | 41.2%-53.5%                    |

Source: Office of Inspector General medical record review, 2012

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**Program for Evaluating Payment Patterns  
Electronic Reports  
(PEPPER)**
  


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**PEPPER**

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- Compare SNF to other SNFs nationally
- Received via mail on or about August 30, 2013
- Envelope with red print on the outside containing your facility specific PEPPER

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**Where is My PEPPER**

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Bridgepoint 1, Suite 300  
 5916 West Courtyard Drive, Austin TX 78730-5036

August 30, 2013

**Chief Executive Officer/Administrator  
Harmony Healthcare International (HHI)  
430 Boston Street, Suite 104  
Topsfield, Massachusetts 01983**

Verify the presence of multiple accounts. These can only be confirmed through a review of individualized documentation, although other data reflects when they purchase the item.  
 Training and Support: At PEPPER@tmf.com or www.tmf.com/pepper User's Guide and a complete TMF PEPPER online manual under the Training and Resources page of the Stakeholder Family website. Questions regarding the TMF PEPPER may be submitted at any time through the website (see Contact Information page).  
 Sincerely,  
  
 Kimberly Fisher, MBA, RHQ, DBC  
 Program Director  
**PEPPER**

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### Where is My Pepper?

- From TMF Health Quality Institute
- Junk mail
- PEPPERResources.org from the PEPPER HELP Desk
- (<http://pepperresources.org/HelpContactUs.aspx>).

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### Where is My Pepper?

- Effective January 1, 2014 TMF will no longer resend copies of SNF PEPPERS (version Q4FY12) which were initially mailed to all SNFs on August 30, 2013.
- The next SNF PEPPER (version Q4FY13) will be distributed in late April-early May 2014 and will be available for access in electronic format by the SNF's CEO/administrator/president. TMF will send an email notification when the Q4FY13 SNF PEPPERS are available.
- TMF encourages you to sign up to receive this email by visiting the Home page of [PEPPERresources.org](http://PEPPERresources.org) and click on the gray box in the upper right area of the page to "Join the email list..."; fill out the requested information and select the "Skilled Nursing Facility". This will ensure that you receive any future information/updates pertaining to the SNF PEPPER.

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### PEPPER

- **Provider-specific Medicare data statistics for services vulnerable to improper payments**
- Compares to all other SNFs across the state, nation or Medicare Audit Contractors(MAC) jurisdiction
- Shared with both Medicare Audit Contractors (MACs) and the Medicare Recovery Auditor Contractors (RACs)

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## PEPPER

- Targeted areas were derived from two recent Office of Inspector General (OIG) Reports:
  - “Inappropriate Payments to skilled Nursing Facilities Cost Medicare than a Billion Dollars in 2009” (November 2012)
  - “Questionable Billing by Skilled Nursing Facilities” (December 2010).

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## Claims Data

- The SNF PEPPER provides SNFs with their jurisdiction, state and national percentile values for each target area with reportable data for the most recent three fiscal years
  - FY 2012 (October 1, 2011 through September 30th ) is displayed on the first table
  - When the target (numerator) count is less than 11 for a target area for a time period, statistics are not displayed

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## Target Areas

- Therapy RUGs with High ADLs
- Non-therapy RUGs with High ADLs
- Change of Therapy Assessment
- Ultra High RUGs
- Therapy RUGs
- 90+ Day Episodes of Care

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## Compare Target Report

- Page 1 (after introduction)
- FY2012 only
- When the SNF's percent is at or **above the national 80th percentile** for a target area, the SNF's percent is printed in red bold
- When the SNF's percent is at or **below the national 20th percentile** for a target area the SNF percent is printed in green italics
- When the SNF is not an outlier, the SNF's percent is printed in black
- Blank if Less than 11 SNFs or episodes in group

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## Target Count

- Number of Episodes of Care
  - Shows Volume of Care
  - The "Target Count" can also be used to help prioritize areas for review
  - Areas in which a provider is at/above the 80th percentile that have a large target count may be given higher priority than target areas for which a provider is at/above the 80th percentile that have a smaller target count

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## Therapy RUGs with High ADLs

- **Numerator:** Rehabilitation and Rehabilitation Extensive RUGs
  - All Rehab "C" or "X" Days
  - Also includes RLB
- **Denominator:** All Rehabilitation RUGs

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### Non Therapy RUGs with High ADLs

- **Numerator:** Nursing RUGs
  - All Non Therapy "E" Days
  - Also includes BB1 and BB2 (Low ADL)
- **Denominator:** All Nursing RUGs

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### Change of Therapy Assessment

- **Numerator:** AI second digit equal to "D" within episodes of care ending in the report period
  - "D" is a Change in Therapy Assessment (COT)
- **Denominator:** All assessments within episodes of care ending in the report period
  - COT initiated October 1<sup>st</sup> 2011 (FY2012)

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### Ultra High Therapy RUGs

- **Numerator:** RUG equal Rehabilitation Ultra High or Ultra High Extensive (RUC, RUB, RUA, RUX, RUL)
- **Denominator:** ALL Rehabilitation RUGs
  - Not Total RUGs

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## Therapy RUGs

- **Numerator:** Rehabilitation RUGs
- **Denominator:** All RUGs

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## Episode of Care

- Based on episodes of care
- Defined as a series of claims for a patient where the difference between the "Through Date" of one claim and the "From Date" of the subsequent claim is less than or equal to thirty days
  - Admission through Discharge
  - Considered same Episode of Care if readmission to SNF (billed again) within 30 Days of discharge
  - **Data includes episodes of care that end in period reported**

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## 90+ Day Episodes of Care

- **Numerator:** A length of stay of 90+ days
- **Denominator:** All episodes of care ending in the report period

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## Closing Thoughts on PEPPER

- There is no “Good” or “Bad” PEPPER
- Compliance chart auditing at regular intervals for outlier areas
- Analyze PEPPER data
- Develop a Compliance Program

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## Compliance

### Audit Process

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## Audit Process

- Significant increase in frequency of Medical Review
  - Office of Inspector General (OIG) Reports
  - Department of Justice (DOJ) Review
  - Zone Program Integrity Contractor (ZPIC)
  - Recovery Audit Contractor (RAC)
  - Budget cuts
- Expect to be Reviewed

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## Denial Reasons

- Services provided were likely clinically appropriate but the documentation did not support:
  - Technical requirements
  - Medical necessity
  - The skills of a therapist were required
  - Functional outcome
  - Need to receive an inpatient level of care

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## Technical Denial Reasons

- Response to Additional Documentation Request (ADR) did contain documentation requested
- Documentation not received within requested time frame
- Physician Certification not signed or missing
- Therapy Billing logs do not support billing
  - Part A – MDS Assessment
  - Part B - 8 Minute Rule
- Illegible documentation
- Hospital documentation was not submitted

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## Clinical Denial Reasons

- Documentation did not support **medical necessity**
- Documentation does not support **daily skilled intervention by a qualified therapist**
- Documentation in the medical records **must support continued progress**

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### Denial Reasons Reasonable and Necessary

- The amount, frequency and duration of services were not reasonable, **given the patient's current status**
- ST documentation demonstrates that the therapist worked **long enough with the beneficiary to develop a restorative program**

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### Denial Reasons Inpatient Level of Care

- Documentation did not support the need for inpatient level of care
- No daily skilled care requiring a stay in the SNF
- Supervised level of care

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### Denial Reasons Medical Record Conflicts

- Nursing notes mostly dependent ADLs/functional tasks throughout the SNF stay. **Nursing note indicated there was no improvement and fluctuation of progress with self-care tasks.**
- MDS assessments indicate that the beneficiary's ability to perform functional tasks/ADLs **did not** improve from the 5-day to the 90-day assessment

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Audit Process

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**On-site Medical Record Audits**

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On-site Medical Record Audits

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- AdvanceMed
- Request for 160-170 medical records
- 14 days to submit
- Requesting ONLY therapy documentation
- Therapy staffing levels were requested
- AdvanceMed interviews with staff

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On-site Medical Record Audits

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- Rehab and MDS Questions
- Sample therapy staff interview questions:
  1. Do you feel pressure to meet your RUG levels?
  2. Who has the say on discharge from therapy?

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## On-site Medical Record Audits

- Sample MDS staff interview questions:
  1. Who decides the ARD?
  2. Do they provide group and concurrent treatments?

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## Examine Your Program

- Effective Programs Consist of:
  - Policies and Procedures
  - Staff Training and education
  - Audit functions
  - Keep apprised of Regulatory Updates
- Is your plan effective?

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## Zone Program Integrity Contractors [ZPICs]

- Newest contractors in the CMS arsenal
- Broad mandate and, unlike the RACs are tasked with ferreting out fraud in addition to recovering overpayments
- Unlike RACs, they have specific investigative powers and do not need to have approval for types of issues they may investigate

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## ZPICs

- Auditors are designed to replace the more fragmented program safeguard contractors (PSCs), which had more limited jurisdiction as to types of providers they were permitted to evaluate
- ZPIC contractors are broken down into seven specific geographic zones

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## ZPICs - Responsibilities

- ZPIC responsibilities are extensive and they are charged with investigating numerous issues.
  - Preventing fraud by identifying program vulnerabilities
  - Proactively identifying incidents of potential fraud that exist within its service area and taking appropriate action on each case

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## ZPICs - Responsibilities

- Investigating factual allegations of fraud made by beneficiaries, providers, CMS, OIG and other sources
- Exploring all available sources of fraud leads in its jurisdiction
- Initiating appropriate administrative actions to deny or to suspend payments that should not be made to providers where there is reliable evidence of fraud

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## ZPICs - Responsibilities

- Referring cases to the Office of Inspector General/Office of Investigations (OIG/OI) for consideration of civil and criminal prosecution and/or application of administrative sanctions
- Referring any necessary provider and beneficiary outreach to the POE staff at the AC or MAC

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## PSC and ZPIC

- Investigations have priority over RAC investigations
- Program Integrity Manual specifically notes that data being utilized for ZPIC reviews will be inaccessible to RAC auditors so as to prevent conflicts in investigations

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## ZPICs Compensation

- Incentives are set forth in specific ZPIC contract with CMS
  - Compensation based on a fixed fee plus an award fee that is determined based on performance
  - Performance award factors:
    - Quality of services
    - Administrative actions

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## ZPICs Auditing

- ZPICS have a wide discretion over the types of issues they may investigate
- Data analysis will play a key role in such investigations

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## ZPIC Auditing: Program Integrity Manual

- Types of issues ZPICs will be auditing
  - Data analysis is an essential first step in determining whether patterns of claims submission and payment indicate potential problems. Such data analysis should include simple identification of aberrancies in billing patters with a homogeneous group, or much more sophisticated detection of patterns within claims or groups of claims that might suggest improper billing or payment.

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## ZPIC Auditing: Program Integrity Manual

- Data analysis itself shall be undertaken as part of general surveillance and review of submitted claims, or shall be conducted in response to information about specific problems stemming from complaints, provider or beneficiary input, fraud alerts, reports from CMS, other ACs, MACs or independent government and non-governmental agencies

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## ZPIC Investigations

- ZPICs examine:
  - Incorrect reporting of **diagnoses** or procedures to maximize payments
  - Billing for **services not furnished** and/or supplies not provided
  - Billing that appears to be a deliberate application for **duplicate payment** for the same services or supplies, billing both Medicare and the beneficiary for the same service, or billing both Medicare and another insurer in an attempt to get paid twice

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## ZPIC Investigations

- **Altering claim forms**, electronic claim records, medical documentation, etc., to obtain a higher payment amount
- Soliciting, offering or receiving a **kickback, bribe or rebate**
  - Paying for a referral of patients in exchange for the ordering of diagnostic tests and other services or medical equipment
- **Unbundling** or “exploding” charges

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## ZPIC Investigations

- Completing **Certificate of Medical Necessity (CMNs)** for patients not personally and professionally known by the provider
- Participating in schemes that involve **collusion between a provider and a beneficiary**, or between a supplier and a provider, and result in higher costs or charges to the Medicare program

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## ZPIC Investigations

- Participating in schemes that involve **collusion between a provider and a contractor** where the claim is assigned
  - The provider deliberately overbills for services, and the AC or MAC employee then generates adjustments with little or no awareness on the part of the beneficiary
- Billing based on “**gang visits**”
  - Physician visits a nursing home and bills for 20 nursing home visits without furnishing any specific service to individual patients

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## ZPIC Investigations

- **Misrepresentations of dates and descriptions of services** furnished or the identity of the beneficiary or the individual who furnished the services
- Billing **non-covered or non-chargeable services** as covered items
- Repeatedly **violating the participation agreement**, assignment agreement and the limitation amount

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## ZPIC Investigations

- Using another person's Medicare card to obtain Medicare care
- Giving **false information** about provider ownership in a clinical laboratory
- Using the adjustment payment process to generate fraudulent payments

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## ZPICs Authority

- ZPICs have considerable latitude regarding fraud investigations and have the authority to refer cases of fraud to OIG and DOJ for civil or criminal sanctions, including the potential filing of a false claims complaint

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## Strategies for Providers

- Critical that providers take any audit request seriously
  - Potential for referral to the OIG or DOJ for civil monetary penalties or criminal prosecution
- It is important to have **knowledgeable counsel** to assist in reviewing the information to determine whether there is potential for serious issues
  - Regardless if the request for information seems routine

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## Strategies for Providers

- **Be Cautious:** If the audit is requesting contractual information that may implicate either **Stark or the Anti-Kickback Act**
  - Such claims can give rise to an FCA complaint
- Consult an appropriate Billing or Financial Consultant if indicated
  - Determine whether the claims have been submitted appropriately

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### Strategies for Providers

- If inappropriate submissions are suspected, counsel should retain the Financial Consultant to assist in the investigation
  - Protected by the attorney-client privilege and/or work product doctrine
- Often self investigation into one area exposes issues in another area.

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### Strategies for Providers

- When information is protected, the provider can make an informed decision as to the nature of the problem and devise a strategy for correction
- May involve **self-disclosure or repayment** of the funds to Medicare

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### Strategies for Providers

- If a provider can be deemed to have **voluntarily returned the funds**, as opposed to have the overpayment discovered by the government (in which case not credited for self-disclosing) they may be entitled to a **reduction in penalty** which self-disclosure may provide

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## Strategies for Providers

- Counsel can assist if there is an inquiry from OIG or DOJ
  - Specifically if either issues a subpoena or investigative demand
- All inquiries must be escalated to the highest levels until the provider can be sure that no real problem exists

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## Vernacular

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## Triggering Audits

- State and Federal investigations
- ZPIC, OIG, DOJ and many other governmental entities
- Etiology of reviews vary
  - UB-04 edits
  - Diagnoses patterns
  - ICD-9 Coding
  - Whistleblowers

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## False Claims

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Also known as qui tam or  
Whistleblower cases

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## False Claims

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### ■ False Claims Act

Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval.....

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## False Claims

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.....is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person

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## False Claims

- Example False Claims:
  - Billing for services of an unlicensed therapy professional
  - Receiving payment for therapy services to patients that were not reasonable or necessary given the patients condition
  - Corporate incentives for therapy staff to provide higher levels of care when not indicated

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## False Claims

- Example 1: Accused entity paid \$1.5 Million for submitting claims to Medicare and Medicaid for services provided by an unlicensed speech therapist

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## False Claims

- Example 2: Accused entity paid \$953,375 for providing services that were unnecessary, and submitting claims to Medicare.
  - For example, occupational therapy was provided to elderly Alzheimer's patients who could never expect to return to the workforce

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## False Claims

- Example 3: Accused entity charged with violating the False Claims Act by encouraging therapists to bill higher amounts and do more expensive therapy—even if patients didn't need therapy or could be harmed by it.
  - Billed nearly 68% of its Medicare Rehab days at Ultra High.

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## False Claims

- Example 4: Accused entity paid \$675,000 for submitting claims for therapy (provided by contract therapy company) that did not match the residents' needs.
  - The provider is suing the therapy company for negligence and breach of contract.
  - Will the contract therapy company face government penalties - it is likely.

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## Allegations

- Medicare Upcoding
- Unnecessary Therapy Treatments
- Systematic Scheme
- Medicare Fraud

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### Allegations

- Corporate guidelines established by Operators or Directors
- Direct front line staff to follow internal guidelines to deliver expensive skilled therapy, OT, PT and ST that is not reasonable or necessary

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### Allegations

- Excessive Goals
  - Rehab Ultra High – regardless of clinical need
  - Length of stay targets paralleling allowable benefit coverage

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### Claim Submissions

**Five important tips** to defend allegations of improper claim submission.

1. **Review the Medical Records** prior to submission to the governmental entity and observe if there is in fact a pattern of misconduct or false claims (i.e., minutes on therapy logs match the MDS). Do not send the medical records without reviewing every claim. It is imperative to know what the auditors will unearth. Scrutinize the charts with a cynical eye.

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Claim Submissions

**2. Identify the patient's functional level** prior to hospitalization, on admission and upon discharge from the SNF setting.

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Claim Submissions

**3. Note whether or not the patient improved** functionally and clinically. If the patient's status declined or stayed the same, see if the record depicts a medical justification.

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Claim Submissions

**4. Assess functional status versus the documentation.** In some instances, the documentation may be lacking content but the gist of the medical status is transparent. If this is the case, write a summary describing the care and status.

**5. Create a summary sheet** of all patients reviewed including: ICD-9 coding, hospital admission diagnoses, clinically anticipated stay at the facility, certification form completion, MDS ARDs, along with the rationale for skilled coverage.

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### Vernacular

- Providers and clinicians are reacting to the abundance of publicized investigations, with a potential negative impact on patient care
- Therapy professionals are questioning therapeutic interventions provided as a covered service and have adopted a **conservative approach** so as not to create a potential overpayment situation for the SNF

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### Knowledge is diluted

- CMS created a complex PPS reimbursement system that focuses on calculating and monitoring therapy minutes to ensure that SNFs are properly reimbursed for services provided.

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### Knowledge is diluted

- The system is so intricate that Rehabilitation Managers are consumed by minute management with attention drawn away from clinical management

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### Knowledge is diluted

- Due to the densities of the system, the Rehabilitation Manager is the only one who understands the system
- Hence Rehabilitation Departments focus on minutes, categories, EOTs, COTs and schedules versus patient care
- Question: Do frustrated therapists that do not understand the complexities of the system fueling the Whistleblower fire?

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### Knowledge is diluted

- Hours and hours of labor are focused on the investigation versus the normal daily tasks of patient care, company development and industry relevance
- Fear and chaos ensue as employees worry about losing jobs and providing for their families

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### Knowledge is diluted

- Anxiety and paranoia bleed out of staff as they replay the time frame under scrutiny and ponder whether or not “they did something wrong”.
- Silent finger pointing manifest in management’s brains, while direct care providers lose confidence in the accused organization’s integrity

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## Vernacular

- The number one goal in post-acute care, as mandated by OBRA '87, is to bring the patient to his/her highest practicable state of wellbeing.

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## Compliance

### Compliance Programs

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## Compliance Program

- Per Federal and State laws and Federal healthcare program requirements
- A system of policies and procedures
- Monitoring and Auditing tools
- Communication and reporting methods
- Enforcement
- Leadership

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## Compliance and Ethics Program

### ■ **OIG Supplemental Guidance:**

“Compliance programs help nursing facilities fulfill their legal duty to provide quality care; to refrain from submitting false or inaccurate claims or cost information to the Federal health care programs; and to avoid engaging in other illegal practices”.

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## Be As Informed As Possible

### ■ **OIG Guidance**

<http://oig/hhs/gov/compliance/complianceguidance/index.asp>

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## Compliance Is Mandatory

- Medicare/Medicaid Condition of Participation
- March 23, 2013
- Patient Protection and Affordable Care Act

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## HIPAA

- Privacy Rule
- Security Rule
- Breach Notification Rule

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## Penalties: HIPAA

- Civil penalties: up to \$50,000 per violation (\$1.5 Million annual maximum per type of violation)
- Criminal penalties: Up to \$250,000 and 10 years imprisonment

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## Efficacy

- Criminal sanctions may be mitigated by a compliance program, but only if that program is **effective**
- Most SNFs lack the policies & procedures, staff training, audit functions, and regulatory updates to keep their compliance programs effective

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### Required Compliance Program Components

- Written Policies & Procedures, Code of Conduct
- Compliance Officer & Compliance Committee
- Training and Education
- Effective Lines of Communication
- Enforcement of Standards
- Responding Promptly to Detected Offenses and Taking Corrective Action
- Auditing and Monitoring

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### Risk Areas

- Quality of Care
- Resident Rights
- Billing & Claims Submission
- Employee Screening
- Kickbacks, Inducements and Self-Referrals
- Cost Reporting
- HIPAA Privacy and Security
- Record Creation and Retention
- Anti-Supplementation
- Medicare Part D

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### Baseline Audit:

- Identify risk areas
- Identify strengths and weaknesses
- Seek input from all departments
- Always be on the lookout for “new” risks

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## Periodic Audits

- Quality of Care
- Resident Rights
- Billing & Cost Reporting
- Employee Screening
- Kickbacks, Inducements and Self-Referrals
- Submission of Accurate Claims
- HIPAA Privacy and Security
- Record Creation and Retention
- Anti-Supplementation
- Medicare Part D
- Additional risk areas identified in the baseline audit

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## Annual Review

- Annual Review of the overall effectiveness of the compliance program

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## Compliance Officer

- Develop a position description
- Essential duties
  - Oversee and monitor the implementation of a corporate compliance program
  - Help the organization, through policies and procedures, auditing, and training, minimize the risk of fraud and abuse

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## Compliance Officer

- Reports to the Compliance Committee
  - Directs facility audits
  - Collect data
  - Develop responsive action plans
- Manages compliance hotline reports
- Compliance training for the organization

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## Compliance Officer

- Manage employee, officer, contractor, and volunteer screening
- Oversee HIPAA compliance activity
- Participate in the Quality Assurance program
- Conduct annual compliance program review and update
- Ensure contractors are aware of your compliance program and resident rights

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## Compliance Officer

- A Compliance Officer can hold another position within the organization at the same time, i.e., staff development coordinator, quality assurance nurse
- Requires a dynamic person will have to interact with Board members, CNAs, housekeepers, department leaders, contractors, volunteers, and regulators

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## Compliance Programs

- Train and educate
  - Provide compliance training to all employees, officers, directors, owners upon hire and annually
  - Create a training schedule for each risk area

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## Compliance Programs

- Audit and Monitor
  - Develop audit tools for each risk area
  - Schedule audits throughout the year
  - Assign responsibility for audits
  - Develop a reporting mechanism for audit results

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## Compliance Programs

- Review annually
  - Acknowledge progress
  - Identify areas to further advance compliance

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**Compliance Programs**

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- Stay current
  - Monitor and incorporate updates into the Compliance Program
    - New regulations
    - OIG updates
    - Recent enforcement actions

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**Compliance Programs**

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Compliance Officer is the key to a successful program

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**Conduct Baseline Audits**

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- Identify areas of exposure
- Identify areas of strength
- Highlight weak areas and prioritize solutions
- Seek interdisciplinary participation

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Compliance

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Care Centered Patient Advocates

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Conclusion

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- Educate, Discuss and Prepare
- Define Medicare Medical Review
- Communicate to all Staff Medicare Skilled Care Criteria
- Conduct internal/external Mock Audits to educate staff
- Refine Interdisciplinary Management of Medicare Appeals

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Sources

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- Public Law 108-173, 117 STAT. 2066
- Public Law 109-432, 120 STAT. 2922
- [www.dcsrac.com/IssuesUnderReview.aspx](http://www.dcsrac.com/IssuesUnderReview.aspx)
- Program Integrity Manual
- John v Sebelius, No. 4:09-CV-00552 (E.D. Ark. 10/6/10)
- 42 C.F.R. Chap. 1136 (f)
- Richardson v. Perales, 402 U.S. 389 (1971)

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## Questions/Answers



- **Harmony Healthcare International**
- **(978) 887 - 8919**
- **[www.Harmony-Healthcare.com](http://www.Harmony-Healthcare.com)**
- **Connect with Us!**



**@KrisMastrangelo**  
**@Harmonyhlthcare**



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**Agenda**  
How to Get Team Members Engaged in Compliance

- 1 Introduction
- 2 WIFM
- 3 Tone at the Top
- 4 Communication
- 5 Employee Buy-In
- 6 Follow-Up
- 7 Summary / Q&A



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**How to Get Team Members Engaged in Compliance**

**Introduction**



- Introduction
- Jeffery Wiggins  
Vice President, Office of Audit & Compliance
- Joy Hardee  
Privacy Officer, Office of Audit & Compliance

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### WIIFM: What's In It For Me



- 1 EXISTING PROCESSES?
- 2 UNDERSTANDABLE
- 3 FEASIBLE
- 4 KIS – Keep It Simple
- 5 RELEVANT
- 6 ACCESSIBLE

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### TONE AT THE TOP



- Demonstrate commitment to compliance
- Proper reporting structure
  - Corp Compliance Officer ↔ CEO
- Dedicate adequate resources
- Support compliance efforts
  - Back up your Compliance Department
- Be Involved!!

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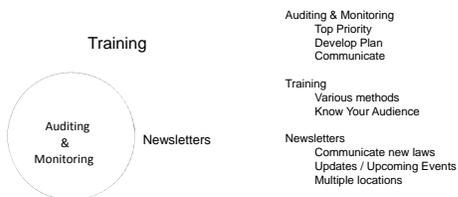
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### COMMUNICATION




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**Employee Buy-In**

- ✓ Create a positive image for your department
  - ✓ Non-threatening
  - ✓ Advisory role
- ✓ Maintain communication
  - ✓ Ask questions first
- ✓ Focus on teamwork
- ✓ Integrate compliance requirements into existing processes (where possible)
- ✓ Follow-up
  - ✓ Compliance
  - ✓ Questions / Issues
- ✓ Maintain "open door" policy
- ✓ **COMMUNICATION IS KEY!**

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**Follow-Up**



Send email      Schedule meeting      Document plan for corrective action

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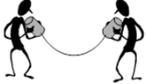
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**How to Get Team Members Engaged in Compliance**

Summary / Q&A



- Know your audience – make compliance relevant
- Top Management – demonstrate importance by supporting compliance initiatives and enforcement
- Utilize various methods of communication
- Teamwork
- Integrate compliance into existing processes
- "Open Door" policy
- **COMMUNICATION**




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**Narrowing Networks, Preferred  
Provider Relationships:  
How Do We Stay Compliant?**

**April 1, 2014**

Alan E. Schabes, Esq.  
Benesch, Friedlander, Coplan  
& Aronoff LLP  
Cleveland, OH  
aschabes@beneschlaw.com  
(216) 363-4589

Marsha Lambert, Consultant  
AccentCare Inc.  
Dallas, TX  
oceanmml@gmail.com  
(714) 904-4351

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**The Issue: Compliance in a New Market**

- The health care system rewards volume and creates fragmented care.
- There is a move toward models that incentivize quality, efficiency, and access.
- Coordinating care will be key ... but how do we do this and stay in compliance?

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**Potential Post-Acute Care Referral Sources**

- Hospitals
- Accountable Care Organizations (ACOs)
- Physician Groups
- Health Plans
- Preferred Provider Organizations (PPOs)

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**Potential Collaborative Arrangements**

- Discounted Fee-for-Service
- Waiver of Medicare Cost-Sharing Amounts
- Preferred Provider Agreement
- Exclusive Provider Agreement
- Risk/Gainsharing Arrangements
- Management Services Organization (MSO)
- Co-Management Arrangements
- Group Purchasing Arrangements
- Data Sales
- Joint Ventures
- Bundled Payment for Care Initiatives

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**Marketing Differentiators: How Can Entities Attract Collaborators?**

- Data that demonstrates high quality, efficiency, and customer satisfaction
- Technology to track metrics, increase efficiency, and coordinate care between providers
  - Communication between providers will be essential
  - EHRs are key
- Ability to care for higher acuity patients in a shorter period of time

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**Marketing Differentiators: How Can Entities Attract Collaborators?**

- Good reputation
- Willingness to take on financial risk
- Willingness to create joint clinical protocols
- Ability to provide Coordinated Care Nurses to coordinate care between providers and follow-up with patients, even after they go home
- Creativity/Diversity – Can the entity provide additional services?

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**Legal Considerations**

- Fraud and Abuse
  - Anti-Kickback Statute (AKS)
  - Stark Law
  - Gainsharing CMP or the Civil Monetary Penalty Law Prohibition on Payments to Reduce or Limit Care (42 U.S.C. § 1320a-7a(b))
  - Beneficiary Inducement CMP or the Civil Monetary Penalty Law Prohibition on Inducements to Beneficiaries (42 U.S.C. § 1320a-7a(a)(5))

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**Legal Considerations**

- Prohibitions Against Charging or Collecting More Than the Medicare Allowable Amount (42 U.S.C. § 1320a-7a(a)(2))
- Contracting Issues
- Anti-Trust Issues
- State Health Plan/Insurance Regulations

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**HOSPITALS**

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# FRAUD AND ABUSE

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**Discounted Fee-For-Service**

- AKS Safe Harbor
  - If buyer is required to submit cost reports:
    - Buyer must report discount on cost report
    - Seller must report discount and notify buyer of obligation to report discount
    - Offeror must inform buyer of obligation to report discount and not impede buyer from doing so
  - If buyer submits for payment on a per-charge basis:
    - Buyer may either make discount immediately or via a rebate
    - Seller must report discount or notify buyer of obligation to report discount

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**Discounted Fee-For-Service**

- Offeror must inform buyer of obligation to report discount and not impede buyer from doing so
- If buyer is an HMO or Competitive Medical Plan:
  - Buyer does not need to report the discount unless required under risk contract
  - Neither Seller nor offeror are required to report the discount

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**Discounted Fee-For-Service**

- **OIG Guidance on Swapping:**
  - Size of discount is not determinative of whether the arrangement involves illegal swapping.
  - Discounting goods or services below cost is an indicator of illegal swapping.
  - It is highly suspect when a vendor offers a higher discount to a customer that is in a position to refer business to the vendor than to a similarly situated customer that is not in a position to refer business.

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**Discounted Fee-For-Service**

- Discounts offered in conjunction with exclusive provider agreements are also highly suspect.
- Any other discount or pricing arrangement made (implicitly or explicitly) for referrals potentially creates an inference of a swapping arrangement.

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**Discounted Fee-For-Service**

- **Swapping**
  - Providing discounts on goods or services in exchange for referrals or other goods and services reimbursable by Medicare.
  - Swapping violates the AKS.
  - There should be no link, either direct or indirect or implicit or explicit, between discounts for goods or services a provider pays a vendor for and the provider's referral of business which the vendor can bill directly to Medicare or another federal health care program.

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**Waiver of Cost-Sharing Amounts**

- Generally implicates CMP for beneficiary inducement and AKS.
- AKS Safe Harbor
  - A waiver of a beneficiary's obligation to pay coinsurance or deductible amounts will not implicate the AKS in the following situation:
    - The provider is a hospital which receives Medicare payments for inpatient hospital services and:
      - The hospital does not shift the burden of the reduction;
      - The hospital offers the reduction or waiver without regard for the reason for admission or length of stay; and
      - The hospital's offer of the reduction or waiver is not made as part of a price reduction agreement.

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**Waiver of Cost-Sharing Amounts**

- CMP Exception
  - Waiver or reduction of cost-sharing amounts will not violate the CMP Law if:
    - The waiver is not offered as part of any advertisement or solicitation;
    - Waivers are not made routinely, but are assessed on individual determination of financial need; and
    - The determination of financial need is based solely on objective criteria.

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**Waiver of Cost-Sharing Amounts**

- OIG Advisory Opinions
  - Common themes of waivers that are treated favorably:
    - Unlikely to result in increased utilization or the need for additional services
    - Unlikely to affect providers' professional judgment
    - Unlikely to result in patient steering
    - Waiver presents minimal anti-competitive risks
    - Waiver is not routine but based on individually assessed financial need
    - Waiver is offered in a geographically underserved location
    - Waiver is offered to an "at-risk" population

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**Preferred Provider Agreements**

- Focus on coordinating care, increasing efficiency, improving the quality of care, and sharing data
- Fraud and Abuse Concerns:
  - Could raise kickback concerns
  - Avoid obligating parties to refer to one another
  - Avoid connecting payments or any form of financial incentive to the agreement
  - If there is no payment or incentive to refer, there is no kickback

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**Exclusive Provider Agreement**

- Same Fraud and Abuse concerns as Preferred Provider Agreements
- OIG Advisory Opinions
  - Common Themes:
    - An arrangement involving an exclusive provider agreement that also involves one provider billing and collecting payment for services performed by the other provider and paying the other provider less than the amount collected raises several concerns for the OIG
    - Providers engaging in these arrangements should be sure they fall into a safe harbor, such as the personal services and management contract safe harbor

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**Gainsharing Arrangements**

- OIG Special Advisory Bulletin
  - Gainsharing arrangements clearly violate the CMP prohibiting hospitals from directly or indirectly compensating physicians for reducing or limiting services to beneficiaries and may violate the AKS
- OIG Advisory Opinions
  - Common Themes
    - Overtime, OIG is becoming more comfortable with gainsharing arrangements

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**Gainsharing Arrangements**

- OIG concerns
  - Stinting on patient care
  - Cherry-picking
  - Patient steering
  - Disguised payment for referrals

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**Gainsharing Arrangements**

- Recommended safeguards for CMP
  - Transparency
  - Credible medical evidence should support each performance measure
  - Establish “floors” below which physicians cannot earn incentive
  - Calculate cost savings based on actual out-of-pocket cost
  - Amounts paid should be:
    - Calculated based on all procedures performed, regardless of payor

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**Gainsharing Arrangements**

- Subject to cap on payment for Federal healthcare program procedures
- Not disproportionately performed on Federal healthcare program beneficiaries
- Reasonable and limited in duration and amount
- Distributed to physician group as opposed to individual physicians
- All supplies/devices should available if needed for particular patient

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**Gainsharing Arrangements**

- Recommended safeguards for AKS
- Arrangements should include pools of 5 or more physicians
- The physicians should be on the hospital's active medical staff
- The physicians should receive per capita payment from the physician group
- There should be limits on the amounts the physicians can earn
- The targets/measures should be re-based if multi-year
- The agreement should be for a limited duration (1-3 years)
- Admissions should be monitored for changes

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**MSOs**

- Management Services Organizations (MSOs)
  - Examples: Administrative, Operational, Financial; Personnel; Education; Coding, Billing and Collection; IT; Compliance; Credentialing; Strategic Planning
- AKS Safe Harbor
  - Compensation paid to an agent by a principal for the services of the agent will not violate the AKS if the following conditions are met:
    - The Agreement is:
      - In writing;
      - Signed by the parties;

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**MSOs**

- For a term of not less than one (1) year; and
- Specific as to services, schedule, and compensation.
- The compensation is:
  - Set in advance;
  - Consistent with FMV in an arm's-length transaction; and
  - Not determined in a manner that takes into account the volume or value of referrals.
- The services do not involve the promotion of any illegal activity.
- The aggregate services are reasonably necessary to accomplish a commercially reasonable business purpose.

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**MSOs**

- Stark Exceptions
  - Personal Services Exception
    - Same requirements as AKS Safe Harbor
  - Fair Market Value Exception
    - Same requirements as AKS Safe Harbor, except:
      - The written agreement must specify the time frame for the arrangement, which can be for any period of time.

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**Co-Management Agreements**

- An agreement between hospital and provider who agrees to assist hospital in co-managing the clinical and operational activities of a hospital-based service line in exchange for a management fee, which typically includes a fixed payment amount, as well as some form of performance-based incentive fee
- Raises AKS and CMP concerns
- OIG has issued favorable Advisory Opinion

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**Co-Management Agreements**

- Recommended Safeguards
  - Base compensation on FMV for a specifically defined set of services.
  - Compensation (both fixed and performance based) does not vary by the number of patients treated or number of patient referrals.
  - Have physician group distribute compensation on pro rata basis.
  - Condition performance-based compensation upon the physician not: (1) stinting on care of patients; (2) increasing referrals; (3) cherry-picking healthy patients with desirable insurance; or (4) accelerating patient charges.
  - Include oversight by utilization review and performance improvement committees.

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**Co-Management Agreements**

- Do not limit or restrict physician's access to supplies or devices.
- Make performance based measures specific, objective, and, when possible, founded on national standards.
- Structure performance measures to incentivize improvement, not reward the status quo; establish a baseline and benchmarks or tiers for payment.
- Limit the duration and scope of the co-management incentive agreement.
- If appropriate or required, disclose incentive agreements to patients prior to the delivery of care.

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**Group Purchasing Arrangements**

- AKS Safe Harbor
  - Payments by a vendor of goods or services to a GPO that provides goods or services to individuals or entities (for which payment may be made in whole or in part under Medicare or a state health care program) as part of a group purchasing agreement will not violate the AKS if two conditions are met:
    - The GPO has a written agreement with each individual or entity that either: (1) states the vendor will pay the GPO a fee of 3% or less of the purchase price; or (2) specifies the amount the vendor will pay the GPO (either a fixed amount or a fixed percentage of the value of the goods or services)

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**Group Purchasing Arrangements**

- If the entity is a health care provider, the GPO must disclose in writing to the entity, at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity
- The individuals or entities contracting with the GPO may not be wholly owned by the GPO nor be subsidiaries of a parent corporation that wholly owns the GPO
- OIG Advisory Opinion
  - OIG has allowed arrangement where GPO and purchasers are wholly owned subsidiaries of the same parent if certain safeguards are in place

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**Data Sales Agreements**

- Similar to MSO arrangement
- Beware of HIPAA and State Privacy Laws
- AKS Safe Harbor for EHR Donation may be useful
  - Recently Amended
    - Extended to December 31, 2021
    - Provisions updated and clarified
    - Electronic prescribing component no longer required
    - Laboratory companies excluded

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**Joint Ventures**

- AKS Safe Harbor
  - 60/40 Investor and Revenue Rules
- OIG Special Advisory Bulletin
  - Common elements of "Questionable Contractual Arrangements":
    - A provider expands into a related line of business, which is dependent on referrals from the provider's existing business
    - The provider neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture

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**Joint Ventures**

- The provider contracts with an established provider of the same services as the new line of business to essentially run the new business
- The two providers share in the economic benefit of the new business
- The aggregate payment to the established provider varies with the value or volume of referrals generated to the new provider
- The parties may agree to a non-compete clause, barring the established provider from providing services in its own right to patients of the new provider

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**Bundled Payment**

- Bundled Payment for Care Improvement Initiative
  - Four Models
    - Model 1: Acute Care
    - Model 2: Hospitals, Physicians and Post-Acute Care
    - Model 3: Post-Acute Care
    - Model 4: Expansion of Acute Care Episode Demonstration

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**Bundled Payment**

- Issues/Concerns with Bundled Payment
  - Establishing adequate payment
  - Management and governance
  - Defining the Bundles
  - Establishing quality and efficiency measures
  - Designing the care model
  - Risk
    - Mitigating risk
    - Allocating risk
    - Allocating reward

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**CONTRACTING**

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**Contracting Issues**

- Contracts should support the three aims of healthcare reform:
  - Improve quality of care
  - Improve patient experience
  - Reduce costs of care
- Issues to be Addressed in Contracts:
  - Duties and Expectations of Parties
  - Duration of Agreement
  - Termination
  - Indemnification

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**Contracting Issues**

- Gainsharing
- Risk of Payment Methods
- Insurance
- Compliance
- Patient Choice
- HIPAA and State Privacy Laws
- Any Willing Provider Statutes
- Managed Care
- Dual Eligibility Programs

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**ANTI-TRUST**

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**Anti-Trust Issues**

- Receiving attention because of high cost of care
- Concern aligned providers will use collective bargaining power to negotiate higher reimbursement rates from private insurers and boycott insurers that refuse to pay higher rates
- Naked price fixing and market-allocation are per se illegal

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**Anti-Trust**

- OIG and FTC's Final Statement of Anti-Trust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program offers all aligning providers guidance
  - Anti-Trust review
  - Rule of Reason
  - Anti-Trust "Safety Zone"

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**Anti-Trust**

- Conduct to Avoid:
  - Sharing competitively sensitive information, such as pricing, discounting, future product offerings, operations, performance, and marketing plans
  - Restricting payors' ability to share cost, quality, efficiency, and performance information with enrollees
  - Tying sales of services to the private payor's purchase of other services from outside providers
  - Exclusive contracting
  - Preventing or discouraging private payors from directing or incentivizing patients to choose outside providers through "anti-steering" or "most-favored-nation" provisions

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# STATE REGULATORY ISSUES

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- ### State Regulatory Issues
- Licensing Issues
    - Does collaboration trigger any type of approval from respective licensing agency?
  - Corporate Practice of Medicine
    - Is there a CPOM statute that will dictate the legal structure?
  - State Health Insurance Laws
    - What qualifies as a state health insurer?
    - What is required of state health insurers?
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- ### State Regulatory Issues
- Third Party Administrator Statutes
    - Who is an administrator?
    - Is a certificate of authority required?
  - Utilization Review Laws
    - Is a license or registration required?
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# ACCOUNTABLE CARE ORGANIZATIONS

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**Accountable Care Organizations**

- Focus on accountability for patients, quality measures, cost efficiency, coordination of care, preventative care
- Similar to managed care arrangements but preserve patient choice
  - Arrangements with Post-Acute Care Providers
    - ACOs need to coordinate with PAC providers to reduce costs
    - Focus on coordinating care and preventative measures
    - PAC providers should seek out alignment early in ACOs development to be in the best bargaining position

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**Accountable Care Organizations**

- Types of ACOS
  - Medicare Shared Savings Program ACOs
    - If the ACOs reach certain quality measures, they share in a portion of Medicare's savings
  - Pioneer ACOs
    - For organizations who already have experience coordinating patient care among several types of providers
  - Advance Payment ACOs
    - Organizations that would like to create an ACO but do not have the necessary capital can receive up-front financial support in the form of an advance on their shared savings

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**Accountable Care Organizations**

- Fraud and Abuse Waivers
  - Waive AKS, Stark, and CMPs
- Types:
  - Pre-Participation Waiver
  - ACO Participation Waiver
  - Shared Savings Distribution Waiver
  - Compliance with Stark Law Waiver
  - Waiver for Patient Incentives

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**QUESTIONS?**

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DEFINE SUCCESS TOGETHER

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## HIPAA Requirements and Mobile Apps

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2014 HCCA Compliance Institute

Adam H. Greene, JD, MPH  
*Partner, Washington, DC*

Anchorage | Baltimore | Los Angeles | New York | Portland | San Francisco | Seattle | Shanghai | Washington, D.C.

www.dwt.com

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### Use of Smartphones and Tablets Is Growing

**INSERT BORING STATISTICS HERE.**

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### How Info Security Sees Smartphones



Easily Lost, Stolen, or Discarded with PHI on It

Camera for Improperly Recording PHI

No Physical Keyboard for complex passwords

Easy Access to Facebook for Improperly Posting PHI

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### How Info Security First Responds

1. Thou Shall Disable Thy Smartphone Camera
2. Thou Shall Not Text
3. Thou Shall Not Place PHI on Thy Smartphone or Tablet

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### How Clinicians and Other Staff Respond



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### Instead ... Design an Effective Mobile App Strategy

1. Identify mobile app needs
2. Integrate into risk analysis
3. Design risk management strategy
4. Obtain business associate agreement if necessary and perform due diligence
5. Document Security Rule compliance
6. For patient/enrollee-facing apps, comply with Privacy Rule

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|   | <b>Identify Mobile App Needs</b>  |
| <p>1. Instead of ... <i>Thou Shall Disable Thy Smartphone Camera</i></p> <ul style="list-style-type: none"> <li>▪ Is there appropriate use of smartphone cameras for certain procedures?</li> <li>▪ Is there an appropriate way to securely share pictures and add them to the record?</li> </ul> |   |
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|   | <b>Identify Mobile App Needs</b>  |
| <p>2. Instead of ... <i>Thou Shall Not Text</i></p> <ul style="list-style-type: none"> <li>▪ Why are members of the workforce texting?</li> <li>▪ Is e-mail effective?</li> <li>▪ Is a no-texting policy effective, or is secure texting needed?</li> </ul> |   |
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|   | <b>Identify Mobile App Needs</b>  |
| <p>3. Instead of ... <i>Thou Shall Not Place PHI on Thy Smartphone or Tablet</i></p> <ul style="list-style-type: none"> <li>▪ Why is PHI ending up on smartphones?</li> <li>▪ Is remote access to PHI sufficient?</li> <li>▪ Is a secure vault for PHI needed?</li> </ul> |   |
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|   | <b>Identify Mobile App Needs</b>  |
| <p>Don't forget about patient smartphones. Consider patient apps to:</p> <ul style="list-style-type: none"> <li>▪ Facilitate access to EHR portal (MU Stage 2)</li> <li>▪ Ability to accept patient health information (e.g., iBlueButton)</li> <li>▪ Improved treatment communications and adherence</li> <li>▪ Appointment reminders</li> </ul> |   |
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|   | <b>Consider Mobile App Solutions</b>  |
| <ul style="list-style-type: none"> <li>▪ Mobile patient diagnostic tools</li> <li>▪ Secure access to e-mail</li> <li>▪ Mobile EHR portal</li> <li>▪ Secure texting</li> <li>▪ Secure container for PHI</li> <li>▪ Secure access to Blue Button data</li> <li>▪ Remote wipe and antivirus</li> </ul> |   |
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|  | <b>Include Mobile Apps in Risk Analysis</b>   |
| <p><b>Identify where PHI is located on mobile devices</b></p> <p><b>C</b> - What apps Create PHI (e.g., diagnostic apps)</p> <p><b>R</b> - What apps Receive PHI (e.g., EHR portal, e-mail, iBlueButton)</p> <p><b>M</b> - What apps Maintain PHI (e.g., e-mail, secure container)</p> <p><b>T</b> - What apps Transmit PHI (e.g., secure texting)</p> |   |
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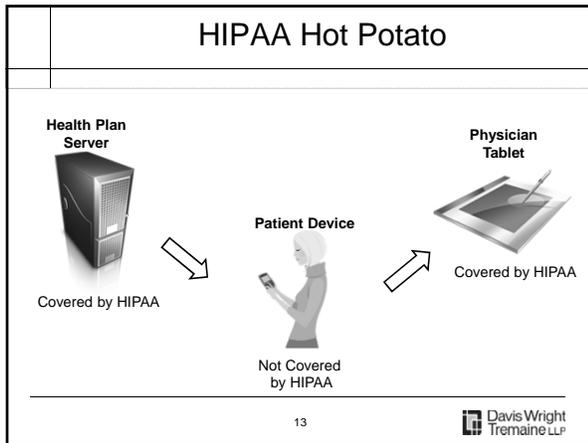
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### Include Mobile Apps in Risk Analysis

**Identify threats and vulnerabilities**

- What if mobile device is lost, stolen, or replaced?
- What if mobile device is shared?
- Can malware on device lead to unauthorized access?
- Can transmissions be intercepted by unauthorized third party?
- Is PHI on device reasonably available?

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### Include Mobile Apps in Risk Analysis

**Identify current security controls?**

- Is information encrypted while maintained?
- Is information encrypted in transit?
- What authentication of app users is in place?
- Is PHI on mobile devices backed up?
- Can PHI be remotely wiped?

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|   | <b>Include Mobile Apps in Risk Analysis</b> |
| <p>Identify likelihood, impact, and aggregate risk</p> <ul style="list-style-type: none"> <li>▪ What is the likelihood of a threat exploiting a vulnerability?</li> <li>▪ What is the impact if exploited?</li> <li>▪ Likelihood x Impact = Risk</li> </ul> |   |
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|  | <b>Implement Risk Management Strategy</b> |
| <ul style="list-style-type: none"> <li>▪ What risks are medium and high?</li> <li>▪ Can risks be lowered to reasonable amounts through: <ul style="list-style-type: none"> <li>▪ Policies</li> <li>▪ Training</li> <li>▪ Additional technical controls (e.g., locking down the device or adding remote wipe features)</li> </ul> </li> </ul> |   |
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|   | <b>Obtain Necessary BAAs &amp; Due Diligence</b> |
| <ul style="list-style-type: none"> <li>▪ Does the app developer create, receive, maintain, or transmit PHI on covered entity's behalf? <ul style="list-style-type: none"> <li>▪ If PHI is encrypted and app developer does not have the key, HIPAA is unclear as to whether BAA is needed</li> </ul> </li> <li>▪ Due diligence - What is app developer's security?</li> <li>▪ Obtain compliant BAA with app developer as necessary (watch out for data mining)</li> </ul> |  |
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|  | <b>Document Security Rule Compliance</b>   |
|  | <ul style="list-style-type: none"> <li>✓ Included in risk analysis</li> <li>✓ Included in risk management</li> <li>✓ Sanctions for violations of policy</li> <li>✓ Reasonably review system activity <ul style="list-style-type: none"> <li>▪ If activity cannot be centrally reviewed, document whether this is reasonable</li> </ul> </li> <li>✓ Authorization, supervision, and clearance <ul style="list-style-type: none"> <li>▪ Who needs access to PHI on mobile devices</li> </ul> </li> </ul> |
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|  | <b>Document Security Rule Compliance</b>  |
|  | <ul style="list-style-type: none"> <li>✓ Termination procedures <ul style="list-style-type: none"> <li>▪ Is PHI on mobile devices secured and access through apps terminated at employment termination</li> </ul> </li> <li>✓ Include mobile apps in security awareness and training</li> <li>✓ Address potential malware on mobile device</li> <li>✓ Address mobile app passwords</li> </ul> |
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|  | <b>Document Security Rule Compliance</b>  |
|  | <ul style="list-style-type: none"> <li>✓ Identify and respond to mobile app security incidents</li> <li>✓ Ensure that PHI in mobile apps is reasonably backed up</li> <li>✓ Integrate mobile apps into contingency planning</li> <li>✓ Evaluate mobile app program</li> </ul> |
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|   | <b>Document Security Rule Compliance</b> |
| <ul style="list-style-type: none"> <li>✓ Address physical security of mobile devices</li> <li>✓ Address which mobile devices need to be inventoried</li> <li>✓ Ensure proper disposal/re-use of mobile devices with apps containing PHI</li> <li>✓ Address whether mobile devices need to be backed up</li> </ul> |  |
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|  | <b>Document Security Rule Compliance</b> |
| <ul style="list-style-type: none"> <li>✓ Address automatic logoff of mobile apps</li> <li>✓ Address encryption of data maintained by apps on device</li> <li>✓ Address encryption of data transmitted by mobile app <ul style="list-style-type: none"> <li>▪ Document basis for transmission of some PHI without encryption</li> </ul> </li> </ul> |  |
| <hr/> <small>23</small>   |  |

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|   | <b>Document Security Rule Compliance</b> |
| <p><b>PRIVACY RULE<br/>AND MOBILE APPS</b></p>  |  |
| <hr/> <small>24</small>  |  |

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|  |   |
|--|---|
|  | <b>Sale of PHI</b>  |
| <b>"There ain't no such thing as a free lunch"</b>   |   |
| <ul style="list-style-type: none"> <li>▪ Is app offered for free?</li> <li>▪ If so, is app developer creating de-identified PHI?</li> <li>▪ May raise issue of remuneration (free app) in exchange for PHI (necessary to create de-identified health information)</li> </ul> |   |
| 25   |  |

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|  | <b>The Wild Card</b>  |
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|  | <b>Right of Access</b>  |
| <ul style="list-style-type: none"> <li>▪ Patient may access copy of designated record set in requested form and format, if readily producible</li> <li>▪ Mobile app to portal may be convenient means of providing access (and support MU Stage 2 objectives)</li> <li>▪ <u>But</u>, patient may prefer unencrypted e-mails (permissible after warning of risk)</li> </ul> |   |
| 27   |  |

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|  | <b>Right to Confidential Communications</b> |
| <ul style="list-style-type: none"> <li>▪ Must accommodate reasonable requests for communications to patient by alternative means or at alternative location             <ul style="list-style-type: none"> <li>▪ Some patients may prefer communications through unencrypted e-mails</li> <li>▪ Other patients may not want unencrypted appointment reminders</li> </ul> </li> </ul> |   |
| <hr/> <div style="display: flex; justify-content: space-between;"> <span>28</span>  </div>  |   |

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|   |  |
| <p><b>Don't Let Security Trump Patient Preference</b><br/>         (No matter how much you paid for that secure mobile app)</p>   |  |
| <hr/> <div style="display: flex; justify-content: space-between;"> <span>29</span>  </div> |  |

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|  |                                |
|--|--------------------------------|
|  | <b>For more information...</b> |
| <div style="display: flex; align-items: center; justify-content: center;">  <div style="text-align: left;"> <p><b>Adam H. Greene, JD, MPH</b><br/>  <b>Davis Wright Tremaine LLP</b><br/> <a href="mailto:adamgreene@dwt.com">adamgreene@dwt.com</a><br/>           202.973.4213</p> </div> </div> |                                |
| <hr/> <div style="display: flex; justify-content: space-between;"> <span>30</span>  </div>  |                                |

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**Beyond Benchmarking**  
Integrating Audit Analytics into Day-to-Day Compliance Operations

Jared Krawczyk – Mathematician  
REVEAL/md

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**Session Roadmap**

1. My Background
2. 3 Purposes of Benchmarking
3. Benchmarking Challenges
4. How to Begin Benchmarking in Your Organization
5. Building Documentation Review Plans Around Benchmarking

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**My Background**

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3 Purposes of  
Benchmarking

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Reduce Your Workload

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Allow You to Plan and  
Allocate Resources

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**Create Transparency  
Throughout Health System**

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**Benchmarking Challenges**

Restricted FTE and Tech Resources

Data Issues

Understanding of Analysis

Fear

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**How to Get Started**

Determine Analysis Areas

Understand Comparative Data Needed

Determine How to Calculate Analysis

Prioritize and Organize Results

Create Documentation Review Plan

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### Determine Analysis Areas

#### Common Sources for Areas

- OIG Work plan
- OIG Audit Reports
- Past Audit Requests
- Internal Knowledge / Sources
- CMS Resources
- News Sources
- Information from Educational Events
- Word on the Street

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### Common Analysis Areas

These are a few common areas that every compliance department should be focusing on with benchmarking.

#### Evaluation and Management

- Audit Risk
- Revenue Potential
- Cross-Category Behavioral Trends

#### Procedures

- Surgical and Imaging
- Drugs and Injections
- High Dollar Services

#### Modifiers

- Mod 24
- Mod 25
- Mod 59

#### Others

- CMS CERT Study
- OIG Time Study
- OIG Identified Services in Reports

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### Understanding Comparative Data

#### You need to Determine

1. The Goal of Analysis
2. Bias to Take into Account

#### Common Bias

- Volume of Data (Total / Specialty / Locality)
- Sub-Specialty Data
- Payer Mix
- Type of Health Systems

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# Comparative Data Examples

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## Mismatching Goals and Bias

**Goal: Determine Audit Risk from Government Payers**  
Comparing data from a University Exclusive Database to the CMS Database.

| New Office |  | UHC    | CMS    | CMS Diff |
|------------|--|--------|--------|----------|
| 99201      |  | 4.02%  | 1.87%  | -2.15%   |
| 99202      |  | 13.75% | 8.58%  | -5.17%   |
| 99203      |  | 44.43% | 37.60% | -6.83%   |
| 99204      |  | 29.41% | 37.64% | 8.23%    |
| 99205      |  | 8.39%  | 14.31% | 5.92%    |
| Est Office |  | UHC    | CMS    | CMS Diff |
| 99211      |  | 2.07%  | 1.53%  | -0.54%   |
| 99212      |  | 25.47% | 21.17% | -4.30%   |
| 99213      |  | 49.13% | 48.78% | -0.35%   |
| 99214      |  | 19.19% | 23.48% | 4.29%    |
| 99215      |  | 4.15%  | 5.03%  | 0.88%    |

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## Aligning Goals and Bias

**Goal: Determine Audit Risk from Government Payers**  
Comparing Data from a CMS CBR and Data from REVEAL/md (created out of a CMS Database)

CMS CBR Utilization of 99214 = 42.27%      REVEAL/md Utilization of 99214 = 42.49%

**Figure 3. Percentage of Each High Level E/M CPT Code (99204, 99205, 99214, and 99215) Among the Seven E/M Code Grouping Rendered by You and the Average Percentage of the Primary Care Specialty Peer Group, 2011**

| CPT   | # National | % Natl | # Est 11 - Sep 12 | % Est  | Variance |
|-------|------------|--------|-------------------|--------|----------|
| 99211 | 831        | 19.39% | 347               | 8.1%   | -11.29%  |
| 99212 | 14         | 0.33%  | 21                | 5.02%  | 4.69%    |
| 99213 | 527        | 12.30% | 72                | 1.72%  | -10.58%  |
| 99214 | 2913       | 67.37% | 5937              | 14.17% | -53.20%  |
| 99215 | 1          | 0.02%  | 1                 | 0.02%  | 0.00%    |

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## Determine how to calculate metrics

For the purpose of this session we will focus of E/M benchmarking.

### Two Step Approach

1. Intra-Category Analysis
2. Single High Risk Service Utilization Analysis

### Start with Intra-Category

- Goal is to get results down to a single metric that can be sorted and prioritized. *The 30,000 ft view.*
- Three important metrics will be calculated:
  - Distribution Variance
  - Risk Metric
  - Adjusted Charge Differential

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## Distribution Variance

Goal: Quantify over/under utilization potential per provider with a single objective differential

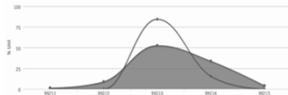
### Analytical Technique

Utilize the RBRVS database to calculate a weighted RVU average per provider per E/M category.

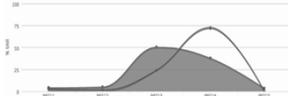
### Assumptions

- As the RVU value per E/M service increases, so does the complexity of the service
- The higher the RVU value within a category – the distribution shifts towards higher utilized services

Weighted Average RVU = 2.56



Weighted Average RVU = 2.89




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## Distribution Variance

How to calculate the E/M category weighted average RVU for a provider

### Step 1

| CPT   | RVUwrk | Provider Count | Total RVU |
|-------|--------|----------------|-----------|
| 99201 | 0.48   | 15             | 7.2       |
| 99202 | 0.93   | 46             | 42.78     |
| 99203 | 1.42   | 168            | 238.56    |
| 99204 | 2.43   | 224            | 544.32    |
| 99205 | 3.17   | 25             | 79.25     |
|       |        | 478            | 912.11    |

### Step 2

Provider Weighted Avg RVUwrk =  $912.11 / 478$

Provider Weighted Avg RVUwrk = 1.908

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## Distribution Variance

How to calculate the E/M category Distribution Variance

Step 1  
**Distribution Variance = Provider Avg RVU / Peer Group Avg RVU**  
**Distribution Variance = 1.908 / 1.801**  
**Distribution Variance = 1.059**

Step 2  
**Distribution Variance = 1.059 - 1**  
**Distribution Variance = 0.059**

Step 3  
**Distribution Variance = 0.059 \* 100**  
**Distribution Variance = 5.9%**

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## Distribution Variance

The End Result

| Specialty | Provider Name | Provider ID | Variance New Office | Variance Est. Office |
|-----------|---------------|-------------|---------------------|----------------------|
|           | Provider_3    | 3           | 28.60%              | 18.9                 |
|           | Provider_4    | 4           | 38.42%              | 18.9                 |
|           | Provider_1    | 1           | -0.09%              | 1.0                  |
|           | Provider_2    | 2           | 26.39%              | -38.9                |
|           | Provider_5    | 5           | -2.89%              | -14.9                |
|           | Provider_7    | 7           | 18.62%              | -3.0                 |
|           | Provider_9    | 9           | -4.77%              | -26.0                |
|           | Provider_10   | 10          | 9.01%               | 18.7                 |
|           | Provider_8    | 8           | -35.16%             | -48.2                |
|           | Provider_6    | 6           | 53.46%              | 16.0                 |

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## E/M Category Risk Metric

Audit Risk is More than Just Being a Utilization Outlier

Assumptions about Auditors

They want to recoup the maximum amount of money in the most efficient manner.

Two Influencers for Audit Risk

- Utilization Outlier
- Volume of Performed Services

How to calculate the E/M category Risk Metric

**Risk Metric = E/M Category Distribution Variance \* E/M Category Volume**  
**Risk Metric = 0.059 \* 478**  
**Risk Metric = 28.202**

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### E/M Category Risk

The End Result

| Specialty Code | Provider Name | Provider ID | New Office | Est. Office |
|----------------|---------------|-------------|------------|-------------|
| GS             | Provider_3    | 3           | 112.11     | 18.22       |
| GS             | Provider_4    | 4           | 44.57      | 82.91       |
| GE             | Provider_1    | 1           | -          | 5.31        |
| GE             | Provider_2    | 2           | 1.58       | -           |
| IM             | Provider_5    | 5           | -          | -           |
| IM             | Provider_7    | 7           | 27.00      | -           |
| PM             | Provider_9    | 9           | -          | -           |
| PM             | Provider_10   | 10          | 1.62       | 117.06      |
| NP             | Provider_8    | 8           | -          | -           |
| PN             | Provider_6    | 6           | 62.01      | 252.69      |

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### E/M Category Risk

Comparing Distribution Variance to the Risk Metric

Distribution Variance

| Provider Name | Provider ID | Variance New Office |
|---------------|-------------|---------------------|
| Provider_3    | 3           | 28.60%              |
| Provider_4    | 4           | 38.42%              |
| Provider_1    | 1           | -0.09%              |
| Provider_2    | 2           | 26.39%              |
| Provider_5    | 5           | -2.89%              |
| Provider_7    | 7           | 18.62%              |
| Provider_9    | 9           | -4.77%              |
| Provider_10   | 10          | 9.01%               |
| Provider_8    | 8           | 35.16%              |

Risk Metric

| Provider Name | Provider ID | New Office |
|---------------|-------------|------------|
| Provider_3    | 3           | 112.11     |
| Provider_4    | 4           | 44.57      |
| Provider_1    | 1           | -          |
| Provider_2    | 2           | 1.58       |
| Provider_5    | 5           | -          |
| Provider_7    | 7           | 27.00      |
| Provider_9    | 9           | -          |
| Provider_10   | 10          | 1.62       |
| Provider_8    | 8           | -          |

When looking only at the Distribution Variance – Provider 4 seems to present the biggest risk for audit.

When volume performed is included with the Risk Metric – Provider 3 is actually where compliance efforts should be focused.

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### Adjusted Charge Differential

Goal: Quantify the potential dollar amount impact from over / under utilization of E/M billing

Analytical Technique

Calculate the difference between a providers actual E/M category charges and hypothetical charges based on redistributing the providers E/M billing within a category to match the peer group.

What does this mean?

If a provider billed exactly like the peer group, what would the difference in their charge amounts be.

Word of Warning

These dollar amounts are ENTIRELY hypothetical and should be only used as a method of prioritizing providers for review. These are not actual overpayment amounts.

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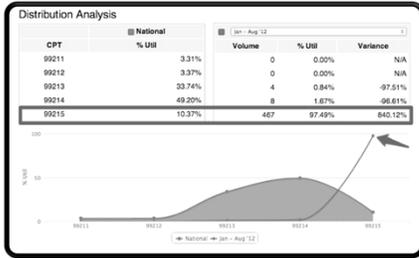
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## Identified Provider

Audit Risk




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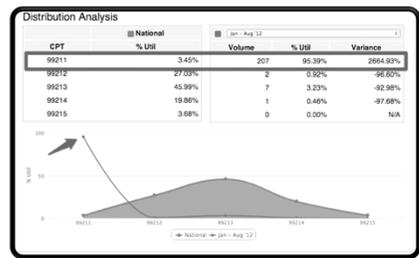
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## Identified Provider

Revenue Potential




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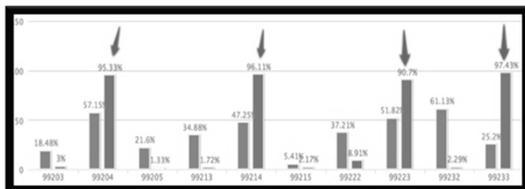
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## Single High Risk Service

Goal: To determine if a provider exhibits similar coding behavior across numerous E/M categories

Analytical Technique

Compare the utilization of high level E/M services across all categories to determine if trends exist.




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## Create Documentation Review Plan

### Three Basic Plans Needed

1. Cycle Audits
2. Early Warning Audits
3. Due Diligence Audits

### What will be accomplished:

- Methodically reduce audit risk currently within health system
- Proactively identify and review signs of audit risk prior to it compounding over time
- Prevent practice acquisition from increasing entire health systems risk profile

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## Cycle Audits

Goal: To efficiently reduce the Health Systems audit profile by reviewing the exact services that would be targeted by audit entities.

### Old Way

Review 10 charts in random for every provider. This process is conducted every 12, 18, or 24 months.

### New Way

Prioritize providers based on risk exposure metric and review only areas that are causing the exposure .

### Benefits

- Instantly making the greatest impact with your documentation reviews because you are directly targeting high risk areas
- Allows for strategic planning (resource management) and monitoring based on statistical evidence.
- Possibly reduce cost by only reviewing providers that are at audit risk. Typically every health system has between 15%-30% of their providers at audit risk.

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## Cycle Audits

### The Process

#### Step 1

| Audit Genius | Gross Charges  | Over/Under   |             |
|--------------|----------------|--------------|-------------|
| Audit Risk   | \$1,407.12     | \$91,407.12  |             |
| Audit Risk   | \$352,392.00   | \$90,203.88  |             |
| Audit Risk   | \$716,760.00   | \$62,973.96  |             |
| Audit Risk   | \$431,616.00   | \$50,820.72  |             |
| Audit Risk   | \$334,932.00   | \$46,005.24  |             |
| General      | Audit Risk     | \$751,764.00 | \$40,020.60 |
| General      | Audit Risk     | \$661,080.00 | \$39,504.00 |
| General      | Audit Risk     | \$431,484.00 | \$38,529.60 |
| General      | Audit Risk     | \$216,024.00 | \$36,483.00 |
| General      | Audit Risk     | \$331,032.00 | \$32,108.16 |
| General      | Audit Risk     | \$626,208.00 | \$30,807.12 |
| General      | Revenue Potent | \$855,744.00 | \$25,342.68 |
| General      | Audit Risk     | \$249,556.00 | \$25,316.76 |
| General      | Audit Risk     | \$277,224.00 | \$23,421.48 |
| General      | Audit Risk     | \$737,556.00 | \$19,774.08 |
| General      | Audit Risk     | \$58,752.00  | \$12,063.84 |

#### Step 2



#### Step 3

The provider that has been identified as having the greatest hypothetical over charges and only is an outlier for 99215. Five 99215's will be reviewed by the staff.

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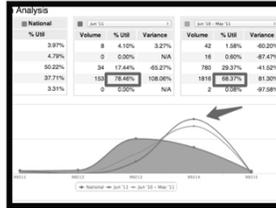
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# Cycle Audits

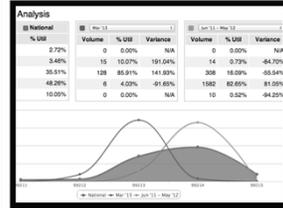
After the Review and Education Process

Incorporating benchmarking following the initial risk identification, documentation review, and provider education processes will allow you to instantly determine if the provider is coding differently. This is a cost savings alternative to completely reviewing the provider again.

Example 1



Example 2




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# Early Warning & Due Diligence Plans

Goal: Proactively identify and remediate potential audit risk concerns prior to them compounding and/or entering your health system.

### Early Warning Identified Audit Concerns

Conduct the benchmarking analysis on a month-to-month basis. This will allow to identify potential problems immediately instead of letting them compound over a significant period of time.

### Due Diligence

Conduct the benchmarking analysis on prospective physicians that the health system is considering purchasing. This will allow you to identify and make leadership aware of any potential risk concerns that would accompany the acquisition of those physicians.

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# Transparency Throughout Health System

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## Thank You

Feel free to contact me with any questions.

Jared Krawczyk

[jkrawczyk@fimed.com](mailto:jkrawczyk@fimed.com)

(414) 727-7144

**Screen Shots and Data Examples from:**  
[www.revealmd.com](http://www.revealmd.com)

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**Health Care Compliance Association's  
18<sup>th</sup> Annual Compliance Institute**

**Medicare Enrollment Application,  
Revocation and Appeals**

March 30 – April 2, 2014  
San Diego, CA

Anne Novick Branan, Esq.  
Attorney  
Broad and Cassel  
abranan@broadandcassel.com

William ("Ted") Cuppett  
Managing Member  
The Health Group LLC  
ted.cuppett@healthgroup.com

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**Objectives**

- ❖ Learn tips to ensure enrollment success and avoid enrollment deficiencies that can result in denial or revocation of billing privileges
- ❖ Discuss how proposed regulations expanding Medicare's authority to deny enrollment and revoke Medicare participation will affect your company
- ❖ Understand appeal rights for enrollment denials and revocations of Medicare privileges.

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**Enrollment Basics**

- ❖ Submit appropriate version of CMS Form 855 – Provider/Supplier Enrollment Application to Medicare Administrative Contractor ("MAC") or National Supplier Clearinghouse for DMEPOS Suppliers
  - 42 C.F.R. 424.510
- ❖ Must include complete, accurate and truthful information and all supporting documentation
- ❖ Signed certification statement by person with authority to bind the enrollee
- ❖ Pay fee when required or get hardship exception

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**Enrollment Basics: The CMS 855 Form**

- ❖ Use Correct CMS Form 855
  - CMS 855A – For institutional providers (i.e. HHA, hospitals, SNF, Rural Health Clinics)
  - CMS 855B – For clinics/group practices, IDTFs, ASCs, and other entities (non-individuals billing under Part B), not DMEPOS suppliers CMS 855I – For individuals (physicians, NPPs) billing under Part B
  - CMS 855O – For registration of ordering/referring physicians and NPPs.
  - CMS 855R Reassigning benefits under Part B
  - CMS 855S For DMEPOS suppliers

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**Enrollment (Cont'd.)**

- ❖ Things to know about the 855 forms:
  - Each particular version of 855 has instructions and definitions, some of which are peculiar to that version
  - Instructions are not always instructive regarding item reported
  - The forms are forms and do not fit all situations (particularly complex CHOWs) well.

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**Enrollment Basics (Cont'd.)**

- ❖ Things to know about the 855 forms:
  - They can be downloaded from CMS's website
- ❖ CMS changes the forms from time to time:
  - If you do not use the right version, your enrollment will be delayed! Important because enrollment is effective beginning on the date that the MAC receives an 855 that can be processed to conclusion, and generally suppliers (and to a lesser extent providers) are not allowed to bill for services furnished before the enrollment date.

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**Enrollment Basics (Cont'd.)**

- ❖ Update changes to information on CMS Form 855 within required time frames
  - 42 C.F.R 424.516(e) and 42 C.F.R. 424.540(a)(2)
- ❖ Update CHOWs, location, adverse legal actions (i.e. loss of license or certification) within 30 days
- ❖ All other changes within 90 days (non-CHOW ownership changes like stock transfers, change in billing services, managing employees)

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**Enrollment Basics (Cont'd.)**

- ❖ Complete accreditation, survey or on-site review requirements for provider type
  - 424 C.F.R 510(d) (5) and (8)
- ❖ On-site review is for purpose of verifying enrollment information is accurate and determining compliance with Medicare enrollment requirements.  
These onsite reviews do "not affect those site visits performed for establishing compliance with COPs."
  - 424 C.F.R 510(d) (8)

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**Enrollment Basics (Cont'd.)**

- ❖ MAC is required to screen all initial applications (including new location and revalidation request responses) based on CMS assessment of risk levels.
  - 42 C.F.R. 424.518
- ❖ Levels are "limited," "moderate," or "high."

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**Enrollment Basics (Cont'd.)**

- ❖ Examples of "limited"— physicians, ASCs, end-stage renal disease centers, hospitals, SNFs, pharmacies
  - Verification of licenses & post-enrollment verifications
- ❖ Examples of "moderate"— Ambulances, CMHCs, Hospices, IDTFs, physical therapists, revalidating HHAs and DMEPOS
  - Includes on-site review
- ❖ Examples of "high"—only newly enrolling HHA and DMEPOS in this category
  - Includes fingerprinting/criminal history check

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**Enrollment Basics (Cont'd.)**

- ❖ PPACA (Section 6401) requires CMS to implement requirements that providers and suppliers establish compliance programs as a condition of enrollment
  - Regulations not yet published
- ❖ Also 6102 of PPACA makes compliance programs mandatory for enrollment of nursing home providers (NF and SNF)
- ❖ Effective March 23, 2013

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**PECOS**

What is PECOS?

- ❖ Provider Enrollment Chain and Ownership System
- ❖ It is a secure Web site that providers and suppliers can access to submit an application to enroll or change information
- ❖ PECOS can be access at:  
<https://pecos.cms.hhs.gov/pecos/login.do>.

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**Results After Filing 855**

- ❖ Follow-up Communication
- ❖ Rejection of Application
- ❖ Denial of Enrollment
- ❖ Revocation of Associated Providers
- ❖ Acceptance and Enrollment

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**Results After Filing 855 (Cont'd.)**

- ❖ Rejection of Application
  - Reasons
    - Incomplete form
    - Failure to submit requested information within 30 days
    - Failure to pay application fee
  - No appeal rights for rejection of form.
  - Must resubmit new 855
  - 42 C.F.R. 424.525

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**Results After Filing 855 (Cont'd.)**

- ❖ Denial of Enrollment
  - ❖ 42 C.F.R. 424.530
  - Many reasons, including:
    - Non-compliance with enrollment requirements
    - False/misleading information on CMS 855
    - Current owner, physician or non-physician practitioner has an existing overpayment
    - Provider (or owner, managing employee, medical director, supervising physician, authorized/delegated official) conduct—excluded, debarred or suspended from federal programs.

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**Denial of Enrollment (Cont'd.)**

**Reasons:**

- Felonies (within 10 years) by provider or any owner (crimes against persons like rape, murder and financial crimes like tax fraud, embezzlement etc.)
  - CMS determines if conduct is "detrimental to best interests of program"
- Current owner, physician or non-physician practitioner on Medicare payment suspension
- Fails on-site review (not operational)
- HHA fails to maintain required initial reserve operating funds

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**Results After Filing 855 (Cont'd.)**

**Denial of Enrollment for Overpayment**

- ❖ CMS Transmittal 479 (August 1, 2013) CR 8039
  - revised Program Integrity Manual, Ch. 15 regarding denial of an 855 when an existing or delinquent overpayment exists
  - MAC required to get CMS approval first
- ❖ October 17, 2013 MLN Matters Article MM8039 "Enrollment Denials When Overpayment Exists"
  - clarified several points with examples of overpayments that would result in denial

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**Results After Filing 855 (Cont'd.)**

- ❖ Revocation of Associated Provider

Denial or Enrollment can result in adverse action (e.g. revocation) of associated providers (i.e. providers with same manager, owners or authorized officials)

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**Results After Filing 855 (Cont'd.)**

- ❖ Acceptance
- ❖ Will receive letter from MAC with date of effective enrollment and additional forms, including provider agreement, to sign

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**Revocation of Enrollment and Billing Privileges**

- ❖ When enrolled provider fails to comply with condition of continued enrollment  
42 CFR 424.535
- ❖ Many reasons, including many of the reasons for denial, plus:
  - Misuse of billing number (sells, allows another to use)
  - Abuse of billing privileges (beneficiary is deceased, out of country)
  - Failure to report information (i.e. CHOW, changes in location)
  - Medicaid termination by State (exhaust appeals first).

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**Revocation of Enrollment and Billing Privileges (Cont'd.)**

- ❖ CMS will also terminate Medicare provider agreement if revokes enrollment.

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**Deactivation of Medicare Billing Privileges**

- 42 C.F.R. 424.540
- ❖ Deactivation means provider's billing privileges were stopped, but can be restored upon the submission of updated information 42 C.F.R. 424.502
- ❖ No effect on provider's participation agreement/can reactivate in most cases
- ❖ Reasons
  - Fails to submit claims for 12 consecutive months
  - Fails to report changes to enrollment information
  - HHA 36-month rule related to CHOWs.

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**Proposed Enrollment Regulations**

- ❖ 78 Fed. Reg. 25013 (April 29, 2013)
- ❖ Dramatically expands CMS authority to deny enrollment and revoke Medicare provider numbers (PTANs) and billing privileges
- ❖ Gives CMS much discretion
- ❖ As of February 2014, rules are still in rulemaking stage; comments were due on June 28, 2013
- ❖ Many proposed changes

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**Proposed Enrollment Regulations**  
(Cont'd.)

- ❖ **Two of the onerous proposals:**
- ❖ Denial of enrollment if the enrolling provider, supplier or owner has an existing overpayment (current rules do not apply to all providers and suppliers)
  - ❖ Must repay in full or have repayment plan
- ❖ Revocation of Medicare enrollment and billing privileges when the provider or supplier has "abused" its Medicare billing privileges

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**Proposed Enrollment Regulations**  
(Cont'd.)

- ❖ **Revocation for "abuse" of its Medicare billing privileges**
  - Current rule is limited (i.e. deceased beneficiary, out of country)
  - For a "pattern or practice" of submitting claims for services that fail to meet the Medicare requirements

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**Proposed Enrollment Regulations**  
(Cont'd.)

- ❖ **Revocation for "abuse" of its Medicare billing privileges**
  - ❖ Preamble says "a common scenario warranting such revocation would be when a provider or supplier is placed on pre-payment review and a significant number of claims are denied for failing to meet the medical necessity requirements (78 Fed Reg. at pg. 25022)
  - ❖ CMS will use discretion to revoke privileges, including factors such as the reasons for the claims denial , % of denials and length of time over which the pattern has continued.

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**Appeals of Enrollment Actions**

- ❖ Covered by 42 CFR Part 498 but also see 42 CFR Part 405 Subpart H
- ❖ Triggered by an unfavorable "initial determination" related to enrollment
  - ❖ 42 CFR §498.3(h)

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**Denial or Revocation of Enrollment:  
The Appeals Process**

❖ **Four steps:**

- Reconsideration before the MAC
  - Also Corrective Action Plan
- ALJ Hearing
- Departmental Appeals Board (DAB) Review
- District Court/Judicial Review

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**Appeals Process – Reconsideration**

❖ Must be requested within 60 days of receipt of Initial Determination

- For list of "Initial Determinations" that can be appealed see 42 C.F.R. 498.3

❖ Request for reconsideration must identify any error made by MAC

- ❖ 42.C.F.R. 498.22

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**Corrective Action Plan (CAP)**

❖ Submit when provider receives notice that CMS will revoke its billing privileges

❖ Must be submitted within 30 days (not a month)

❖ Use in addition to Request for Reconsideration

❖ For some MACs, provider must use the form on the MAC website

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**Corrective Action Plan (CAP)**  
(Cont'd.)

- ❖ MAC/CMS required to process within 60 days.
  - Much discretion in terms of review, approval and processing
  - Get to know the people processing your CAP.
- ❖ Rejection of CAP is not appealable (Medicare Program Integrity Manual CMS-100-08, Ch. 15 §25 1.1.B.)

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**Corrective Action Plan (CAP)**  
(Cont'd.)

- ❖ To correct deficiencies that resulted in the proposal to revoke
  - Identify what was wrong and how it was corrected
  - Carefully consider how you "agree to improve" something without agreeing that you are at fault
- ❖ Provider must establish that it is in compliance with Medicare requirements

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**Corrective Action Plan (CAP)**  
(Cont'd.)

- ❖ Submitting a CAP does not substitute for submitting a request for reconsideration and does not toll the time for submitting a request for reconsideration.
  - If you choose to submit a CAP and miss the appeal deadline, you are out.
  - File reconsideration request at same time you file CAP, but it may not be processed at same time.

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**Appeals Process – ALJ Hearing**

- ❖ 42.C.F.R. 498.40
- ❖ Request for hearing must be made within 60 days of notice of reconsideration determination
- ❖ ALJs are bound by statute, regulations and CMS Rulings (but not manual instructions)
- ❖ DAB sends out prehearing order within about 10 days after the request is filed.

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**Appeals Process – ALJ Hearing**  
(Cont'd.)

- ❖ OGC Regional Counsel has 30 days put case together
  - OGC attorneys generally have been reasonable to deal with and settle many of the cases
- ❖ Better chance of favorable ruling at ALJ level than below

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**Appeals Process – ALJ Hearing**  
(Cont'd.)

- ❖ The ALJ hearing is an adversarial process.
- ❖ Parties may present oral arguments, question and cross-examine witnesses, and file briefs or other written statement.
- ❖ The ALJ, upon his or her own motion or at the request of a party, may issue subpoenas.

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**Appeals Process – DAB Review**

- ❖ Either party may request DAB review of the ALJ's decision or dismissal.
  - 42 C.F.R. 498.80; 42 C.F.R. 498.82
- ❖ 60-day deadline

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**Appeals Process – DAB Review**

- ❖ The DAB may grant, deny or dismiss a request for review.
- ❖ Upon request by the DAB, the parties will be permitted to file briefs or other written statements and (rarely) an opportunity to present to the DAB oral arguments and evidence.

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**Appeals Process – ALJ Hearing**  
(Cont'd.)

- ❖ Upon taking review, the DAB may issue a decision, or it may remand the case back to the ALJ either for a hearing and decision or for a recommended decision (in which case, the final decision will be issued by the DAB).

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**Appeals Process – District Court**

- ❖ Following a final *decision* by the Secretary "made after a hearing" a party can seek review in the district court
- ❖ This generally means that one must receive a DAB "decision," or an ALJ "decision" (if the DAB declines review)
  - A "dismissal" does not count – one must have a "decision" in order to get into court
  - Exhaustion of remedies generally required, but if no right to administrative appeal (e.g., deactivation), there may be federal question jurisdiction. *See Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 557 (1986).

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**Another Type of Enrollment: Ordering and Referring Physicians/Practitioners**

- ❖ Affordable Care Act requires that physicians and "other eligible professionals (OEP)" be enrolled in Medicare to order or refer certain items or services for Medicare beneficiaries.
- ❖ "OEPs" are:
  - Physician Assistants
  - Clinical Nurse Specialists
  - Nurse Practitioners
  - Clinical Psychologists
  - Interns, Residents, and Fellows
  - Certified Nurse Midwives
  - Clinical Social Workers

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**Ordering and Referring Physicians/Practitioners**

- For claims from:
  - Part A HHAs
  - Clinical Laboratories for ordered tests
  - Suppliers of DMEPOS
  - Imaging Centers (Technical portion only)

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**Ordering and Referring Physicians/Practitioners (Cont'd.)**

- ❖ Effective January 6, 2014, CMS turned on the edits to **deny** Part B clinical lab and imaging, DMEPOS, and Part A HHA claims that fail the ordering/referring provider edits.
  - MLN Matters SE 1305 Revised (November 6, 2013); and
  - MLN "Medicare Enrollment Guidelines for Ordering/Referring Providers" ICN 906223 (December 2013).

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**How to Check Enrollment Record**

- ❖ Providers & suppliers may check the Ordering Referring Report or Internet-based PECOS to verify their enrollment records
  - The Ordering Referring Report is published by CMS
  - Report shows all physicians & OEPs who have an approved record in PECOS to order and refer and those who have an application that has been received and is pending approval
  - Report is available at:  
[http://www.cms.gov/MedicareProviderSupEnroll/06\\_MedicareOrderingandReferring.asp#TopOfPage](http://www.cms.gov/MedicareProviderSupEnroll/06_MedicareOrderingandReferring.asp#TopOfPage)

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**APPENDIX  
OF  
STATUTORY AND  
REGULATORY  
AUTHORITIES**

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**Enrollment Authorities**

Provider and Supplier Enrollment Regulations

- 42 CFR Part 424, Subpart P (the 424.500's) – establishing and maintaining Medicare billing privileges (including rules for denying, revoking and deactivating billing privileges, and special rules on HHA changes in majority ownership)
- 424.57 – DMEPOS supplier standards
- 424.58 DMEPOS accreditation procedures
- 410.33 IDTF Standards
- 42 CFR, Part 498 – appeals procedures (see also 42 CFR Part 405, Subpart H (the 424.800's))

Manual Provisions

- Medicare Program Integrity Manual (Pub. 100-08 Chapter 15 – available at <http://www.cms.gov/Manuals/OM/list.asp>)

PECOS Guide

- "Getting Started With Internet-based Provider Enrollment, Chain and Ownership System (PECOS)" – available at: <http://www.cms.gov/MedicareProviderSupEnroll/downloads/Internet-basedPECOS%20%80%93GettingStartedGuideforDMEPOSSuppliers.pdf>

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**Enrollment: Recent Final Rules**

- ❖ April 27, 2012 – final rule in furtherance of May 5, 2010 interim final rule with comment period (see below), on enrollment requirements for ordering/referring physicians and NPI requirements (77 FR 25284)
- ❖ March 14, 2012 – further changes to DMEPOS supplier standards, including changes to patient anti-solicitation provision (77 FR 14989)

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**Enrollment: Recent Final Rules (Cont'd.)**

- ❖ February 2, 2011 – implementing provision of PPACA on screening requirements, application fees, temporary enrollment moratoria, payment suspensions, and Medicaid terminations of providers and suppliers that have been terminated or that had their billing privileges revoked (76 FR 5682)
- ❖ August 27, 2010 – additional DMEPOS supplier standards (75 FR 166).

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**Enrollment: Recent Final Rules (Cont'd.)**

- ❖ May 5, 2010 – implementing provisions of PPACA to require all providers and suppliers that qualify for an NPI to include their NPI on all applications to enroll in the Medicare and Medicaid programs and on all claims for payment submitted under the Medicare and Medicaid programs (75 FR 24437)
- ❖ January 2, 2009 – surety bond requirement for DMEPOS suppliers (74 FR 166)

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**Enrollment: Recent Final Rules (Cont'd.)**

- ❖ November 19, 2008 – established the re-enrollment bar of 1 to 3 years on providers and suppliers that have had their billing privileges revoked, and placed limitations on retroactive billing by providers and suppliers (73 FR 69726)
- ❖ June 27, 2008 – "Appeals of CMS or CMS Contractor Determinations When a Provider or Supplier Fails to Meet the Requirements for Medicare Billing Privileges" (73 FR 36448).

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**Enrollment: Recent Final Rules (Cont'd.)**

- ❖ November 27, 2007 – changes to IDTF provisions in 410.33 (72 FR 66222)
- ❖ December 1, 2006 – established performance standards for IDTFs (71 FR 69624)
- ❖ April 21, 2006 – "Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment," implementing section 1866(j)(1)(A) of the Act (71 FR 20754)
- ❖ October 11, 2000 – additional standards for DMEPOS suppliers (65 FR 60366).

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**QUESTIONS???**

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## Evaluating Audit Error Rates and Deciding What to Do Next

**April 1, 2014**

**Tizgel K. S. High, Esq.**  
Assistant General Counsel  
LifePoint Hospitals, Inc.

**M. Timothy Renjilian, CPA**  
Senior Managing Director  
FTI Consulting

**Sara Kay Wheeler**  
King & Spalding

KING & SPALDING

LIFEPPOINT  
HOSPITALS, INC.

FTI  
CONSULTING

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### Presenters

Tizgel K. S. High Esq.  
Assistant General Counsel  
LifePoint Hospitals, Inc.  
103 Powell Court  
Brentwood, TN 37207-5079  
(615) 372-8504  
Tizgel.High@lpnt.net

Tim Renjilian, CPA  
Senior Managing Director  
FTI Consulting  
1201 W. Peachtree Street  
Atlanta, GA 30309  
(404) 460-6222  
tim.renjilian@fticonsulting.com

Sara Kay Wheeler  
Partner  
King & Spalding  
1180 Peachtree St., NE  
Atlanta, GA 30309-3521  
(404) 572-4685  
skwheeler@kslaw.com

KING & SPALDING

LIFEPPOINT  
HOSPITALS, INC.

FTI  
CONSULTING

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### Agenda

- Enforcement / Oversight Landscape
- Audit Design & Error Rate Considerations
- What Is An Acceptable Error Rate?
- Interpreting External Error Rate Benchmarks
- Analyzing Internal Error Rates
- Additional Considerations
- Questions

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## Enforcement / Oversight Landscape

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## Error Rate Game Changers

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## Healthcare Enforcement and Oversight Landscape

- Pressure from Congress to identify fraud, waste and abuse in deficit reduction efforts
- Technology and resources improving
- Continued efforts to identify “baseline” error and overpayment rates
- Ongoing enforcement activity
- **All** providers are at risk in the current environment

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### Contractors

- Federal and state governments outsourcing oversight responsibilities
- Greater number of private companies authorized to request and analyze information from provider community
- Contractors are not created equally
- Understanding different roles and authority of each contractor category will enhance providers' ability to interpret and understand the results of their work
  - e.g., authority to extrapolate?

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### Consider One State... Georgia

#### Medicaid

- Thomson Reuters (Review of Provider MIC)
- Health Integrity (Audit MIC)
- Strategic Health Solutions (Education MIC)
- Medicaid Fraud Control Unit of Georgia (MFCU)
- Myers & Stauffer (Medicaid RAC)



#### Medicare

- Cahaba Government Benefit Administrators (A/B MAC)
- CIGNA Government Services (DME MAC)
- Palmetto GBA (Home Health and Hospice MAC)
- Connolly Consulting (A/B RAC)
- Part C RAC (TBD)
- ACLR (Part D RAC)

#### Potential Fraud

- AdvanceMed Corporation (ZPIC)

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### But Each State Is Unique



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### “Baseline” Error Rate Studies

- Comprehensive Error Rate Testing (“CERT”) Program -- Medicare fee-for-service
- Historical Hospital Payment Monitoring Program (“HPMP”)
- Payment Error Rate Measurement System (“PERM”) -- Medicaid
- OIG studies
  - Review of industry questionable billing practices
  - Facility-specific audits (e.g., Medicare Compliance audits)

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### What is An Acceptable Error Rate?

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### Potential Consequences of High Error Rates

- Further reviews
- Corrective actions
- Overpayments/extrapolation
  - Voluntary Repayment
  - Self Disclosure
  - FCA Liability
- Stakeholder notification requirements
- Other consequences
  - Possible Payment Suspension
  - Referral to Law Enforcement
  - Increased Contractor Activity

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### What is An “Acceptable” Error Rate? It Depends . . .

- Type of audit
  - External or internal audit?
  - Nature and purpose of audit (CERT vs. ZPIC)
- Issues being probed
- Audit design
  - Review criteria
  - Universe
  - Sample size
  - Random (e.g., CERT reviews) vs. Risk-Based Audit (e.g., RAC reviews)
  - Statistically valid
  - Definition of an “error”
- Types of Errors
  - Financial vs. claim error rates
  - Net versus gross
  - Internal error rate thresholds/history
- Expectations

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### How Do I Compare to My Peers?

- Must understand how to interpret various government “error rate” data to determine how you “compare” to other providers
- Need to determine when your performance deviates from the norm and what sort of corrective actions and remediation steps might be necessary

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### Interpreting External Error Rate Benchmarks

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### External Audit Considerations

- Generally speaking, contractors do not publish their error rate thresholds
- However, potential consequences from contractor audits can often be gleaned from their findings:
  - References to the FCA?
  - References to extrapolation and / or statistically valid sample?
  - Findings include provider education -- could signal a potential re-audit.
  - Referral to another contractor for additional auditing?
  - Prepayment review or payment suspension?

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### External Audits: CERT

- Calculates Medicare fee-for-service improper payments
- The 2012 improper adjusted payment rate was **8.5%**
  - Part A Acute Inpatient Hospital Claims had an error rate of **6.8 percent**
  - Stays of one day or less had an improper payment rate of **36.1 percent**
  - DMEPOS had an improper payment rate of **66.0 percent**
  - E&M services had an improper payment rate of **14.0 percent**

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### External Audits: Medicare Program Integrity Manual

- CMS has **not** articulated an error rate threshold in the context of Medicare contractor reviews
- However, in a section of the Program Integrity Manual addressing corrective action, CMS outlines several scenarios to provide guidance regarding how MACs should respond to varying levels of errors
  - "Twenty claims from one provider are reviewed. Once claim is denied because a physician signature is lacking on the plan of care. The denial reflects **7 percent of the dollar amount of claims reviewed**. Judicious assessment of medical review resources indicates **no further review is necessary at this time.**"
  - "Forty claims from one provider are reviewed. Twenty claims are for services determined to be not reasonable and necessary. These **denials reflect 50 percent of the dollar amount of claims reviewed. One hundred percent prepayment review is initiated** due to the high number of claims denied and the high dollar amount denied."
  - "Forty claims from one provider are reviewed. Thirty-five claims are denied. **These denials reflect 70 percent of the dollar amount of claims reviewed. Payment suspension is initiated** due to the high denial percentage and the Medicare dollars at risk."

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### External Audits: State Medicaid Agencies

- State Medicaid agencies may provide guidance concerning “acceptable” error rates
- **Texas, Tex. Admin. Code tit. 1, § 371.214**
  - (I) For Utilization Reviews conducted on September 1, 2008 through August 31, 2009, HHSC-OIG Utilization Review will extrapolate to the population only when the error rate exceeds 25%
  - (II) For Utilization Reviews conducted on September 1, 2009 through February 28, 2010, HHSC-OIG Utilization Review will extrapolate to the population only when the error rate exceeds 20%
  - (III) For Utilization Reviews conducted on March 1, 2010 through August 31, 2010, HHSC-OIG Utilization Review will extrapolate to the population only when the error rate exceeds 15%

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### 2014 IPPS Final Rule: Two-Midnight Rule

- **From the Preamble – Error Rates:**
  - “In 2012, the CERT contractor found that Medicare Part A inpatient hospital admissions for **1-day stays or less had an improper payment rate of 36.1 percent**. The improper payment rate decreased significantly for 2-day or 3-day stays, which had improper payment rates of 13.2 percent and 13.1 percent, respectively.” (FR 50943).

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### 2014 IPPS Final Rule: Probe & Educate Reviews

- **NOT a delay in enforcement.**
- **Applies to dates of admission on or after October 1, 2013 but before September 30, 2014.**
- Medicare Administrative Contractors (MACs) will **conduct patient status reviews** using a “probe and educate” strategy
  - MACs will select a sample of 10 claims for prepayment review for most hospitals (25 claims for large hospitals).
  - Based on the results of these initial reviews, MACs will conduct educational outreach efforts and may conduct additional reviews
- *Contractors may continue other types of inpatient hospital reviews, including coding reviews and inpatient hospital patient status reviews for dates of admission prior to October 1, 2013.*

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### 2014 IPPS Final Rule: Probe & Educate Reviews

The MACs will categorize concern levels and implement provider-specific action.

- **Minor Concern:** A provider with a low error rate and no pattern of errors, defined as 0-1 errors out of 10 claims or 0-2 errors out of 25 claims.
  - Action: MACs will educate the provider via the results letter indicating the reasons for denial of the inpatient claim.
- **Moderate-Significant Concern:** A provider with a moderate error rate, defined as 2-6 errors out of 10 claims or 3-13 errors out of 25 claims.
  - Action: MACs will offer 1:1 telephonic provider education in addition to the written review results letters. *MACs will repeat the probe strategy.*
- **Major Concern:** A provider with a high error, defined as 7+ errors out of 10 claims or 14+ errors out of 25 claims.
  - Action: MACs will offer 1:1 telephonic provider education in addition to the written review results letters. *MACs will repeat the probe strategy.*

• If continuing major concerns are identified, MACs will select 100 claims (for providers with 10 sampled claims) and 250 claims (for providers with 25 sampled claims) for review.

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### Analyzing External Error Rates – Recap

- What was the purpose of the audit?
- How was the universe (sampling frame) defined?
- How was the sample selected?
- How were errors defined?
- How was the error rate calculated?
- What sort of follow-up steps were required?

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### Analyzing Internal Error Rates

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DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Office of Inspector General

October 11, 2011

**Subpoena Request**

Accompanying this letter is a subpoena addressed to you returnable at the Office of Inspector General.

3. All internal or external reviews conducted for or by, or complaint(s) or concern(s) presented to or received by [redacted] that refer or relate to an evaluation of [redacted]'s billing practices or monitoring of compliance with Medicare, Medicaid, or TRICARE/CHAMPUS regulations, including, but not limited to, all interim and final reports from the audit performed by [redacted]

Failure to appear at the time and place specified in the subpoena may be taken as a failure to comply with the subpoena. However, as a convenience you may assemble the documents requested and mail them by certified mail on or before December 16, 2011 to [redacted]

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**Internal Audits**

- Can control design of audit
  - Random?
  - Risk-Based?
  - Statistically valid?
  - Reviewer expertise
  - Issues reviewed
  - Standards employed
- Internal Auditing & Monitoring Policies
  - Differences between auditing and monitoring
  - Who is authorized to *initiate* audits that may generate error rates?
  - Who is notified of the audit findings and error rates?

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**Internal Error Rate Considerations**

- Always trying to drive error rates down
- When is the Chief Legal Officer (CLO) and Chief Compliance Officer (CCO) notified of error rate results?
  - All error rates over 15%? 20%?
- How are error rates intended to be used?
- How are error rates communicated?
  - What documentation is created and how is it maintained and used?
  - Are audit findings typically issued in draft form?

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**Internal Error Rate Considerations**

- Confirm that appropriate stakeholders are notified of “significant” error rates
  - Consider an internal policy for notifying the CLO and CCO of significant error rates
- Document the nature, purpose and design of the audit in the report (*e.g.*, best practices / company policies audited)
- Document any and all corrective action measures

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**Internal Error Rate Considerations**

- Consider when a re-probe is needed to test corrective action
- When refunding overpayments, consider messaging of error rate (*e.g.*, are you clearly explaining the audit design?)
- Corporate culture implications
  - Internal communications
  - Whistleblower considerations

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**Additional Considerations**

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### False Claims Act Litigation

- The government and qui tam relators may attempt to use **error rates as a sword**:

- *United States ex rel. Keltner v. Lakeshore Medical Clinic, Ltd.*

- “Relator’s allegations are sufficiently detailed to survive defendant’s Rule 12(b)(6) and 9(b) motions. Although she does not allege that defendant knew that specific requests for reimbursement for E/M services were false, **she claims that defendant ignored audits disclosing a high rate of upcoding** and ultimately eliminated audits altogether.”

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### False Claims Act (cont’d)

- Some providers have been able to use **error rates as a shield**:

- *United States v. Prabhu (D. Nev.)*

- “[T]he existence of such a low alleged error rate [5.5%] disproves the contention that Defendants ‘knowingly’ engaged in a pattern of submitting false or fraudulent claims.”

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### Additional Considerations

- CMS Proposed Rule on Reporting and Refunding Overpayments
- Halifax Order
- Potential managed care reporting requirements

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**QUESTIONS AND ANSWERS**

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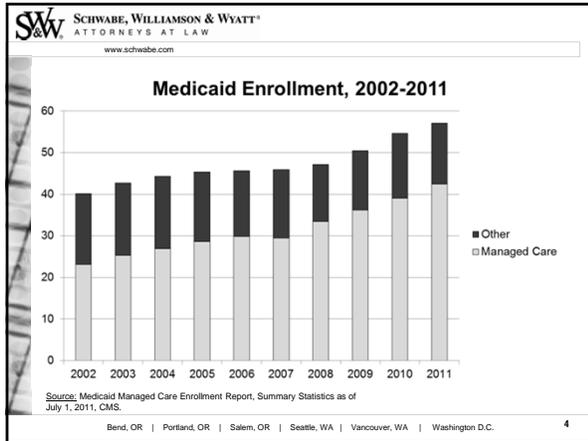
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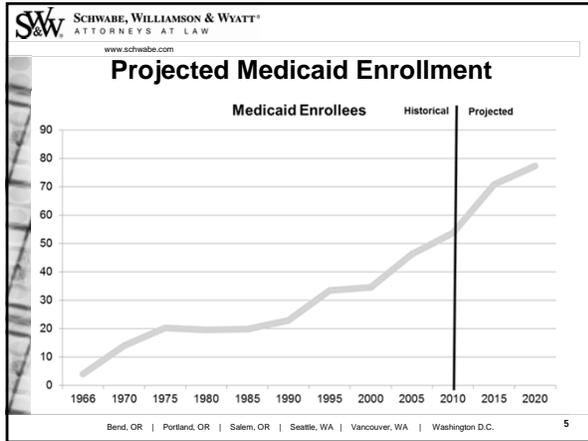
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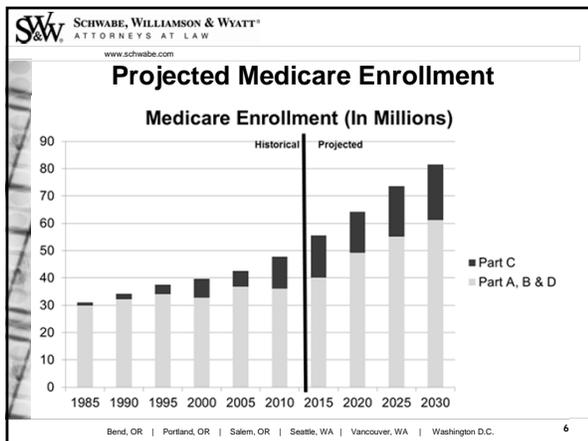
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## Medical Errors are Prevalent

- Healthcare errors are believed to harm millions of patients each year and add billions to healthcare costs.
- The CDC estimates 1.7 million healthcare associated infections occur each year, leading to 99,000 deaths
- Adverse Medication Events Cause More than 77,000 injuries and deaths each year
- CBO found that there were over 180,000 severe injuries attributable to medical negligence in 2003.
- OIG found that one in seven Medicare patients are injured during hospital stays and that adverse events during the course of care contribute to the deaths of 180,000 patients every year

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## Historical Context of Medicare Reimbursement Methods

- Hospital Cost-Based
- Fee for Service
- DRGs & RVUs
- Capitation Models
- Quality and Value Initiatives
- ACOs

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## National Strategy for Quality Improvement in Health Care

- Section 3011 of PPACA Required the Establishment of a National Strategy to Improve:
  - Delivery of Health Care Services
  - Patient Health Outcomes
  - Population Health
- CMS required to identify national priorities that:
  - Have greatest potential for improving health outcomes, efficiency, and patient-centeredness
  - Identify areas for rapid improvement in quality and efficiency
  - Improve federal payment policy to emphasize quality and efficiency.
  - Enhance use of health care data, and others

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## National Strategy for Quality Improvement in Health Care

- Develop comprehensive plan to achieve priorities
  - Must address coordination among agencies
  - Establish benchmarks for agencies
  - Develop reporting by agencies of implementation
  - Align public and private payers re quality and patient safety
- Submit plan to Congress and regularly update

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## National Strategy for Quality Improvement in Health Care

1. Making care safer by reducing harm caused in the delivery of care.
2. Ensuring that each person and family is engaged as partners in their care.
3. Promoting effective communication and coordination of care.
4. Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease.
5. Working with communities to promote wide use of best practices to enable healthy living.
6. Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new healthcare delivery models.

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## Hospital Inpatient Reporting Program (IQR)

- Established by sec. 5001(a) of the Deficit Reduction Act of 2005 (P.L. 109-171)
- Participating Hospitals Submit Quality Indicators
- Failure to Submit Results in Reduction of the Annual Payment Update (APU) (Market Basket Increase) by two Percentage Points

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## Hospital Inpatient Reporting Program (IQR)

- Sample Clinical Categories of Indicators Collected
  - Acute Myocardial Infarction (AMI)
  - Heart Failure
  - Stroke
  - Venous Thromboembolism (VTE)
  - Pneumonia (PN)
  - Children’s Asthma Care (CAC)
  - Surgical Care Improvement Project (SCIP)
  - Emergency Department (ED)\*\*

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## Hospital Inpatient Reporting Program (IQR)

### Sample Measures

| Heart Failure (HF)**   | Submission Required | Collected | For | On Hospital |
|--|---------------------|-----------|-----|-------------|
| HF-2 Evaluation of LVS Function (1)                                | New 2003            | CMS/STAC  | Yes | Yes         |
| Stroke (STK)**   | Submission Required | Collected | For | On Hospital |
| STK-1 Venous Thromboembolism (VTE) Prophylaxis (10)                | 1Q 2013             | CMS/STAC  | Yes | Yes         |
| STK-2 Discharged on Antithrombotic Therapy (10)                    | 1Q 2013             | CMS/STAC  | Yes | Yes         |
| STK-3 Anticoagulation Therapy for Atrial Fibrillation/Flutter (10) | 1Q 2013             | CMS/STAC  | Yes | Yes         |
| STK-4 Thrombolytic Therapy (10)                                    | 1Q 2013             | CMS/STAC  | Yes | Yes         |
| STK-5 Antithrombotic Therapy By End of Hospital Day 2 (10)         | 1Q 2013             | CMS/STAC  | Yes | Yes         |
| STK-6 Discharged on Statin Medication (10)                         | 1Q 2013             | CMS/STAC  | Yes | Yes         |
| STK-8 Stroke Education (10)  | 1Q 2013             | CMS/STAC  | Yes | Yes         |
| STK-10 Assessed for Rehabilitation (10)                            | 1Q 2013             | CMS/STAC  | Yes | Yes         |

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## Hospital Inpatient Reporting Program (IQR)

- Categories of Data Required:
  - Measures Requiring Abstraction and Submission by the Hospital or its Vendor
    - Example: Median Time from ED Arrival to ED Departure for Admitted ED Patients - Overall Rate
  - Measures Requiring Web-Based Hospital Data Entry
    - Participation in a Systematic Clinical Database Registry for Stroke Care
  - Measure Information Obtained from Claims-Based Data
    - Pneumonia (PN) 30-Day Readmission Rate (7)

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## Hospital Inpatient Reporting Program (IQR)

- CMS & AHRQ developed the Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS);
- Survey asks patients 27 questions about their hospital experience, including:
  - communication with doctors,
  - communication with nurses,
  - responsiveness of hospital staff,
  - cleanliness and quietness of hospital environment,
  - pain management,
  - overall rating of hospital.

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## Hospital Inpatient Reporting Program (IQR)

Data is Posted Online at Hospital Compare Web Site:

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## Hospital Inpatient Reporting Program (IQR)

Data is Posted Online at Hospital Compare Web Site:

|   |      |      |                   |
|---|------|------|-------------------|
| Heart failure patients given discharge instructions<br>Higher percentages are better  | 98%  | 98%  | 98% <sup>2</sup>  |
| Heart failure patients given an evaluation of left ventricular systolic (LVS) function<br>Higher percentages are better             | 100% | 100% | 100% <sup>2</sup> |
| Heart failure patients given ACE inhibitor or ARB for left ventricular systolic dysfunction (LVSD)<br>Higher percentages are better | 100% | 97%  | 98% <sup>2</sup>  |

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### Hospital Inpatient Reporting Program (IQR)

- Accuracy: Hospitals must pass the validation requirement of a minimum of 75% reliability based on chart-audit validation for clinical process measures
- A random sample of 800 hospitals is selected for validation annually
- Hospitals who did not meet the 75% threshold for the previous year are also selected.

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### Hospital Inpatient Reporting Program (IQR)

#### Reconsideration / Appeals

- IQR Program reconsideration from CMS must submit their request within 30 days following the date identified on Hospital IQR Program Annual Payment Update (APU) notification letter
- The request must identify the hospital's specific reason(s) for believing the Hospital IQR Program requirements were met and why the hospital should receive the full Inpatient Prospective Payment Systems (IPPS) APU
- When a hospital is dissatisfied with the result of CMS's reconsideration, the hospital may file a claim under 42 CFR Part 405, Subpart R (a Provider Reimbursement Review Board [PRRB] appeal).

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### Hospital Inpatient Reporting Program (IQR)

- Authorities & Information
  - Section 1886(b)(3)(B)(viii) of the Social Security Act
  - Code Federal Regulations: 42 CFR 412.140
  - FY 2014 IPPS Final Rule: 78 FR 50775
  - <http://www.qualitynet.org/>
  - [qnetsupport@sdps.org](mailto:qnetsupport@sdps.org)
  - QualityNet Help Desk: 1-866-288-8912
  - Your State's QIO

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### Hospital Outpatient Reporting Program (OQR)

- Program established under the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act (MIEA-TRHCA) of 2006
- The first reporting period began with April 1, 2008 patient encounter dates
- Voluntary quality measure data reporting program for outpatient hospital services;
- Modeled on the Hospital Inpatient Reporting Program

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### Hospital Outpatient Quality Reporting (OQR) Program Overview

- Hospitals that Fail to Meet Receive two percent Reduction in OPPI annual payment update
- Reduction only impacts payment year involved
- CMS Prefers to adopt National Quality Forum measures
- CMS focuses on “high impact” reporting measures
- 27 Measures, including:
  - Clinical Performance
  - Imaging Efficiency
  - Web-Based Structural
- Public Reporting of Data

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### Hospital Outpatient Reporting Program (OQR) Measures

| Hospital OQR Quality Measures |   |
|-------------------------------|---|
| OP-1                          | Median Time to Fibrinolysis   |
| OP-2                          | Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival   |
| OP-3                          | Median Time to Transfer to Another Facility for Acute Coronary Intervention   |
| OP-4                          | Aspirin at Arrival  |
| OP-5                          | Median Time to ECG  |
| OP-6                          | Timing of Antibiotic Prophylaxis  |
| OP-7                          | Prophylactic Antibiotic Selection for Surgical Patients   |
| OP-8                          | MRI Lumbar Spine for Low Back Pain  |
| OP-9                          | Mammography Follow-up Rates   |
| OP-10                         | Abdomen CT Use of Contrast Material   |
| OP-11                         | Thorax CT Use of Contrast Material  |
| OP-12                         | The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC-Certified EHR System as Discrete Searchable Data |
| OP-13                         | Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery   |
| OP-14                         | Simultaneous Use of Brain Computed Tomography (CT) and Sinus CT   |
| OP-15                         | Use of Brain CT in the Emergency Department (ED) for Atraumatic Headache - REPORTING POSTPONED*   |
| OP-17                         | Tracking Clinical Results between Visits  |

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## Physician Quality Reporting System

- Tax Relief and Health Care Act of 2006 (TRHCA) initially authorized the Physician Quality Reporting System.
- PQR is a uses a combination of incentive payments and payment adjustments to promote reporting of quality information by eligible professionals (EPs).
- Individual EPs who meet satisfactory submission of PQR quality measures data for services furnished during a 2014 will qualify to earn a PQR incentive payment equal to 0.5% of their total estimated Medicare Part B Physician Fee Schedule (PFS) allowed charges for covered professional services furnished during that same reporting period.

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## Physician Quality Reporting System

|                                     |   |
|-------------------------------------|---|
| <b>Medicare physicians</b>          | <b>Practitioners</b>  |
| Doctor of Medicine                  | Physician Assistant   |
| Doctor of Osteopathy                | Nurse Practitioner  |
| Doctor of Podiatric Medicine        | Clinical Nurse Specialist   |
| Doctor of Optometry                 | Certified Registered Nurse Anesthetist*<br>(and Anesthesiologist Assistant) |
| Doctor of Oral Surgery              | Certified Nurse Midwife   |
| Doctor of Dental Medicine           | Clinical Social Worker  |
| Doctor of Chiropractic              | Clinical Psychologist   |
| <b>Therapists</b>                   | Registered Dietician  |
| Physical Therapist                  | Nutrition Professional  |
| Occupational Therapist              | Audiologists  |
| Qualified Speech-Language Therapist |   |

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## Physician Quality Reporting System

- Group practices can register to participate in PQR through the group practice reporting option (GPRO) to be analyzed at the group level
- A "group practice" under 2014 PQR consists of a physician group practice, as defined by a single Tax Identification Number (TIN), with 2 or more individual EPs
- An individual EP who is a member of a group practice participating in PQR GPRO is not eligible to separately earn a PQR incentive payment as an individual EP

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## Physician Quality Reporting System

- Reporting options generally require an EP or group practice to report 9 or more measures covering at least 3 National Quality Strategy (NQS) domains:
  - Patient Safety
  - Person and Caregiver-Centered Experience and Outcomes
  - Communication and Care Coordination
  - Effective Clinical Care
  - Community/Population Health
  - Efficiency and Cost Reduction

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## Physician Quality Reporting System

Individual EPs may choose to report quality data via:

1. EHR Direct Product that is Certified Electronic Health Record Technology (CEHRT)
2. EHR data submission vendor that is CEHRT
3. A qualified PQRS registry
4. Participation through a Qualified Clinical Data Registry (QCDR)
5. Medicare Part B claims submitted to CMS

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## Physician Quality Reporting System

- Authorities & Information
  - Section 1848(a), 1848(k), & 1848(m) of the Social Security Act
  - Code Federal Regulations: 42 CFR 414.90
  - 77 FR 44805

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### Ambulatory Surgery Center Quality Reporting

- Tax Relief and Health Care Act of 2006 (TRHCA) initially authorized the ASCQR Program
- Section 1833(i)(2)(D)(iv) of the Act authorizes CMS to implement payment system "in a manner so as to provide for a reduction in any annual update for failure to report on quality measures
- Intended to mirror the hospital outpatient quality program

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### Ambulatory Surgery Center Quality Reporting

- An ASC that Fails to Meet Reporting Requirements has a 2% Reduction to any Annual Increase Provided Under the Revised ASC Payment System
- APU Rates are Effected Starting in CY 2014
- Reductions for One Year Are Not Taken into Account in Computing Annual Increase for Subsequent Year

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### Ambulatory Surgery Center Quality Reporting

**ASC Quality Measures**

- ASC-1: Patient Burn
- ASC-2: Patient Fall
- ASC-3: Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
- ASC-4: Hospital Transfer/Admission
- ASC-5: Prophylactic Intravenous (IV) Antibiotic Timing
- ASC-6: Safe Surgery Checklist Use
- ASC-7: ASC Facility Volume Data on Selected ASC Surgical Procedures
- ASC-8: Influenza Vaccination Coverage among Healthcare Personnel
- ASC-9: Endoscopy/Polyp Surveillance: Appropriate Follow-up Interval for Normal Colonoscopy in Average Risk Patients
- ASC-10: Endoscopy/Polyp Surveillance: Colonoscopy Interval for Patients with a History of Adenomatous Polyps - Avoidance of Inappropriate Use
- ASC-11: Cataracts- Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery

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### Ambulatory Surgery Center Quality Reporting

- Authorities & Information
  - Section 1833(i)(2)(D)(iv) of the Social Security Act
  - Code Federal Regulations: 42 CFR 416.160
  - 78 FR 75130

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### Other CMS Programs

- Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP)
- Long-term Care Hospitals Quality Reporting Program (LTCHQR)
- PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR)
- Ambulatory Surgical Center Quality Reporting (ASCQR) Program

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### Other CMS Programs

- Inpatient Psychiatric Facility Quality Reporting Program (IPFQR)
- Home Health Quality Reporting Program (HH QRP)
- Hospice Quality Reporting Program
- End-Stage Renal Disease (ESRD) Quality Initiative
- Hospital Readmissions Reduction Program
- Hospital Acquired Conditions Reduction Program

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## Cases

- Valley Presbyterian Hospital (Van Nuys, CA) v. BlueCross BlueShield Association/First Coast Service Options, PRRB Hearing Dec. NO 2011-D28, Case No. 08-2579, May 13, 2011.
- CMS Reduced Market Basket Increase by 2.0 for FY 2008 due to failure to Conduct a Dry Run Submittal.
- Hospital Submitted Majority of Quality Data on Time, But Did Not Meet All Statutory Requirements
- Hospital: Prolonged Technology Problems Interfered with Ability to Participate and Vendor Failed to Notify Hospital of Dry Run Requirement
- Hospital: Substantial Performance
- **Held:** Secretary defined precisely what was required, and hospital failed to meet.

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## Cases (Continued)

- Pacific Alliance Medical Center (Los Angeles) v. Wisconsin Physician Services, PRRB Hearing Dec. No. 2011-D15, Case No. 09-1796, December 14, 2010.
- Hospital failed to submit required hospital quality data by deadline.
- Hospital: we acted reasonably, diligently and good faith. The vendor missed the submission deadline due to a technical error, and the error was corrected promptly and the data was submitted 12 hours after the deadline expired.
- Hospital: we "substantially complied" with requirements and CMF suffered no damages as the result of minor breach.
- Intermediary: 4.5 months following last day of discharge to submit quality data to the QIO – plenty of time.
- **Held:** Hospital failed to comply with requirements, hospital not entitled to full market basket update.

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## Cases (Continued)

- Western Medical Center – Santan Ana v. BlueCrossBlueShield Association/First Coast Service Operations-CA, PRRB Hearing Dec. No. 2011-D13, Case 08-1695, December 3, 2010.
- Hospital argued that CMS did not follow APA requirements by giving proper notice of CMS' scoring methodology for parent/child questions.
- Intermediary argued that notice was provided though QualityNet.org.
- **Held:** CMS published policy is inconsistent with CMS practice and clearly did not provide hospitals with notice relative to the scoring methodology for parent/child questions or the penalties that result from answering a parent question incorrectly.

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## Conclusions

- CMS Programs Likely to Continue & Increase
- President's FY 2015 Budget Proposal
- Impact on State Initiatives
- Impact on Commercial Payers

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## Questions?

**Contact information:**

**Peter D. Ricoy**  
Shareholder Attorney  
Schwabe, Williamson, & Wyatt, P.C.  
1211 SW 5th Ave., Ste. 1900, Portland, OR 97204

Direct: 503-796-2973  
Email: [pricoy@schwabe.com](mailto:pricoy@schwabe.com)

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*the* **DataBank**  
National Practitioner | Healthcare Integrity & Protection

Health Care Compliance Association's Compliance Institute  
April 1, 2014

**The National Practitioner Data Bank:  
What Compliance Officers Need to Know**

David Loewenstein  
Compliance Branch Chief  
U.S. Department of Health and Human Services  
Health Resources and Services Administration  
Division of Practitioner Data Banks



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**Presentation Overview**

- General Provisions
- What Hospital Compliance Officers Need to Know
  - Hospital Querying
  - Hospital Reporting
  - Potential Sanctions
  - Intersecting Roles of Compliance Officers, Medical Staff Services, and Human Resources
- Hospital Compliance Initiative
- Resources & Contacts



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**General Provisions**

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### General Provisions

**Purpose**

Created under three statutes to meet several needs:

- Flagging system for effective credential reviews
- Protection against unfit practitioners
- Deter fraud and abuse in the health care system



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### General Provisions

**Types of Information Collected**

- Medical malpractice judgments, settlements
- Adverse licensing, certification actions
- Clinical privileges actions
- Professional society membership actions
- Negative actions/findings from private accreditation organizations and peer review organizations
- Government administrative actions, e.g., exclusions from programs
- Civil, criminal health care-related judgments

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### General Provisions

Merger Goal: Eliminate duplication between the NPDB and Healthcare Integrity Protection Data Bank

- The 3 statutes-- Title IV of Public Law 99-660, Section 1921 of the *Social Security Act*, and Section 1128E of the *Social Security Act* --remain in effect
- ONE Data Bank
- ONE set of regulations governing the Data Bank's operations



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### General Provisions



**Recovering Costs**

- By law, the Data Bank must recover the full cost of operations. It does so by collecting fees for each query.

**Confidentiality**

- Information reported to the Data Bank is confidential, not available to the general public, and may not be disclosed except as provided by law.

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### What Hospital Compliance Officers Need to Know

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### What Compliance Officers Need to Know

Federal law dictates reporting to and querying from the Data Bank

Health care quality

The Data Bank reduces risk by providing information to help facilitate good decision-making

Patient safety

Deterring fraud and abuse

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### Hospital Querying Overview

**Must query on:** Health care practitioners when practitioners apply for staff appointments (courtesy or otherwise) or clinical privileges (including temporary privileges); every two years for practitioners on staff or with clinical privileges

**May query on:** Health care practitioners with whom the hospital has entered (or maybe entering) employment or affiliation relationships

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### Use of NPDB Queries

- Centralized Credentialing
- Querying Through an Authorized Agent
- Delegated Credentialing
- Continuous Query



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### Hospital Reporting Overview

**Must report on:** Physicians and dentists

**Must report:** Adverse clinical privileges actions >30 days related to professional competence or conduct

**May report on:** Other practitioners

**May report:** Adverse clinical privileges actions >30 days related to professional competence or conduct

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### NPDB Reporting

“While under investigation or in return for not conducting such an investigation”

- Denials, reductions, and restrictions of privileges
- Withdrawals and Nonrenewals
- Investigations
- Summary suspensions
- Report forwarding to State Licensing Boards



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### Potential Sanctions

**Failure to Report**  
Loss of immunity protections provided for professional review activities that occur during the 3-year period

**Failure to Query**  
Plaintiff access to NPDB information on that practitioner for use in litigation against the hospital.



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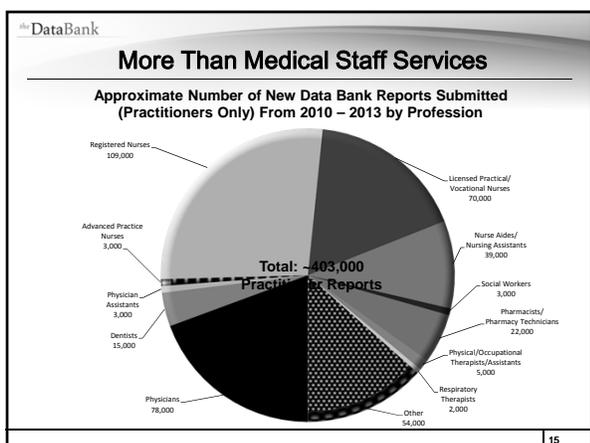
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## Hospital Compliance Initiative

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## Hospital Compliance Initiative



- **Develop and implement stakeholder outreach/education**
- **Develop and implement individual hospital outreach/education**
- **Design and implement hospital attestation**

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## Resources and Contact Information

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### Resources

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Web Site - [www.npdb.hrsa.gov](http://www.npdb.hrsa.gov)

- NPDB Guidebook
- Interactive Training
- FAQs, Brochures, and Fact Sheets
- Statistics
- Annual Reports
- Instructions for Reporting and Querying

Customer Service Center

- (800) 767-6732 or (800) SOS-NPDB
- [help@npdb.hrsa.gov](mailto:help@npdb.hrsa.gov)

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### Contact Information

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David Loewenstein  
Compliance Branch Chief  
Division of Practitioner Data Banks  
Bureau of Health Professions  
Health Resources and Services Administration  
U.S. Department of Health and Human Services

Telephone: 301-443-8263  
Email: [DLoewenstein@hrsa.gov](mailto:DLoewenstein@hrsa.gov)



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**COMPLIANCE & THE C-SUITE**

HCCA'S 18<sup>TH</sup> ANNUAL  
COMPLIANCE INSTITUTE  
MARCH 31- APRIL 2, 2014  
SAN DIEGO, CA

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**SESSION HIGHLIGHTS**

- UNDERSTANDING A CEO'S EXPECTATION OF COMPLIANCE IN A HIGHLY REGULATED ENVIRONMENT
- COMMUNICATING COMPLIANCE ISSUES TO THE EXECUTIVE BRANCH
- IMPLEMENTING COMPLIANCE TO A HOSPITAL'S VISION, MISSION & VALUES

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**TRANSFORMATION OF HEALTHCARE**

- INCREASED NUMBER OF REGULATIONS
- ADAPTATION TO CHANGE IN ORDER TO:
  - PROVIDE HIGH QUALITY – SAFE CARE
  - MANAGE NEW ILLNESSES
  - EMBRACE SCIENCE & TECHNOLOGY
- DEPENDENCY OF COMPLIANCE PROGRAMS IN THE FACE OF INCREASED ENFORCEMENT

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**TONE AT THE TOP**

- CEO'S CHIEF OBJECTIVES:
  - ENSURE BEST QUALITY & SAFEST CARE
  - GIVE THE HOSPITAL A COMPETITIVE ADVANTAGE
  - SERVICE EXCELLENCE
  - DEVELOPING THE RIGHT ORGANIZATIONAL CULTURE
  - HIRING EMPLOYEES WITH THE BEST CHARACTER & PERSONALITY

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**CHARACTER & PERSONALITY**

- CHARACTERISTICS NECESSARY TO ACHIEVE SUCCESS AS COMPLIANCE PROFESSIONALS
- CHARACTER & PERSONALITY ALLOWS COMPLIANCE PROFESSIONALS TO:
  - ADVANCE THE INSTITUTION'S MISSION; AND
  - ENGAGE & COLLABORATE WITH EMPLOYEES OF ALL LEVELS

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**CHARACTER & PERSONALITY**

- ALWAYS LOOK TO HELP
  - EMPLOYEES WELCOME OPPORTUNITIES TO BE BETTER
  - ENGAGES EMPLOYEES – RALLIES EMPLOYEES
- ENGAGE IN AN EFFORT TO PROTECT
- BE BOLD – BELIEVE IN YOUR OPINIONS – BUILD TRUST

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**KNOWLEDGE**

- **KNOW YOUR FIELD**
  - RESEARCH
  - READ
  - BUILD RELATIONSHIPS
- **KNOW THE IMPACT YOUR RECOMMENDATIONS HAVE**
- **DETERMINE OPERATIONAL SOLUTIONS TO KEEP DEPARTMENTS ON THE RIGHT PATH TO SUCCESS**

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**KNOWLEDGE**

- **COMPLIANCE OFFICERS HAVE AN ENORMOUS RESPONSIBILITY**
- **BE THE MORAL BACKBONE OF YOUR ORGANIZATION**
- **UNDERSTAND HEALTHCARE TO GUIDE THE ORGANIZATION TOWARDS WHAT IS RIGHT**



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**KNOWLEDGE**

- **IMPROVES RELATIONSHIPS WITH:**
  - **CHIEF OPERATING OFFICER (COO)**
  - **CHIEF FINANCIAL OFFICER (CFO)**
  - **CHIEF MEDICAL OFFICER (CMO)**
  - **CHIEF NURSING OFFICER (CNO)**
  - **LEGAL COUNSEL**
- **COUNSEL INTERPRETS LAW – COMPLIANCE KNOWS THE OPERATIONAL IMPACT**

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**COMMUNICATION**

- DRIVES SUCCESS IN ALL OTHER FACTORS
- SUCCESSFUL COMMUNICATION IS DETERMINED BY YOUR ABILITY TO BE EFFECTIVE & TIMELY WITH YOUR MESSAGE
- RECITATION OF STATUTES WILL NOT ENGAGE – IT WILL NOT CONVINCE
- TELL A STORY – GIVE REAL EXAMPLES FROM YOUR INSTITUTION



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**COMMUNICATION**

- EXECUTIVE & BOARD LEVEL REPORTING – NO SURPRISES
- COMMUNICATE WITH PURPOSE
  - KNOW WHAT CEOs NEED TO KNOW IMMEDIATELY
  - KNOW WHAT CAN WAIT
- KNOW YOUR BOARD – UNDERSTAND THEIR FIDUCIARY & JUDICIARY RESPONSIBILITIES

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**COMMUNICATION**

- COMMUNICATE WITH A CEOs EXECUTIVE TEAM FIRST
  - COMPLIANCE IS PART OF THIS TEAM
  - EXPECTATION OF A CEO THAT THIS TEAM TO MITIGATE ISSUES OF NON-COMPLIANCE



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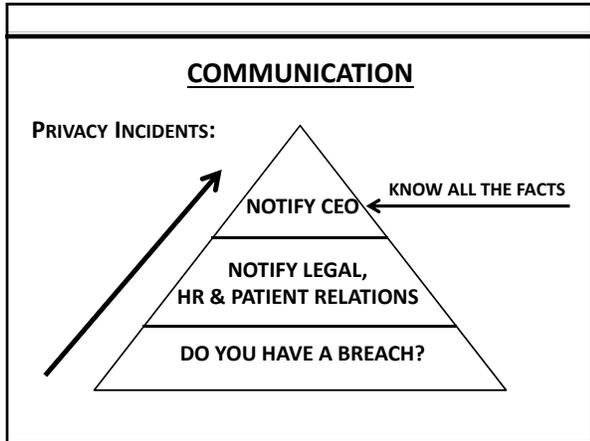
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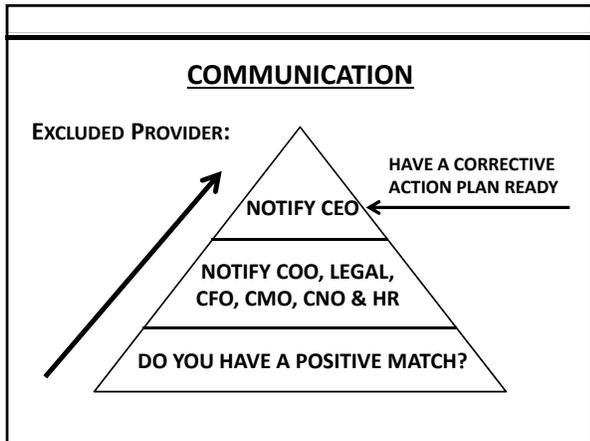
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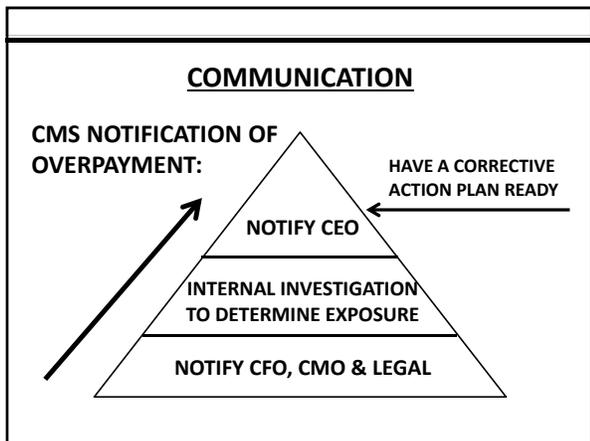
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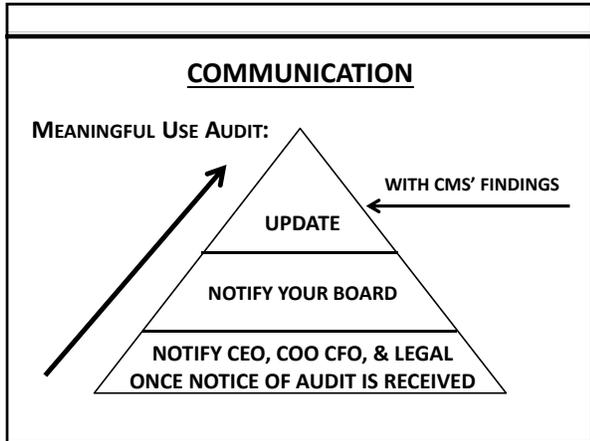
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- COMMUNICATION**
- **BOARD REPORTING:**
    - **QUARTERLY REPORTING – AT MINIMUM**
    - **PROVIDE THEM THE INFORMATION TO HELP THEM MEET THEIR RESPONSIBILITIES**
    - **EDUCATE – PROMINENT COMMUNITY MEMBERS, NOT NECESSARILY WELL VERSED IN HEALTH CARE OPERATIONS**

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- MOTIVATION**
- **OPTIMIZE THE PERFORMANCE OF YOUR DEPARTMENT**
  - **LEARN THE DIRECTION HEALTHCARE & YOUR ORGANIZATION IS MOVING IN**
  - **PROVIDE RELEVANT GUIDANCE**
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**MOTIVATION**

- **TRIPLE AIM**
  - **CURRENT APPROACH TO PROVIDING HEALTH CARE**
  - **INCREASED LONGEVITY OF AGING POPULATION**
  - **CHRONIC HEALTH PROBLEMS – NEW DEMANDS**

The Triple Aim

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**MOTIVATION**

- **FULLFILLING THIS AIM REQUIRES:**
  - **FOCUS ON INDIVIDUALS & FAMILIES**
  - **REDESIGN PRIMARY CARE SERVICES & STRUCTURES**
  - **MANAGE POPULATION HEALTH**
  - **CREATE A COST CONTROL PLATFORM; AND**
  - **SYSTEM INTEGRATION & EXECUTION**

The Triple Aim

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**MOTIVATION**

- **COMPLIANCE INVOLVEMENT IN TRIPLE AIM**
  - **ACCOUNTABLE CARE ORGANIZATIONS**
  - **BUNDLED PAYMENTS**
  - **INNOVATIVE FINANCIAL APPROACHES**
  - **NEW PRIMARY CARE MODELS – PATIENT CENTERED HOMES**
  - **SANCTIONS FOR AVOIDABLE EVENTS**
  - **INTEGRATION OF INFORMATION TECHNOLOGY**

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**MOTIVATION**

- **PAY-FOR-PERFORMANCE**
  - **FINANCIAL INCENTIVES TO HEALTH CARE ENTITIES**
  - **MEASURED BY:**
    - **PROCESS MEASURES**
    - **OUTCOME MEASURES**
    - **PATIENT EXPERIENCE**
    - **STRUCTURE MEASURES**

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**MOTIVATION**

- **PATIENT EXPERIENCE & PATIENT SATISFACTION**
  - **STRIVE TO EXCEED PATIENT EXPECTATIONS**
  - **COMPLIANCE OFFICERS SUPPORT PATIENT SATISFACTION**
  - **ROUND UNIT FLOORS TO:**
    - **ENGAGE FRONT LINE STAFF**
    - **EDUCATE FRONT LINE STAFF**
    - **PERFORM HIPAA SAFEGUARD REVIEWS**

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**MOTIVATION**

- **PATIENT EXPERIENCE & PATIENT SATISFACTION**
  - **STRIVE TO EXCEED PATIENT EXPECTATIONS**
  - **COMPLIANCE OFFICERS SUPPORT PATIENT SATISFACTION**
  - **ROUND UNIT FLOORS TO:**
    - **ENGAGE FRONT LINE STAFF**
    - **EDUCATE FRONT LINE STAFF**
    - **PERFORM HIPAA SAFEGUARD REVIEWS**

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VISION, MISSION AND VALUES

**VISION**

Yale New Haven Health enhances the lives of those we serve by providing access to integrated, high-quality, patient-centered care in collaboration with others who share our values.

**MISSION**

Yale New Haven Health is committed to innovation and excellence in patient care, teaching, research, and service to our communities.

**VALUES**

INTEGRITY: Doing the right thing.  
 PATIENT-CENTERED: Putting patients and families first.  
 RESPECT: Valuing all people.  
 ACCOUNTABILITY: Being responsible and taking action.  
 COMPASSION: Being empathetic.

**YALE NEW HAVEN HEALTH**

Bridgeport Hospital | Greenwich Hospital | Yale-New Haven Hospital | Northeast Medical Group

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**LEADERSHIP**

- COMPLIANCE OFFICERS MUST BE LEADERS
- CEOs SET THE TONE OF THE ORGANIZATION
- CEOs HIRE INDIVIDUALS TO LEAD THEIR DEPARTMENT

**BE THE CEO OF YOUR DEPARTMENT**

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**QUESTIONS**

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| <b><u>SPEAKERS</u></b>  |
|---|
| <ul style="list-style-type: none"><li>• <b>FRANK CORVINO</b><ul style="list-style-type: none"><li>• <b>PRESIDENT &amp; CEO GREENWICH HOSPITAL;</b></li><li><b>EXECUTIVE VICE PRESIDENT YALE-NEW HAVEN HEALTH SYSTEM</b></li></ul></li><br/><li>• <b>FAHAD AHMED</b><ul style="list-style-type: none"><li>• <b>COMPLIANCE &amp; PRIVACY OFFICER,</b></li><li><b>BRIDGEPORT &amp; GREENWICH HOSPITAL;</b></li><li><b>DIRECTOR COMPLIANCE &amp; PRIVACY,</b></li><li><b>YALE-NEW HAVEN HEALTH SYSTEM</b></li></ul></li></ul> |

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## Strategies for Successfully Transitioning into a New Compliance Position

Vicki L. Dwyer, MN, CPC, CHC  
Compliance & Privacy Officer  
Vail Valley Medical Center  
Vail, CO

Nancy Kennedy, RHIT, CPC  
Chief Compliance & Privacy Officer  
Galichia Medical Group  
Wichita, KS

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- Understand the significant challenges and stress associated with moving into a new compliance position.
- Learn to develop and define your uniqueness to the role of Compliance Officer to expel the "Ghosts of Compliance Officers Past".
- Identify simple marketing techniques to build or bolster your perceived credibility, reliability and expertise with the Board of Directors, Executive Team, Medical Staff and Employees.

### Objectives

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- Transitioning to New Position / New Location
  - Relocating
  - New Faces
  - Facing the Unknown
- Promotion to New Position / Same Location
  - New Role, New You, New Box
  - Staying Out of Your Comfort Zone
  - Relocating within the Practice

### Challenges, Changes, and Stesses New Position

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- The One That Got Away – The Spirit
  - Away but Close
  - Far, Far, Away
- The One That Didn't Leave – The Presence
  - The Good
  - The Not So Good

**Ghosts of Compliance Officers Past**

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- Where You Excel
  - Government Investigations
  - TJC Surveys
  - Coding
  - Medical Records
  - Compliance
  - Education & Training
    - Physicians
    - Staff
- What You Will Learn

**Marketing – Toot Your Horn LOUDLY**

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- Market Yourself as a Consultant
  - 1 Page Dossier
    - Contact Information
    - Experience in Compliance
    - Education
    - Areas of "Expertise"

**Gaining Respect Up Front**

Tuesday, April 1, 2014  
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**Nancy Kennedy, RHIT, CPC**  
Chief Compliance & Privacy Officer  
Chief Operating Officer  
Office Phone: 316-858-2233  
Cell Phone: 316-619-5731  
[nkennedy@galichia.com](mailto:nkennedy@galichia.com)

**To Make an Anonymous Report:**  
Compliance Hotline: 316-858-2566 or  
1-800-657-7250, ext. 2566  
[compliance@galichia.com](mailto:compliance@galichia.com)

### Here's How You Contact Me

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**Education:**  
Diploma in Nursing – St. Francis School of Nursing  
Bachelor of Science in Nursing – WSU, Wichita  
Masters in Nursing – WSU, Wichita  
Graduate Certificate in Healthcare Corporate  
Compliance – George Washington University

**Experience:**  
Nursing: Registered Nurse – 30+ years (Critical Care , Pediatrics, TJC, QI, Risk  
Management, Staffing, Education)  
Advanced Practice Registered Nurse - Clinical Nurse Specialist – 10+ years  
Adjunct Faculty, WSU School of Nursing 20+ years

**Compliance:** 15+ years as Chief Compliance Officer, Wichita, KS  
Development & Implementation of Comprehensive Compliance Programs  
Government Investigations / Integrity Agreements  
Documentation – Evaluation & Management Services  
Regional and National Speaker on Compliance

**Certifications:** Certified in Healthcare Compliance (CHC)  
Certified Professional Coder (CPC)

### Background and Experience

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### Services Available to Physicians

- Education and Training
  - Documentation of Evaluation & Management Services
  - Procedural Coding and Documentation
  - Anti-Kickback Statutes / Stark Law
  - False Claims Act
  - Patient Inducement Regulations
  - HIPAA / HITECH
- Auditing and Monitoring
  - Evaluation and Monitoring
  - Procedural Coding and Supporting Documentation
  - Compliance with Stark Exceptions & AKS Safe Harbors

### What You Have to Offer

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**Fun Facts:**  
**Family** Children – Jim in Wichita, Amy in Denver  
 Grandsons – Keegan in Wichita (2)  
 Grayden in Denver (3)  
 Parents – Both living in Wichita, KS  
**Pets** 3 cats (Tequila, Trouble & Velvet)  
**Favorite Things** Playing with grandsons, Reading  
 by the fire with a cup of tea and my cats  
**Favorite Colors** Pink and Purple  
**Favorite Food** Prime Rib and Lobster  
**Favorite Movie** Sweet Home Alabama

**The Approachable Person**

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**Fun Facts:**  
**Family** DO NOT DO BABIES!  
 Sister, Niece, Nephew –  
 Best Friend  
**Pets** Cat Kiki  
**Little Known Facts**  
 Competed in Rodeo, Barrel Racing . . . National Rodeo Association  
 2 weeks in New Supervisor of Coding Job when Government came in with  
 Search Warrant (Cousin by Marriage one of the Agents)  
**Favorite Movie Character** The Wicked Witch of the West  
**Favorite Food** Ribeye Steak, well done  
**Favorite Author** Diane Gabaldon

**The Approachable Person**

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- Advisor & Advocate
- “Go-to-Person”
- Visible & Available
  - Physician Meetings
  - Staff Meetings
  - Compliance Coffees / HIPAA Teas
  - Clinical Areas
  - Standing Meetings

**Create a “New” You**

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- Meet (Re-meet) and Get to Acquainted (Reacquainted) with Key People
- Hold "Interviews"
  - What are their expectations
  - What did they like best about the previous Compliance Officer
  - What would they change if they could
  - What do they see as priorities
  - What can you do to make their life easier

**Learning / Relearning the Organization**

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- Take time to Evaluate (Re-evaluate) and Learn (Re-learn)
  - Approach with Fresh Eyes, Open Mind
  - Don't Rush in with Changes
  - Don't Bad-Mouth the Former Compliance Officer or the Existing Program
  - Develop Networks and Resources

**Learning / Relearning the Organization**

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- If It Ain't Not Broken, Don't Fix It (Immediately)
- Learn the Organization from Your New Role
  - Coding
  - Billing
  - Documentation
- Assess and Prioritize
  - Slow and Steady

**Take Baby Steps**

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- Build (don't ~~BURN~~) Your Bridges
  - LISTEN, LISTEN, LISTEN
  - Be a Yay Sayer, NOT a Nay Sayer
  - Know What's Important to the Board, Officers, Leadership Team, Medical Staff, and Staff.
  - One Size DOES NOT fit All
  - Deep Breath, Count to 10, 100, 1000
  - Avoid Conversation Stoppers
  - ALWAYS Follow-Through

**Opening Lines of Communication**

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- Don't be Afraid to Ask
  - How Am I Doing
  - Are We Going in the Right Direction
- Create a Compliance Officer's Report
  - Accomplishment
    - Education & Training
    - Internal Auditing
    - Policies & Procedures
    - Communication Activities
    - Compliance "Fixes"

**Ask for Feedback and Continue to Toot Your Horn**

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A cartoon illustration of a man with spiky hair, looking very confused. He has his hands on his head and a wide-eyed, open-mouthed expression. Several question marks are floating around him. At the bottom of the illustration, the word "QUESTIONS?" is written in a bold, stylized font.

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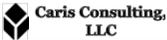
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## Business Associate Satisfactory Assurances

What should you ask for?

Presented By:

- Christine M. Duprey – Caris Consulting, LLC
- Daniel Steiner – Baker Tilly – Virchow Krause, LLP





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2

## Your Presenters

**Chris Duprey, Owner – Caris Consulting, LLC**



- > Has spent the past thirteen years consulting many organizations in the public and private sector through their HIPAA initiatives in assessment, planning and execution.
- > Retained as the Privacy Official for Business Associates and Covered Entities over the past 8 years.
- > Performs business analyses to determine best practice for integrating compliance into your business operations.




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## Your Presenters

**Dan Steiner, Manager  
MBA, CPA, CFE, ARM**



- > Dan Steiner is a Manager in the Baker Tilly Enterprise, Risk and Information Services Group
- > Specializes in enterprise risk management, internal controls, HIPAA compliance, Service Organization Control (SOC) reporting, crisis management, and business continuity planning



Candor. Insight. Results.

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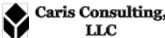
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## Agenda

- History of Business Associates
- Omnibus Updates
- Current State of Compliance and Requirements
- Breaches in the Headlines
- Managing Business Associates




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## Historical Compliance for Business Associates

2000

Covered entity must obtain the written assurances (Business Associate Agreement) – monitoring not required.

2003

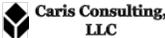
Security finalized, additional requirements for BAA language from Security regulations requires revision to BAA.

2009

ARRA deems the Business Associate just as responsible for the execution of the Business Associate Agreement and applies Civil Monetary Penalties to BA's.

2013

Business Associates are responsible to obtain BAA with their subcontractors. May need to provide or obtain satisfactory assurances that they or their subcontractors are compliant.




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## Omnibus Rule Modifications to Privacy and Security - January 25, 2013

### Privacy

- > Modified the notice of privacy practices
- > Modified the individual authorization
- > Enabled access to decedent information
- > Set limitations on use and disclosure of PHI for Marketing and Fundraising
- > Modified Privacy to incorporate GINA Act requirements
- > Expanded individual rights
- > Business Associates are directly liable, fines and penalties now apply to BA's, BAA Agreements must be updated




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## Omnibus Rule Modifications to Privacy and Security - January 25, 2013

**Security**

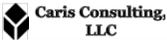
- > Business Associates are directly liable
- > Modifies Security regulations to include business associate requirements of ARRA

**Breach Notification**

- > Final rule on Breach Notification

**Enforcement**

- > Increased and tiered Civil Money Penalties
- > Adopt HITECH Act enhancements to the Enforcement Rule addressing willful neglect





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## Purpose of the Business Associate Agreement

- From the Comments and Responses:
  - 13404 of HITECH Act provides BA are now directly liable for civil money penalties under HIPAA Privacy Rule for impermissible uses and disclosures however; it does not apply all requirements of the Privacy Rule to BA, thus an agreement is still required.
  - Designation of the HIPAA responsibilities based on the functions or activities the BA is performing for or on behalf of the covered entity.
  - Clarify and limit, as appropriate the permissible uses and disclosures by the business associate.
  - Notifies the BA of its status under HIPAA Rules so they are fully aware of their obligations and potential liabilities.
  - Other provisions or requirements that may dictate and describe the relationship.





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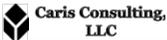
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"You can either run from it or learn from it..."



Walt Disney, Lion King





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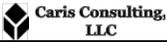
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### Has Behavior been Altered?

- Did the requirement for the Business Associate Agreement alter the relationships between covered entities and business associates?
- Did the implication of Civil and Monetary Penalties alter the behavior of Business Associates?
- Has the concern for compliance become enhanced?




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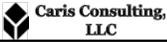
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### Compliance Responsibility

#### 164.504 (e)(1) Standard: Business Associate Contracts

- (i) The contract or other arrangement required by § 164.502(e)(2) must meet the requirements of paragraph (e)(2), (e)(3), or (e)(5) of this section, as applicable.
- (ii) **A covered entity is not in compliance with the standards in § 164.502(e) and this paragraph, if the covered entity knew of a pattern of activity or practice of the business associate that constituted a material breach or violation of the business associate's obligation under the contract or other arrangement, unless the covered entity took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.**
- (iii) A business associate is not in compliance with the standards in § 164.502(e) and this paragraph, if the business associate knew of a pattern of activity or practice of a subcontractor that constituted a material breach or violation of the subcontractor's obligation under the contract or other arrangement, unless the business associate took reasonable steps to cure the breach or end the violation, as applicable, and, if such steps were unsuccessful, terminated the contract or arrangement, if feasible.




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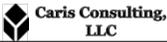
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### Is it a Gotcha or Responsibility?






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### Requirement vs. Responsibility

- Monitoring, Auditing, Oversight, Review – Is it a requirement of the Covered Entity to perform these activities for each Business Associate or a Business Associate to perform these activities for their sub-contractors?
- The simple answer is No, nothing in the rule suggests Monitoring, Auditing, Oversight or Review is required by the Covered Entity or the Business Associate for the relationships they have other than obtaining the written agreement (aka satisfactory assurances).  
So what about the responsibility?



**Requirement**      **Responsibility**

**Caris Consulting, LLC**      **BAKER TILLY**  
Candor. Insight. Results.

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### Compliance Responsibility

164.504 (e)(1) Standard: Business Associate Contracts

- (ii) A covered entity is not in compliance with the standards in § 164.502(e) and this paragraph, if the covered entity knew....
- (iii) A business associate is not in compliance with the standards in § 164.502(e) and this paragraph, if the business associate knew....

**Caris Consulting, LLC**      **BAKER TILLY**  
Candor. Insight. Results.

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### § 160.410 Affirmative defenses.

- (b) For violations occurring prior to February 18, 2009, the Secretary may not impose a civil money penalty on a covered entity for a violation if the covered entity establishes that an affirmative defense exists with respect to the violation, including the following:**
  - (1) The covered entity establishes, to the satisfaction of the Secretary, that it did not have knowledge of the violation, determined in accordance with the Federal common law of agency, and by exercising reasonable diligence, would not have known that the violation occurred; or**
  - (2) The violation is--**
    - (i) Due to circumstances that would make it unreasonable for the covered entity, despite the exercise of ordinary business care and prudence, to comply with the administrative simplification provision violated and is not due to willful neglect; and ...**

**Caris Consulting, LLC**      **BAKER TILLY**  
Candor. Insight. Results.

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16

## Analyzing Definitions

- **Definition of diligence (n)**
- *Bing Dictionary*
  - **dil-i-gence**
  - persistent effort: persistent and hard-working effort in doing something
  - legal carefulness: the care or attention expected by the law in doing something such as fulfilling the terms of a contract
- **Definition of prudent (adj)**
- *Bing Dictionary*
  - **pru-dent**
  - having good sense: having good sense in dealing with practical matters
  - carefully considering consequences: using good judgment to consider likely consequences and act accordingly
  - careful in managing resources: careful in managing resources so as to provide for the future





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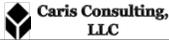
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## What is your Position?



- If I don't ask, I won't know, if I don't know it can't be my fault...they are responsible for their activities under the same rules --- "Is this a "head in the sand approach"? Is it exercising **reasonable diligence**? Or **ordinary business care and prudence**?
- Understanding your risk, evaluating the abilities of your vendors and ensuring proper controls are in place protects your risk and your "castle"!



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## Balancing the Risk with Satisfactory Assurances

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|---|--|
| <p><b>Which functions will the BA perform for or on the CE's behalf?</b></p> <p>Receiving, accessing, creating, modifying, storing or transmitting data</p>   | <p><b>What level of exposure to PHI would there be?</b></p> <p>Unauthorized use or disclosure;<br/>Increased risk of breach due to lack of security controls around data;<br/>Potential Security Incident due to lack of encryption surrounding data in use, at rest and in motion</p> |
| <p>Type of Business Associate / Vendor</p>  |  |
| <p><b>Risk Associated to the Exposure of PHI:</b></p> <p>Reputational Risk to the Covered Entity/Business Associate<br/>Personal and financial impacts to members, patients or customers<br/>Loss of Business</p> | <p><b>Commitment of the Vendor for Compliance</b></p> <p>Signed the BA Agreement;<br/>Indicates Policies and Procedures are in place<br/>Training for employees<br/>Data Security Controls<br/>Security Risk Assessments conducted annually</p>  |





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## Breaches in the Headlines

- In January, Howard University Hospital (HUH) discovered that a contractor's vehicle had been broken into and a laptop that held patients' EPHI taken. A total of 34,503 patients' information was stolen.
- A September 2011 breach affecting 4.9 million individuals involving Science Applications International Corp., a business associate of TRICARE, the military health program;
- A December 2010 incident affecting 1.7 million patients involving New York City Health and Hospitals Corp. and its business associate, GRM Information Management;
- A March 2012 breach that compromised data of 780,000 individuals and involved the Utah Department of Health and its business associate, the Utah Department of Technology.

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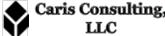
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## Healthcare Data Breach Numbers

- 24 million ePHI records compromised between 2009 and 2013
- 730 incidents reported during the same period
- Business associates accounted for approximately a quarter of these incidents
- Each incident averaged approximately 40,000 records compromised in 2013
- Nearly half of all incidents result from theft with unauthorized access/disclosure and individuals losing data coming in second and third respectively
- Hacking is a relatively small amount with approximately 20 per year

Reference: <http://securityintelligence.com/healthcare-data-breach-numbers/>

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## Managing Third Party Relationships

- Planning
  - Defining strategic purpose
  - Understanding relationship complexity
  - Security and confidentiality implications
- Due diligence and third party selection
  - Past breach occurrences
  - SOC 1/SOC 2
- Contract negotiation
- Ongoing monitoring
- Termination

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22

Vendor Type → IT Company

| Vendor Responsibilities   | Potential Risk   | Satisfactory Assurance Suggestions  |
|---|--|---|
| Network Administrator<br>• Access to data<br>• Transmission of data | • Malicious software<br>• Hacking<br>• Unauthorized access to the data | • Security Risk Assessment<br>• Compliance Calendar<br>• Patching Policy and Schedule   |
| Server Maintenance<br>• Access to data<br>• Storage of data         | • Compromised data<br>• Security Incidents                             | • Business Continuity / Disaster Recovery   |
| Troubleshooting – Help Desk<br>• Access to data                     | • Unauthorized Access  | • Access and Audit Controls<br>• Security Incident Policy   |
| Data Storage and Maintenance  | • Unauthorized Access<br>• Compromised Data<br>• Security Incidents    | • Access and Audit Controls<br>• Security Maintenance<br>• Encryption for data in motion, data at rest and data in use<br>• Business Continuity / Disaster Recovery<br>• Security Incident Policy |




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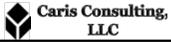
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Analyzing the Assurances

| Satisfactory Assurance                 | Documentation   | What to look for in the documentation   |
|--|---|---|
| Security Risk Assessment               | • Summary of the Risk Assessment Results<br>• Scan results<br>• Vulnerabilities | • Consistent Assessments have been completed<br>• High level risks and potential threat or vulnerability identified and remediation has been planned or completed<br>• Quarterly scan results on network activity |
| Compliance Calendar                    | • Schedule of compliance events<br>• Training curriculum                        | • Dates assigned for table top testing of disaster recovery<br>• Planned security assessments<br>• Scheduled scans or updates<br>• Annual training  |
| Patching Policy and Schedule           | • Patching Policy   | • Is it appropriate for the activities they are performing on your behalf?  |
| Business Continuity/ Disaster Recovery | • Contents of the BC/DR plan<br>• Testing format<br>• Testing results           | • Framework for the BC/DR plan<br>• Escalation Process<br>• Recovery Process<br>• Assessment and Assignment   |




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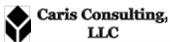
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Vendor Type → Billing Company/ Clearinghouse

| Vendor Responsibilities   | Potential Risk  | Satisfactory Assurance  |
|---|---|---|
| Conversion and transmission of claim files in compliant formats | • Vendor not current with most up to date format changes and requirements<br>• Delay in claim transmission<br>• Timely filing issues<br>• Loss in Revenue | • Updates on ICD-10 capabilities<br>• Format Acceptance<br>• Testing results<br>• Timeframes to meet regulatory deadlines<br>• Prevention plan for delays or loss of revenue during transition to new formats |
| Storage and Maintenance of claim file data                      | • Unauthorized Access<br>• Potential Security Incident<br>• Potential breach  | • Encryption standards<br>• Data back up and storage policies<br>• Risk Assessment results  |
| Staff Training  | • Lack of staff preparedness  | • Curriculum outline  |




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### Analyzing the Assurances

| Satisfactory Assurance                  | Documentation   | What to look for in the documentation  |
|---|---|--|
| Updates on ICD-10 compliance            | <ul style="list-style-type: none"> <li>Position paper</li> <li>Timeline for Testing and Implementation</li> </ul>   | <ul style="list-style-type: none"> <li>Organization dedication to meeting the compliance deadlines</li> <li>Transition plan from ICD-9 to ICD-10</li> <li>Plan for organizations that do not hit the date for receiving ICD-10 format after the compliance date</li> </ul> |
| Format Testing                          | <ul style="list-style-type: none"> <li>Format Acceptance Test results</li> </ul>  | <ul style="list-style-type: none"> <li>Readiness to accept and transmit compliant 5010 format with ICD-10 coding</li> </ul>  |
| Prevention of delays or loss to revenue | <ul style="list-style-type: none"> <li>Position paper on the transition plan to minimize the delay or loss in revenue due to lack of preparedness in the industry for the new formats.</li> </ul> | <ul style="list-style-type: none"> <li>Dual operation plans for providers or health plans not ready for the compliance changes</li> </ul>  |




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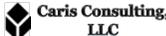
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### Vendor Type Third Party Administrator (TPA)

| Vendor Responsibilities   | Potential Risk  | Satisfactory Assurance   |
|---|---|--|
| Delegation of ALL Health Plan Activities: <ul style="list-style-type: none"> <li>Claims Adjudication</li> <li>Risk Analysis and Actuarial support</li> <li>Customer Service</li> <li>Appeals</li> <li>Enrollment / Disenrollment</li> <li>Underwriting</li> </ul> | <ul style="list-style-type: none"> <li>Non-compliance</li> <li>Willful Neglect</li> <li>Breach</li> <li>Security Incidents</li> <li>Misuse and disclosure</li> <li>Unauthorized Access</li> </ul> | <ul style="list-style-type: none"> <li>Plan Sponsor Document</li> <li>Risk Assessment Documentation</li> <li>Network Scan results</li> <li>Policy and Procedure Manual – Contents</li> <li>Notice of Privacy Practices</li> <li>Acknowledgement</li> <li>Authorization for the Release of PHI</li> <li>Business Associate Listing</li> <li>Attestation to compliance activities</li> </ul> |




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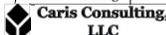
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### Analyzing the Assurances

| Satisfactory Assurance                 | Documentation  | What to look for in the documentation  |
|--|--|--|
| Plan Sponsor Document                  | <ul style="list-style-type: none"> <li>Actual document</li> </ul>                | <ul style="list-style-type: none"> <li>Language modifications are completed, re-distribution has occurred</li> </ul>   |
| Risk Assessment Documentation          | <ul style="list-style-type: none"> <li>Summary of Security Assessment</li> </ul> | <ul style="list-style-type: none"> <li>Review of the high risks identified and remediation plans to mitigate the risks identified</li> </ul>   |
| Network Scan results                   | <ul style="list-style-type: none"> <li>Scan results</li> </ul>                   | <ul style="list-style-type: none"> <li>Risks to the Network that could allow unauthorized access or breach opportunities for malicious software</li> </ul>   |
| Policy and Procedure Manual – Contents | <ul style="list-style-type: none"> <li>Table of contents</li> </ul>              | <ul style="list-style-type: none"> <li>Determine whether or not the necessary policies and procedures have been addressed</li> <li>Attestation that privacy and security standards and implementation specifications of documentation have been completed</li> </ul> |
| Notice of Privacy Practices            | <ul style="list-style-type: none"> <li>Copy of the Notice</li> </ul>             | <ul style="list-style-type: none"> <li>Language modifications, distribution or posted updates to the website</li> </ul>  |
| Business Associate Listing             | <ul style="list-style-type: none"> <li>Attestation</li> </ul>                    | <ul style="list-style-type: none"> <li>Attestation that all BA's have been contracted with updated language</li> </ul>   |




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### Summary

- Everybody is struggling to keep their head above the water with the compliance requirements...
- Throw yourself a life preserver and ask for the additional satisfactory assurances that may put you at ease.



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Candor. Insight. Results.

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### Contact info slide

Chris Duprey  
Caris Consulting, LLC  
[chris@carisinnovation.com](mailto:chris@carisinnovation.com)  
920-639-6615

Dan Steiner  
Baker Tilly  
[Daniel.Steiner@BakerTilly.com](mailto:Daniel.Steiner@BakerTilly.com)  
608-220-5528

**Caris Consulting, LLC**

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## Turning Coal into Gold: Assessing and Tracking Risk Mitigation to Improve Operations

HCCA Compliance Institute  
San Diego CA

LYNDA HILLIARD, CHC, CCEP  
CONSULTANT

SHERYL VACCA, CHC-F, CHRC, CHPC, CCEP-F, CCEP-I  
UNIVERSITY OF CALIFORNIA

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## Presentation Objectives

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The participant will be able to:

- List methodologies to effectively identify compliance risks
- Outline strategies to aggregate risks into a dynamic risk profile
- List key “markers” for tracking the progress of identified risk mitigation to value-add process improvement

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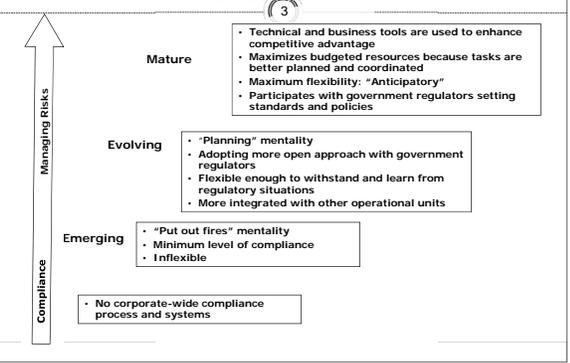
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## Compliance Program Maturity Determination: Tool in Determining Applicable Risks

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**Definitions** 4

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**Effectiveness**

- “producing a decided, decisive, or desired effect . . . capable of producing a result.”
- “the extent to which the outcomes of an activity achieve its stated objectives.”

**Process Indicators**

- Measurements that depict an organization’s completion of a specific goal or objective that may be one element of a larger outcome, e.g., implementation of a policy.

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**Definitions** 5

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**Outcome Indicators**

- Measurements that depict an organization’s achievement of a goal or objective that are based upon the output of a process, e.g., decreased billing errors and repayments;

**Risk Profile**

- Compilation of prioritized compliance risks of an organization that is measured through assessments, interventions, and ongoing audit and monitoring.

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**Identifying Compliance Risks** 6

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**Methodologies to Identify Risk**

**Internal Sources**

- Interviews
- Surveys
- Review of documents, e.g., internal/external audits, compliance matters reported-trends
- Testing of compliance controls

**External sources**

- Enforcement actions
- Announced enforcement priorities
- New regulations/laws
- Market considerations and activity

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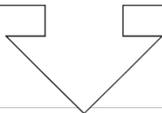
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### Key Objectives of a Risk Assessment

- ✓ Identify and manage compliance risks and gaps proactively
- ✓ Prioritize limited resources to ensure efforts are focused on the most significant risks
- ✓ Inform senior management of most significant compliance risks



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### Key Objectives of a Risk Assessment (CONT)

- ✓ Meet government regulators expectations (e.g., FSG, OIG, CMS, FDA, others).
- ✓ Prioritize and allocate audit resources
- ✓ Inform business decisions (M&A, product launches, geography expansions, etc.)

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### Risk Assessment Considerations

- This exercise should be meaningful for risk identification.
- The scope of this risk assessment should be defined clearly for the organization.
- Documentation of findings and prioritizing risks will add to effective implementation and management of risk assessment process.
- Risks identified will be prioritized for further action.
- Compliance plays the role of oversight through monitoring, auditing, follow-up and reporting related to management's action plan that are implemented to mitigate risks.

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**Analyze Risks That Have Been Identified**

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- > Question should be asked as to how risks may affect the business (e.g., which affect regulatory status, reputation, can lead to prosecution, etc.)
- > Is it a known risk and even though it may occur in your industry, has management done everything they can to “manage” the risk? Ie: inherent risks managed as best they can be, controls in place

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**Analyze Risks That Have Been Identified**

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- > Look at information collected...trends, themes, inaction evident, transition of leadership, new products, etc.?
- > Risks identified can be grouped in common themes to help ease the load of the prioritization, ie: code of conduct sections such as confidentiality/privacy, protection of intellectual property, protection of company assets, etc.

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**Risk Assessment: Prioritizing Risks**

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**Risk Likelihood:** Probability that a risk can occur. Factors taken into account in the determination of likelihood are:

- Source of the threat,
- Capability of the source,
- Nature of vulnerability and
- Existence and effectiveness of current controls.

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## Risk Assessment: Prioritizing Risks

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**Risk Ranking:** use you can use a high, medium and low OR numbers such as 1-5 method of ranking.

- o **High:** An event is expected to occur in most circumstances
- o **Medium:** An event will probably occur in many circumstances
- o **Low:** An event may occur at some time

Source: World Intellectual Property Organization; [http://www.wipo.int/about-wipo/en/oversight/audit/risk\\_assessment.html](http://www.wipo.int/about-wipo/en/oversight/audit/risk_assessment.html)

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## Map Risk Assessment Findings & Prioritize: Define Criteria For High, Medium, and Low

|        | Reputation  | Legal/Regulatory   | Financial  |
|--------|---|--|--|
| High   | Systemic loss of public/client confidence resulting in loss of customers; major media coverage - headline news for several days | Major infraction resulting in criminal or civil prosecution and/or significant discipline; loss of ability to operate in one or more countries | Significant financial impact with widespread liability |
| Medium | Loss of confidence among large number of customers and a segment of the general public; major media coverage for 1-2 days       | Infraction resulting in civil prosecution and/or discipline; loss of ability to operate within local jurisdiction                              | Considerable financial impact with regional liability  |
| Low    | Loss of confidence among a limited number of customers in local market/country; limited local media coverage                    | Minor infraction that is readily remediated; no loss of ability to operate   | Minimal financial impact with localized liability      |

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## Risk Profile (Priorities listing)\*

\*combination of all risks, not necessarily just compliance

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| Risk Area                       | High | Med | Low | Mgmt Action |  |
|---------------------------------|------|-----|-----|-------------|--|
| Physician Relations             |      |     |     |             |  |
| Safety                          |      |     |     |             |  |
| Third Party Contracts           |      |     |     |             |  |
| Add Other Risk Profile elements |      |     |     |             |  |

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### Next Steps

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- Review Identified Compliance Risks
- Determine Outcome Indicators (example)
  - Discrimination/EEO Issue:
    - Increased Sexual Harassment/Discrimination Claims
    - Non-compliance to mandatory education
    - Lack of enforcement
    - High cost of legal services and/or payouts
- Assign weight to outcomes measures
- Recalculate risk ranking
- Calculate "risk" for internal risk profile

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### Compliance Risk Ranking: Program Design, Culture and Identified Risks

| Campus/Location | Campus/Location Ethics & Compliance Program Structure and Reporting Relationships |     |     |     |     |     |     |     |     |     | Campus/Location Compliance "Culture" Measurements |     |     |     |     |     |     |     |     |     | Campus/Location Key Potential Compliance Risks |     |     |     |     |     |     |     |     |     | Overall Risk Rating |
|-----------------|---|-----|-----|-----|-----|-----|-----|-----|-----|-----|---|-----|-----|-----|-----|-----|-----|-----|-----|-----|--|-----|-----|-----|-----|-----|-----|-----|-----|-----|---------------------|
|                 | ...   | ... | ... | ... | ... | ... | ... | ... | ... | ... | ...   | ... | ... | ... | ... | ... | ... | ... | ... | ... | ...  | ... | ... | ... | ... | ... | ... | ... | ... | ... |                     |
| 1               | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓  | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | 0.5                 |
| 2               | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓  | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | 0.5                 |
| 3               | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓  | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | 0.7                 |
| 4               | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓  | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | 0.6                 |
| 5               | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓  | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | ✓   | 0.8                 |

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### Measuring Risk Intelligence

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**Illustrative**

1. How capable is your company today to manage its risk profile?  
2. Is compliance integrated into the risk infrastructure?

**Stakeholder Value** (y-axis) vs **Risk Management Capability** (x-axis)

**Tribal & Heroic** | **Specialist Silos** | **Top Down** | **Systemic Risk Management** | **Risk Intelligent**

**Risk Intelligent Description**

- Embedded in strategic planning, capital allocation, product development, etc.
- Early-warning risk indicators
- Linkage to performance measurement/ incentives
- Risk modeling/scenarios
- Industry benchmarking

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### Tracking Mitigation Efforts

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| Risk Area             | High | Med | Low | Acct Person        | Mgmt Action                            | Risk Status Update*   |
|-----------------------|------|-----|-----|--------------------|--|---|
| Physician Relations   |      |     |     | John Smith, legal  | Education Monitor Policy               | Mitigation efforts decreases risk, +/- might change culture |
| Safety                |      |     |     | Sarah Stumble EH&S |  |   |
| Third Party Contracts |      |     |     |                    | Revise format Education Rewrite policy |   |

\* timeframe should be established for updates: quarterly, monthly, biannually

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### Aggregating Risk Profile Data

| Mission & Objectives   | Risk Assessment  | Prioritize and Plan  | Audit and Monitoring Activities   | Reporting on Risk Profile and Outcomes Measures  |
|--|--|--|---|--|
| <ul style="list-style-type: none"> <li>• Identify key high compliance risk areas relating to regulatory requirements</li> <li>• <i>What is your organization's vulnerability to risk occurring?</i></li> </ul> | <ul style="list-style-type: none"> <li>• Prioritize Risks</li> <li>• Evaluate Implementation Plans</li> <li>• Compliance with Applicable Rules and Regulations</li> <li>• <i>What is currently being done to prevent, detect, correct, or escalate risk?</i></li> <li>• <i>Other data to consider, i.e.: HR, risk management, legal</i></li> </ul> | <ul style="list-style-type: none"> <li>• Management Controls</li> <li>• Identify process indicators that link to planned outcomes</li> <li>• <i>What further actions are required to cost effectively mitigate value at risk?</i></li> </ul> | <ul style="list-style-type: none"> <li>• Best Practices/ Benchmarks</li> <li>• Assessment Checklists</li> <li>• Ongoing monitoring</li> <li>• Re-evaluating risk rankings</li> <li>• <i>How do we get reasonable assurance that existing mitigation is reliable and effective?</i></li> <li>• Monitor risk profile</li> </ul> | <ul style="list-style-type: none"> <li>• Recommendations</li> <li>• Performance Assessment</li> <li>• <i>Reporting assurance that risk is mitigated - outcome measure</i></li> </ul> |

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### Summary

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- Risk assessment processes, which are meaningful and inclusive of all disciplines, provide one of the best ways to help an organization identify its risk
- Aggregation of risks identified needs a qualitative/ quantification system to help prioritize those risks in a dynamic fashion, ie: high, med, low, reputational, financial, point systems, etc.
- Risk profiles are dynamic and need periodic review to assure the organization is focusing on the right risks.
- All risk mitigation activity should be reviewed for closure and potential re-prioritization.
- Key "markers" for tracking the progress of identified risk mitigation to value-add process improvement are important to identify in a method that is measurable and objective.

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# Questions

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FOR FURTHER INFORMATION

[SHERYL.VACCA@UCOP.EDU](mailto:SHERYL.VACCA@UCOP.EDU)  
[LYNDAHILLIARD@HOTMAIL.COM](mailto:LYNDAHILLIARD@HOTMAIL.COM)

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**RUTGERS**  
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School of Osteopathic Medicine

**Walking the Straight and Narrow Between Requirements of IRB Protocols and Compliance with HIPAA**

**Julie Kligerman, Esq.**  
Associate Counsel for Health Services  
Office of General Counsel  
Rowan University

**Donna Hoagland, BS, CHRC, CIP, CCRC**  
Director, Institutional Review Board Director  
Rutgers Biomedical Health Sciences  
Rutgers, The State University

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**HIPAA**

- Health Insurance Portability and Accountability Act
- 45 C.F.R. 164.501 et. seq.

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**Definition of Protected Health Information**

- Individually identifiable health information, held or maintained by a covered entity or its business associates acting on behalf of the covered entity, that is transmitted or maintained on any form or medium.

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Definition of Protected Health Information (cont'd)

- PHI includes identifiable health information relating to past, present, or future physical or mental health or condition of any individual

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18 Components of Identifiable Information

- 1. Names
- 2. Geographical addresses smaller than a state: street address, city, county. In well populated areas: last two digits of zip code; in less populated areas: entire zip code.
- 3. Dates: birth date, admission date, discharge date, date of death (years are not considered identifiable), except all dates including years for those over 89 years old are considered identifiable
- 4. Telephone numbers

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18 Components of Identifiable Information (cont'd)

- 5. Fax numbers
- 6. Email addresses
- 7. Social security numbers
- 8. Medical record numbers
- 9. Health Plan Beneficiary numbers
- 10. Account numbers
- 11. Certificate/license numbers
- 12. Vehicle IDs including serial and license plate numbers

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**18 Components of Identifiable Information (cont'd)**

- 13. Device IDs and Serial numbers
- 14. Web Universal Resource Locators (URLs)
- 15. Internet Protocol address numbers (IP)
- 16. Biometric IDs, such as finger prints and voice prints
- 17. Full face photos and comparable images
- 18. Any other uniquely identifying number, characteristic, or code

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**Institutional Review Board (IRB)**

- The Institutional Review Board is a committee whose responsibility is to protect the rights and welfare of research subjects.
- Guided by Federal and State Regulations
  - Food and Drug Administration (FDA)
    - o Title 21 Food & Drugs
  - DHHS: Office of Human Research Protection (OHRP)
    - o 45CFR46
  - Applicable State Laws

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**IRB Responsibilities**

**45 CFR 46.111 Criteria for IRB Approval of Research**

1. Risks to subjects are minimized
2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
3. Informed Consent will be sought from each prospective subject or the subjects legally authorized representative
4. Informed Consent will be appropriately documented
5. When appropriate there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

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### How does the IRB protect PHI

By assuring that 45 CFR 46.111 criteria are satisfied:

- By requiring the researcher use de-identified data whenever feasible
- By requiring the researcher obtain the subjects informed consent and HIPAA authorization when practicable
- By requiring the researcher use a Limited Data Set and a Data Use Agreement when Informed Consent and HIPAA Authorization will not be obtained from the subject, and, a Limited Data Set is necessary to conduct the research
- By requiring the researcher justify and obtain a Waiver of Informed Consent and a Waiver of HIPAA Authorization whenever the subjects Informed Consent and HIPAA Authorization are not obtained

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### Authorizations to Release PHI for Research

- Plain language
- Specific description of PHI that can be disclosed
- Description of purpose of the disclosure, specifically related to research study
- Who specifically can make disclosure of PHI-names and classes of persons
- Who specifically can receive disclosed PHI-names and classes of persons

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### Authorizations to Release PHI for Research (cont'd)

- Expiration of Authorization
  - Date
  - Event "end of research"
  - None "can be used to create and maintain database"
- Right to Revoke (excepting use of PHI disclosed before revocation)
- Description of relationship between authorization and receipt of treatment, payment, benefits
- Potential for PHI to be re-disclosed by recipient
- Signature and date
- Reminder: Distinction between Informed Consent for research and Authorization for release of PHI

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**Waivers and Alterations of HIPAA Authorizations in Research Context**

- 45 C.F.R. 164.512 i
- Must be approved by IRB or Privacy Board as long as:

-Use of PHI involves no more than minimal risk to privacy of individuals

-Research is not practicable to conduct without alteration or waiver

-Research is not practicable to conduct without PHI

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**Conditions for Waivers**

- Privacy risks to individuals are reasonable in relation to anticipated benefits, to individual, if any, and importance of knowledge expected from research
- Adequate plan to protect identifiers
- Written assurances that PHI will not be used or disclosed to any other entity

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**No Authorization Required**

- All 18 identifiers are stripped
- Research on decedents
- Data Use Agreements
- Activities preparatory to research

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### Data Use Agreements

- Are available only when the PHI includes only city, state, ZIP code, elements of date, numbers, characteristics or codes which are not direct identifiers and does NOT include any other component of identifiable information. ("Limited Data Set")
- Must describe the intended recipient of the information, the purpose for which data disclosure and the ways the information will be used consistent with the purpose, and the ways the information will be protected

**Decedents**  
**Activities Preparatory to Research**

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### Coordination of Activities Related to HIPAA

Structure of University of Medicine & Dentistry Prior to Integration  
(Integrated with Rutgers, The State University & Rowan University on July 1, 2013)

- Office of Human Subjects Protection Program
  - 3 Separate Campus IRB's
    - New Brunswick/Piscataway 4 committees
      - » Donna Hoagland, IRB Director
    - Newark 4 committees
    - Stratford 1 committee
  - Also functioned as the Campus HIPAA Privacy Board
- Office of Ethics and Compliance
  - HIPAA Privacy Officer
- Office of Legal Management
  - Stratford Director of Legal Management serving as IRB Legal Counsel
    - Julie Kligerman, Esq.

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### Case Study

- Our Human Subjects Protection Program (HSPP) received a complaint from a potential subject's husband alleging that his wife received several unsolicited, medically targeted mailings and telephone calls from a physician
- This complaint suggested that his wife was not a patient of the physician, and that since her clinical data had clearly been obtained from the Electronic Medical Record without her consent, her PHI had been unethically used to recruit her for a study.
- The IRB Executive Committee reviewed the allegation and the IRB file and requested a for cause audit by the Universities HSPP

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**Case Study (cont'd)**

**Study file specifics:**

- Minimal Risk Retrospective Chart Review
- Investigators:
  - UMDNJ Faculty as Principal Investigator
  - Co-Investigators from outside University:
    - Student (PHD candidate)
    - Faculty (Dissertation Committee Chair)
  - UMDNJ is the covered entity
    - UMDNJ patients Protected Health Information
  - Purpose was to test a new method for detecting non-adherence to long-term treatments required for chronic illness management and prevention

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**Case Study (cont' d)**

IRB Approved Subject Recruitment Plan:

- Recruitment letters given to patients waiting in the General Internal Medicine (GIM) waiting room and/or mailed to the patients at their homes.
  - letter would include a post card to be mailed back if subjects wished to be contacted with more information
- Flyers posted at UMDNJ that provided a telephone number to call for additional information
- Provider participants
  - other GIM physicians who would invite their patients to participate during their clinic visits

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**Case Study (cont' d)**

IRB Requested For Cause Audit:

**Recruitment process**

- identify how the PI obtained the list of subjects and from whom
- identify who had access to the list
- identify how the mailing occurred and by whom

**Protected Health Information (PHI)**

- identify if there was any inappropriate contact with the subjects
- identify if personal identifiers along with health information was transferred from UMDNJ to outside University prior to obtaining subject consent
- evaluate the tracking system for subject responses to the invitation letters

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**RUTGERS**  
BIOMEDICAL AND HEALTH SCIENCES

**Rowan University**  
School of Osteopathic Medicine

**Case Study (cont' d)**

For Cause Audit Findings:

- The recruitment process described by the investigator and co-investigator during the audit interviews did not match the IRB approved protocol
- Based upon documents reviewed during the audit, the interview process that occurred did not match the IRB approved protocol
- A co-investigator removed personal identifiers and health information from the covered entity in order to prepare the mailings at an Outside University prior to subject informed consent being obtained

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**RUTGERS**  
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**Rowan University**  
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**Case Study (cont' d)**

Initial IRB Determination:

- Suspend Research Activities
  - Require the PI provide a written response to the audit report and attend a meeting to discuss the matter
- Refer the matter to the UMDNJ Office of Compliance for further investigation and appropriate action due to issues related to HIPAA

As a result of the suspension, the Office of Human Subjects Protection (OHRP) was notified

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**Case Study (cont' d)**

Final IRB Determination:

- Revoke suspension of the protocol
  - Violations noted in the audit report did not meet the criteria for serious or continuing non-compliance
- Use of Data/Re-consent
  - Subjects data could be included in the full data set without requiring re-consent
- Requirements for future submissions
 

Protocols for all future studies must include a detailed description of how any students involved in the study will be mentored and supervised to ensure they comply with the protocol approved by the IRB

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**RUTGERS**  
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**Rowan University**  
School of Osteopathic Medicine

**Overlap Between Requirements of IRB  
Protocols and Compliance with HIPAA**

**Institutional Review Board (IRB)**

- Office of Human Research Protection (OHRP)
  - o 45CFR46
- Applicable State Laws

**HIPAA Privacy Board / HIPAA Privacy Officer**

- Office of Civil Rights (OCR)
  - o 45 C.F.R. 164.501 et. Seq

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**RUTGERS**  
BIOMEDICAL AND  
HEALTH SCIENCES

**Rowan University**  
School of Osteopathic Medicine

**Questions**

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# SAMPLE AUTHORIZATION LANGUAGE FOR RESEARCH USES AND DISCLOSURES OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION BY A COVERED HEALTH CARE PROVIDER

## Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

### REQUIRED ELEMENTS:

If you sign this document, you give permission to [name or other identification of specific health care provider(s) or description of classes of persons, e.g., all doctors, all health care providers] at [name of covered entity or entities] to use or disclose (release) your health information that identifies you for the research study described here:

[Provide a description of the research study, such as the title and purpose of the research.]

The health information that we may use or disclose (release) for this research includes [complete as appropriate]:

[Provide a description of information to be used or disclosed for the research project. This may include, for example, all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.]

The health information listed above may be used by and/or disclosed (released) to:

[Name or class of persons involved in the research; i.e., researchers and their staff\*]

[Name of covered entity] is required by law to protect your health information. By signing this document, you authorize [name of covered entity] to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

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\* Where a covered entity conducts the research study, the Authorization must list ALL names or other identification, or ALL classes, of persons who will have access through the covered entity to the protected health information (PHI) for the research study (e.g., research collaborators, sponsors, and others who will have access to data that includes PHI). Examples may include, but are not limited to the following:

- Data coordinating centers that will receive and process PHI;
- Sponsors who want access to PHI or who will actually own the research data; and/or
- Institutional Review Boards or Data Safety and Monitoring Boards.

If the research study is conducted by an entity other than the covered entity, the authorization need only list the name or other identification of the outside researcher (or class of researchers) and any other entity to whom the covered entity is expected to make the disclosure.



Please note that [include the appropriate statement]:

- You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment.  
**(When the research involves treatment and is conducted by the covered entity or when the covered entity provides health care solely for the purpose of creating protected health information to disclose to a researcher).**
- [Name of covered entity] may not condition (withhold or refuse) treating you on whether you sign this Authorization.  
**(When the research does not involve research-related treatment by the covered entity or when the covered entity is not providing health care solely for the purpose of creating protected health information to disclose to a researcher)**

Please note that [include the appropriate statement]:

- You may change your mind and revoke (take back) this Authorization at any time, except to the extent that [name of covered entity(ies)] has already acted based on this Authorization. To revoke this Authorization, you must write to: [name of the covered entity(ies) and contact information].  
**(Where the research study is conducted by an entity other than the covered entity)**
- You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, [name or class of persons at the covered entity involved in the research] may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to: [name of the covered entity(ies) and contact information].  
**(Where the research study is conducted by the covered entity)**

This Authorization does not have an expiration date [or as appropriate, insert expiration date or event, such as "end of the research study."]

\_\_\_\_\_  
Signature of participant or participant's  
personal representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of participant or  
participant's personal representative

\_\_\_\_\_  
If applicable, a description of the  
personal representative's authority to  
sign for the participant



# DATA USE AGREEMENT FOR A LIMITED DATA SET

## Part A – Study Information

- 1. Protocol Title:**
- 2. The Limited Data Set contains the following elements of Protected Health Information** [list all such information and data elements in a specific and meaningful fashion (e.g., results of blood tests, data from survey, test results from MRI, related conditions, all records relating to diabetes)]:
- 3. Recipient-Investigator agrees to use the Limited Data Set solely for conduct of the following research entitled** (provide complete title of the research project):
- 4. The purpose of this research is to** (provide complete description of the purpose of the research project):
- 5. Recipient-Investigator agrees to use the Limited Data Set solely in the following manner** (provide complete description of all proposed uses of the data set):
- 6. Recipient-Investigator agrees to limit access to the Limited Data Set to the following individuals or classes of individuals** (provide complete list of all individuals, or classes of individuals, who will access the Limited Data Set):
- 7. Recipient-Investigator agrees to take the following actions and/or institute the following controls to prevent unauthorized use or disclosure of the Limited Data Set** (provide complete description of such measures):

## Part B – Conditions and Stipulations

Recipient-Investigator further agrees to the following conditions and stipulations:

1. The Limited Data Set information will not be used or further disclosed other than as permitted by this Agreement or as otherwise required by law.
2. Appropriate safeguards will be implemented as described above to prevent use or disclosure of the Limited Data Set information other than as provided for by this Agreement.
3. The Limited Data information set will not be re-identified.
4. Individual(s) whose information is contained in the Limited Data set will not be contacted.
5. The Protected Health Information contained in the Limited Data set represents the minimum necessary for the research purposes described above.
6. Upon learning of any use or disclosure of information not provided for by this Agreement, such unauthorized use or disclosure will be reported to the covered entity releasing the information.
7. Any individuals or organizations, including subcontractors, to whom the Limited Data Set is provided, must first agree to the same restrictions and conditions set forth in this Agreement.





# UNIVERSITY POLICY

**SUBJECT:** RESEARCH

**TITLE:** HUMAN SUBJECTS RESEARCH:  
PROTECTION OF HUMAN SUBJECTS

**CODING:** 00-01-05-10:10

**ADOPTED:** 11/01/95

**AMENDED:** 04/18/06

**LAST REVIEWED:** 04/18/06

## I. PURPOSE

To set University policy that will ensure, through the University’s Human Subjects Protection Program (HSPP), that human subjects research (1) conducted by UMDNJ faculty, staff, house officers, students or other agents, **or** (2) conducted on UMDNJ premises, **or** (3) otherwise conducted under UMDNJ auspices, is conducted in conformance with all applicable Federal, State and other regulations (including 45 CFR 46,164 and 21 CFR 50, 56), and with the Federal Wide Assurances (FWAs) filed by the University with the Office for Human Research Protections (OHRP). The University’s mission includes dedication to the pursuit of excellence in research, including human subjects research; the broader purpose of this policy is therefore to foster and help ensure the ethical conduct of and the attainment of excellence in human subjects research.

## II. ACCOUNTABILITY

Under the direction of the President and the Executive Vice President for Academic and Clinical Affairs, the Vice President for Academic Affairs, the Deans and the Executive Director of Human Subjects Protection shall ensure compliance with this policy, and the Research Deans, Campus Institutional Review Board (IRB) Chairs and Campus IRB Directors shall implement this policy through the University’s HSPP. The Executive Director of Human Subjects Protection shall implement the HSPP, which includes education and training, IRB review, and monitoring of approved research. The Executive Vice President for Academic and Clinical Affairs or designee shall be the University’s Institutional Official under the University’s three FWAs.

## III. APPLICABILITY

This policy shall apply to (1) human subjects research sponsored by UMDNJ; (2) human subjects research directed or performed by any UMDNJ faculty, housestaff, other employee, student, volunteer or other agent in connection with his or her institutional responsibilities or educational program, whether or not the research is carried out on UMDNJ premises; (3) human subjects research conducted by any individual, regardless of institutional affiliation, using any property or facility of UMDNJ; and (4) human subjects research using UMDNJ’s non-public information to identify or contact human research subjects or prospective subjects, regardless of affiliation of investigator or location of the research. This policy shall apply to all such research, regardless of sponsorship or if the research is unsponsored. Only a UMDNJ IRB has the authority to make a final determination of exemption of research from further review.

## IV. REFERENCES

- A. Records Management [00-01-10-50:00](#)
- B. Standards for Privacy of Individually Identifiable Health Information [00-01-15-05:00](#)
- C. Access of Individuals to Protected Health Information [00-01-15-10:00](#)

|    |  |                                |
|----|--|--------------------------------|
| D. | Uses and Disclosures of Health Information with and Without an Authorization                   | <a href="#">00-01-15-15:00</a> |
| E. | Accounting of Disclosures of Health Information  | <a href="#">00-01-15-20:00</a> |
| F. | Request for Amendment of Individual Health Information   | <a href="#">00-01-15-25:00</a> |
| G. | Requests for Restrictions of Uses and Disclosures of Protected Health Information              | <a href="#">00-01-15-30:00</a> |
| H. | Facsimile (Fax) Machine Transmittal of Confidential, Sensitive or Protected Health Information | <a href="#">00-01-15-35:00</a> |
| I. | Disclosures of Personally Identifiable Health Information to Business Associates               | <a href="#">00-01-15-40:00</a> |
| J. | Protected Health Information-Destruction and Disposal  | <a href="#">00-01-15-45:00</a> |
| K. | Protection of Sensitive Electronic Information (SEI)   | <a href="#">00-01-15-50:00</a> |
| L. | Research Misconduct  | <a href="#">-01-20-60:00</a>   |
| M. | Human Research Subjects: Medical Care  | <a href="#">00-01-20-85:00</a> |
| N. | Investigator Conflict of Interest  | <a href="#">00-01-20-89:00</a> |

## V. DEFINITIONS

- A. **Human Subject:** an individual, living or deceased, about whom an investigator conducting research obtains data through intervention or interaction with the individual or through identifiable private information.
- B. **Research:** systematic investigation designed to develop or contribute to scientific knowledge, including the generation of data for publication.
- C. **Human Subjects Research:** research involving human subjects; the use of human organs, human tissues, human body fluids, human cell lines, and human materials for stem cell research; and the use of clinical records or data derived from clinical records, including individual case reports. Research involving human cell lines obtained from human cell repositories that comply with U.S. Department of Health and Human Services regulations for the protection of human subjects will NOT be subject to this policy; these repositories must have Institutional Review Board oversight under an FWA approved by OHRP, and it must be documented that recipient-investigators are denied access to identities of donor-subjects and to information through which identities of donor-subjects may be ascertained.
- D. **Behavioral Research involving Human Subjects:** research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factor evaluation or quality assurance methodologies.

## VI. POLICY

- A. Requirements:

1. The University is responsible for the compliance with all applicable laws and regulations of human subjects research to which this policy applies (see Section III above). Therefore the University and its administrative officers must maintain adequate administrative involvement with and oversight of all policies and procedures relating to this research. This administrative oversight shall be vested in the University's Office of Human Subjects Protection under an Executive Director. The Campus IRB Directors will be responsible for the administrative support of the Campus IRBs which review human subjects research for the schools and units of UMDNJ.
2. All proposed human subjects research to which this policy applies (see Section III above) must be reviewed and approved by a University IRB as established under a UMDNJ FWA. The pertinent Campus IRB for review and approval shall be determined by the investigator's institutional affiliation, appointment, enrollment or employment. However, with the approval of the Executive Vice President for Academic and Clinical Affairs and the appropriate Research Dean, and/or Dean, cooperative IRB authorization agreements with other institutions may be entered into. The HSPP is responsible for working with the requesting investigator/institution to assure that appropriate site visits and reviews are conducted prior to executing an IRB authorization agreement.
3. The Executive Vice President for Academic and Clinical Affairs and the Vice President for Academic Affairs, through the Executive Director of the HSPP and in collaboration with the Research Deans and the Campus IRB Directors, shall exercise administrative oversight of all policies and procedures involved in reviewing, approving, conducting, monitoring and documenting human subjects research in order to ensure that the rights and welfare of human subjects are being protected and that the schools and units of the University are in compliance with their FWAs. This administrative oversight shall consist of the following activities and responsibilities:
  - a. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall be responsible for the development, periodic review and revision of written policies and procedures, including applicable forms, for the conduct of human subjects research covered by this policy, and shall ensure that all individuals proposing and/or performing such research are aware of these policies and procedures. These policies and procedures shall ensure compliance with the requirements for human subjects research set forth in Federal, state and other regulations, in this policy and by the Campus IRBs.
  - b. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall ensure the orientation and training of investigators proposing and of all personnel conducting human subjects research covered by this policy. Training designed to enhance the development of high quality protocols shall be encouraged, and training in good research practices and in methods for minimizing risk shall be provided. In addition, the Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall communicate widely the University's policies and procedures for protecting human subjects to department chairs, research administrators, clinical care staff and appropriate institutional officials. A statement of principles, such as the Belmont Report, shall be included in material used in orientation and training, and shall be made part of the Campus IRB policies and procedures regarding human subjects research.
  - c. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall be responsible for the establishment of an IRB under an FWA to review and approve all human subjects research, as defined above, at each campus.

- i. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Director shall ensure that IRB membership is in accordance with Federal regulations, that the Campus IRB conducts an appropriate review of research utilizing the required elements of review and consent, and functions autonomously in accordance with all applicable regulations. The Campus IRBs also shall function as the privacy boards for the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The Executive Director of the HSPP shall advise the Campus IRB Directors and Campus IRB Chairs concerning adherence to all applicable regulations, and shall work with the Campus IRB Directors and Campus IRB Chairs to ensure that all applicable regulations are being observed. If the Executive Director of the HSPP or the Campus IRB Chair or the Campus IRB Director is unable to ensure compliance of the Campus IRB with all applicable regulations, he or she shall inform the Executive Vice President for Academic and Clinical Affairs and the Vice President for Academic Affairs, who shall take appropriate action.
- ii. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall ensure the appropriate initial orientation and training, as well as periodic continuing education, of current and new IRB members in human subjects research regulations, institutional policies and procedures, and other relevant matters. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall encourage and support the attendance by IRB members at workshops and other educational opportunities focused on IRB functions.
- iii. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall ensure the preparation of written procedures and guidelines to be followed by the IRBs when conducting their initial and continuing reviews of research, and for reporting their findings and actions to the investigator.
- iv. The Executive Director of the HSPP in collaboration with the Research Dean and the Campus IRB Directors shall be responsible for providing the IRBs with sufficient meeting space and staff to support their review and record-keeping duties. Designated, confidential storage space to maintain IRB records shall be provided.
- v. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall ensure the adequate documentation of IRB activities, including maintenance of all research protocols reviewed (including IRB applications, funding submissions such as grants and sponsor contracts, Investigator Financial & Other Personal Interests Disclosure Forms, sponsor protocols, informed consent documents, etc.), agenda and minutes of IRB meetings, records of continuing review activities (including study modifications, advertising and recruitment activities, adverse reactions and/or adverse events, etc.), copies of all correspondence between the IRB and investigators, and statements of new findings provided to subjects.
- vi. The Executive Director of the HSPP in collaboration with the Research Deans and the Campus IRB Directors shall ensure that all records pertaining to an IRB-approved protocol are accessible to the pertinent study investigators as appropriate, to IRB members, to authorized

representatives of the sponsor of the research, and to appropriate Federal regulatory agencies.

- d. New applications from investigators wishing to undertake human subjects research, reports of progress of approved research in the frequency prescribed by the IRB, requests for periodic IRB review and for continuing approval, and proposed changes to ongoing protocols shall be forwarded to the Campus IRB by the Campus IRB Director and IRB Staff. The decisions of the IRB and the administrative status of applications shall be communicated in writing to the investigators by the Campus IRB Chair or designee.
  - i. The Campus IRB may require that applications for human subjects research be scientifically reviewed prior to final IRB review.
  - ii. A pertinent school representative, such as the Dean, Research Dean or department chair, shall review all new applications for human subjects research and decide whether the institution will permit the research. Human subjects research may proceed **only** following approval by the Campus IRB, the UMDNJ school or unit, and the research site (hospital, clinic, office, etc.).
  - iii. In addition to the principal investigators, the department chair and Research Deans shall receive certifications of IRB review and approval of all human subjects research.
- e. External regulatory agency (e.g., FDA, OIG) communications and reports, and sponsors' site-visit and monitoring reports about research covered under this policy shall be sent to the Campus IRB Director by the investigator for review by the Campus IRB.
- f. The Campus IRB Chair or designee shall promptly inform the Executive Director of HSPP and the pertinent Research Dean of any significant or material finding or action with regard to the human subjects research being conducted by UMDNJ individuals or on UMDNJ premises, including but not limited to injuries to human subjects or other unanticipated problems involving risks to human subjects or to others. The Research Dean shall promptly inform the Dean. If of sufficient seriousness, the Executive Director of HSPP shall inform the Executive Vice President for Academic and Clinical Affairs, the Vice President for Academic Affairs, the OHRP, and the research sponsor.
- g. Allegations and complaints regarding inappropriate conduct of human subjects research and/or non-compliance by investigators with Federal regulations, institutional policies or IRB requirements shall be reported to the Executive Director of the HSPP, the Research Dean, the Campus IRB Chair and Campus IRB Director, and shall be documented in writing. The Campus IRB Chair or designee shall investigate the facts of any allegation. At the end of the fact-finding process, the Campus Executive IRB shall make a determination of the merits of the allegation. If, after fact-finding, the allegation demonstrates merit, the Campus IRB Chair or designee shall inform the Executive Director of the HSPP and the pertinent Research Dean, and the Campus IRB Director shall undertake a full investigation. After the fact finding and investigative process, if a finding of serious noncompliance is determined by the Campus Executive IRB, the Executive Director of the HSPP shall report such finding to the pertinent Research Dean who shall inform the Dean, the Executive Vice President for Academic and Clinical Affairs, the Vice President for Academic Affairs, OHRP and the research sponsor.

- h. The Executive Director of the HSPP shall promptly be informed by the Campus IRB Chair and Campus IRB Director of a suspension or termination of any human subjects research by the IRB. The Executive Director of the HSPP shall report any suspension or termination of a human subjects research project by the IRB, or by the institution (if an institutional decision), to the Executive Vice President for Academic and Clinical Affairs, the Vice President for Academic Affairs, OHRP and the research sponsor.
  - i. The Executive Director of the HSPP shall ensure that procedural and record-keeping internal audits are conducted not less than once a year for the purpose of detecting, correcting and reporting administrative and/or material breaches in the protection of the rights and welfare of human subjects, as required by Federal and state regulations and institutional policies. The Executive Director of the HSPP shall ensure the establishment of written internal audit procedures to accomplish this responsibility. Written reports describing the results of internal audits shall be sent to the Campus IRB Chair or designee for Campus IRB review, to the pertinent Research Dean, the Vice President for Academic Affairs and the Executive Vice President for Academic and Clinical Affairs.
4. Infractions of Federal regulations or of institutional policies and procedures for human subjects research can result in immediate, temporary or permanent termination of the research by the Campus IRB, or the Campus IRB Chair acting for the IRB, or the Institutional Official. The Executive Director of the HSPP shall refer these infractions to the department chair and Research Dean, and shall inform the Vice President for Academic Affairs and the Executive Vice President for Academic and Clinical Affairs. Referral should be made to the pertinent Campus Committee on Research Integrity only if the behavior meets the definition of research misconduct as set forth in University policy Research Misconduct, 00-01-20-60:00.
- Infractions of IRB requirements shall be handled by the IRB. There may be additional administrative action under school or University policies.
- 5. The University's FWAs shall be signed by the Executive Vice President for Academic and Clinical Affairs or designee as the "institutional official" and by the Executive Director of Human Subjects Protection as the "Human Subjects Protection Administrator."
  - 6. All human subjects records, especially those containing subjects' names or other identifying information, shall be kept confidential within the limits of the law.
  - 7. The Executive Director of the HSPP in consultation with the Research Deans and the Campus IRB Directors, and with the approval of the Vice President for Academic Affairs, shall decide whether to impose an administrative fee for review of human subjects research protocols from non-governmental sponsors, and how much this fee shall be. The Executive Director of the HSPP shall determine the uses within the HSPP that may be made of the proceeds of such a fee. No direct fee shall be levied upon investigators for non-sponsored investigator-initiated research.

By Direction of the President:

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Vice President for Academic Affairs

## Managing an Effective Compliance Program on a Limited Budget: “Doing More with Less”.

Teri Morris, RN, CHC Director of Quality/Compliance  
Cherokee Indian Hospital

Lea Fourkiller, Chief Compliance Officer, Conifer  
Health Solutions



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## “Doing More with Less”

- Consider your business/practice today and tomorrow when setting goals and implementing a compliance program – What’s your vision and mission
- Embedding the seven elements of an effective compliance program into the foundation of your practice and employee culture impacts budgets
- Consider people, process and technology resources as a means to safeguard your business/practice and elevate your compliance program
- Keep in mind: Scalable and Reasonable



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## Why Spend Resources on a Compliance Program?

- With the passage of the Patient Protection and Affordable Care Act of 2010, physicians who treat Medicare and Medicaid beneficiaries will be required to establish a compliance program.
- Establishing and following a compliance program will help physicians avoid fraudulent activities and ensure that they are submitting true and accurate claims.
- Consider your business/practice today and tomorrow when setting goals, establishing and implementing a compliance program



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### Effective management of “many hats”

- Understand the culture
- Utilize effective communication techniques
- Conduct HIPAA privacy training and use specific examples
- Share settlements and stories of enforcement initiatives in your area
- Set a realistic budget and be creative in planning annual activities
- Utilize outside assistance to maintain independence

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### Effective Management, cont'd

- Set realistic goals and schedules.
- Allow flexibility.
- Designate a back-up.
- Compliance Manual with compliance policies and procedures is up-to-date and easily accessible.
- Delegate and/or defer non-compliance issues to appropriate personnel.

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### Daily Operations

- Keep a log of daily activities/issues and CO response.
- Utilize resources such as HCCA site, OIG guidance, etc.
- Include compliance updates to staff via email or by company newsletters.
- Build relationships with staff.
- Build a network of compliance professionals in your area.
- Network, Network, Network!

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Although we are “small”, we must have an “EFFECTIVE” compliance program!



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### The Definition of “Effectiveness”

“producing a decided, decisive, or desired effect... capable of producing a result.”

“ready for service or action.”

Webster’s Dictionary

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### What is an effective Compliance Program?

- Assuring all 7 elements are operational
- Communicating effectively
- Assessing risk and prioritizing action to be taken
- Recommending consistent and fair discipline
- Monitoring for excluded providers/vendors
- Effective policies and procedures
- Education of all staff
- Having the “right” culture: Tone at the Top

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## Risk Areas: Coding & Billing

- Billing for items or services not rendered
- Double billing resulting in duplicate payment
- Provider misidentification (using another provider's ID number to bill for services rendered by another provider)
- Inadequate documentation
- Unbundling (billing for each component instead of an all-inclusive code)
- Failure to properly use modifiers
- Up-coding the level of service provided

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## Risk Area: Stark and Anti-Kickback

- Remuneration for referrals is illegal
- Arrangements should be reviewed by counsel
- Must adhere with the Stark Law
- Must adhere to the Anti-Kickback Statute
- Conduct review of all contracts
- Track non-monetary compensation

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## Obtaining buy-in and commitment

- Is critical to the success of your program
- Identify champions
- Involve providers/management/staff on committees and work groups
- Provide one-on-one education and feedback
- Work with management so they understand the importance of compliance
- Listen

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## The Future of Compliance



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## The Future of Compliance

- Will compliance programs survive into the Year 2020?
- Will they help us navigate healthcare reform?
- Will they be supported by your Organization: too expensive, too distracting and too hard to measure?
- The easy answer is that compliance programs will be thriving in the Year 2020
  - because they will be mandatory
  - fines are too high and the reputational risk is too great not to have one



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## The Future of Compliance

- Many Organizations will find that up to 80% of their revenue will be derived from a Federal program
- Compliance Programs need to be refined to survive in a post-reform environment
- The Compliance Program must deliver high quality for low cost
- The Compliance Program must have proven value
- Value Challenges
  - Organization culture
  - Structure today typically seen as reactive and responsive instead of insightful and proactive
- Compliance Programs of 2020
  - Integral in the delivery of better patient care
  - Function within cost constraints
  - Improve employee engagement
  - Protect the organization's reputation
  - Break down barriers and silos of healthcare



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## Compliance Program Qualities of the Future

- Support of Mission and Values
- Independence
- Clear Scope
- Business Focus
- Employee Engagement
- Collaboration
- Credibility
- Real Change



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There will always be many hats, finding just the right one is important.



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“It seems impossible until it is finished.”

Nelson Mandela



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## Tools

- Non-retaliation Policy
- Code of Conduct

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## Questions and Discussion

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**CODE OF CONDUCT**  
**EASTERN BAND OF CHEROKEE INDIANS**  
**CHEROKEE INDIAN HOSPITAL**

**Policy**

The Code of Conduct provides a "common language" of standards that we at Cherokee Indian Hospital are committed to sharing. The principles set forth herein provide the foundation for the actions we take and the decisions we make in furtherance of our goals while upholding the laws and regulations and the code of conduct at the Cherokee Indian Hospital. Each employee and agent must read the Code of Conduct carefully and integrate these principles into our daily clinical and business activities. The Code is not a static list of rules, but is a dynamic document, which provides the basic guidance by which we seek to achieve the highest ethical and professional standards and compliance with all applicable laws and regulations. Because Cherokee Indian Hospital will be defined by our actions, it is the personal responsibility of Cherokee Indian Hospital employees and agents to understand and uphold these standards.

The Code of Conduct must be a part of the daily activities of the Cherokee Indian Hospital. The Code of Conduct is in addition to, and does not limit, specific policies and procedures of the Cherokee Indian Hospital. The Code of Conduct is a living document and all the Cherokee Indian Hospital Employees and agents are encouraged to suggest revisions to the Code. Employees are required to sign an attestation that they have read and agree to adhere to the Cherokee Indian Hospital's Code of Conduct.

Behavior that violates these standards will result in disciplinary action. It is every individual's responsibility to act ethically and to report any activity that could violate these standards.

These standards of conduct cannot, and do not, cover every situation you may face. If there is question or doubt regarding any situation, seek advice from your supervisor, other management staff, the Compliance Officer Teri Price, or the compliance hotline (800-455-9014).

**Standards of Conduct**

1. We provide high quality medical care.
2. We keep patient information confidential.
3. We are honest.
4. We keep thorough and accurate records.

5. We avoid even the appearance of a conflict of interest.
6. We report behavior or requests that may be unethical or illegal. We do not retaliate against those who make such reports.
7. We are good stewards of the property and resources entrusted to us.
8. We maintain a safe working environment.
9. We learn what we need to know to fully comply with these standards and the law.

### **Guidelines and Explanations**

#### **1. We provide high quality medical care to the Cherokee people.**

This standard includes:

- Providing high quality health care services that meet the needs of our patients in a way that is consistent with the history and culture of the Cherokee people.
- Provide all appropriate medically necessary services that patients need, in compliance with professional and legal standards.
- Treating all patients with dignity and respect, consistent with our mission.

#### **2. We keep patient information confidential.**

This standard includes:

- Respecting the privacy of all patients.
- Not disclosing any information about a patient's medical condition except as authorized by that patient, as needed for appropriate medical treatment, or as required by law.
- Not retrieving or gathering information about a patient that is not required in the performance of ones duties.
- Full compliance with other written confidentiality policies.

#### **3. We are honest.**

This standard includes:

- Honest and accurate communication with patients and their families, as well as co-workers, supervisors, and outside agencies.
- Billing only for the services we actually provide.
- Avoiding “upcoding” or billing for a higher level of service than was actually provided, in order to obtain a higher reimbursement rate.
- Avoiding “undercoding” or billing for a lower level of service than was actually provided, to obtain reimbursement for services that insurers may not cover.
- Billing only for those medically necessary procedures (including not submitting a bill to Medicare, Medicaid or other insurance provider, for services that are above and beyond the funding source’s standards).
- Seeking guidance from others before submitting a bill or taking any action that appears uncertain or questionable.
- Accepting responsibility for mistakes and working quickly and cooperatively to resolve any problems created by those mistakes.

**4. We keep thorough and accurate records.**

This standard includes:

- Thoroughly documenting all medical treatment and other patient information.
- Endeavor to ensure that all books of account, financial statements, records and other documents are handled honestly and recorded accurately.
- Maintaining all documentation necessary to support services billed to patients, the Federal government, or other third-party payers.
- Endeavor to ensure that Tribal funds are well spent and accounted for.

**5. We avoid even the appearance of a conflict of interest.**

This standard includes:

- Avoiding all personal interests (financial investments, family businesses, etc.) that could impact, or appear to impact, decisions made for the programs.
- Cherokee Indian Hospital employees will not solicit or accept personal gifts, favors, loans, cash, uncompensated services or other types of gratuities or

hospitality from organizations doing business with Cherokee Indian Hospital, competitors of CIH, co-workers, patients, and families of patients or referral sources. However, it does not violate this standard to accept culturally appropriate gifts from patients or their families which would be considered rude to reject, so long as the patient or family are not doing business with the hospital. If an employee has doubt as to the appropriateness of a gift, he or she should seek guidance from Administration, Human Resources, the Compliance Officer or the CIHA Hotline (800-455-9014).

- Fully disclosing any potential conflict of interest to supervisors and the Compliance Officer

**6. We report behavior or requests that may be unethical or illegal. We do not retaliate against those who make such reports.**

This standard includes:

- Reporting immediately any actions that are believed in good faith to be illegal, unethical or to violate these standards, including self-reporting.
- Reporting immediately any request by another person to break the law or violate these standards.
- Making the report to a supervisor, other management staff, the Tribal Internal Audit office, the Legal Division, or the compliance hotline (800-455-9014).
- Never retaliating against any staff member who makes a good faith report under this standard.
- Keeping as confidential as possible, all those who do report in good faith any actions believed to be illegal, unethical or to violate these standards.

**7. We are good stewards of the property and resources entrusted to us.**

This standard includes:

- Treating program property with care and protecting it from damage, loss or theft.
- Using financial resources wisely and frugally.
- Avoiding frivolous or unnecessary expenditures of program funds.

- Working to maximize program resources by generating accurate and careful documents needed to obtain reimbursement from appropriate sources.

**8. We maintain a safe working environment.**

This standard includes:

- Reporting any conditions that may create a safety hazard for patients or staff.
- Properly disposing of all hazardous materials and medical waste.
- Reporting all accidents involving injury to a patient, employee or visitor.

**9. We learn what we need to know to fully comply with these standards and the law.**

This standard includes:

- Devoting the time necessary to learn the complex medical and legal requirements that govern our work, and providing training opportunities for all staff.
- Complying with all applicable Tribal and Federal regulations and guidance about documenting, coding, billing, and accounting for financial resources.
- Complying with the Cherokee Indian Hospital's Personnel Policy, applicable department policies and procedures, and all other applicable rules and regulations.

## ***EMPLOYMENT ACKNOWLEDGMENT***

All employees of Cherokee Indian Hospital as a condition of their employment are required to comply with all policies and standards of Cherokee Indian Hospital. Cherokee Indian Hospital has implemented a Compliance Program representing its commitment to compliance with all billing and claims submissions, fraud and abuse laws, and regulations. All employees are therefore expected to comply with the policies of the Compliance Program. Employees are expected to:

- Attend required educational and training sessions relating to the Compliance Program;
- Be aware of all procedures of the Compliance Program, including the mandatory duty of all employees to report actual or possible violations of all billing and claims submission fraud and abuse laws and regulations; and
- Understand and adhere to the policies of the Compliance Program, especially those which relate to the employee's functions within Cherokee Indian Hospital.

To document Cherokee Indian Hospital's efforts with respect to educating and training employees as to the Compliance Program, employees shall acknowledge in writing their acceptance and understanding of the Program and its requirements.

Failure to follow the policies of Cherokee Indian Hospital's Compliance Program (including the duty to report misconduct) is considered to be a violation of policy and may be grounds for disciplinary action by Cherokee Indian Hospital, including termination of employment when warranted.

I hereby acknowledge that I have received and reviewed Cherokee Indian Hospital Compliance Program, including its Policy Statement on Ethical Practices. Fully understand that, as an employee, I have an obligation to fully adhere to these policies and principles. I hereby acknowledge and affirm that:

1. I fully understand Cherokee Indian Hospital Compliance Plan, and I acknowledge my commitment to comply with Cherokee Indian Hospital Compliance Plan as an employee of Cherokee Indian Hospital.
2. When I have a concern about a possible violation of Cherokee Indian Hospital policy or the plan, I will promptly report the concern to the Compliance Officer in accordance with the Compliance Plan.

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**Employee Signature**

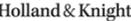
**Date**

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**Printed name of employee**

2014 HCCA Annual Compliance Institute

Session 706:  
**Hospice Enforcement and Compliance**

- Cat Armato, The Corridor Group 
- Latour "LT" Lafferty, Holland & Knight 
- Bill Musick, The Corridor Group 

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Today's Panel



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**Healthcare Fraud Cases Hit Record High in 2013**



Frank Renier/Stock Illustration RF/Getty Images

Hospice Enforcement and Compliance  
**WELCOME/CONTEXT**

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## Flow

- Context
  - Evolution of Hospice Compliance
  - What We're Seeing Today
  - Coming Down the Pike
- How to Mitigate Risk
  - Audit/Monitoring
  - Training/Education
  - Case Example
- When A Regulator Shows Up at Your Door
  - Tips – The New Era of Hospice Enforcement
  - Case Example
  - Tips – “prevention is the best cure”



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## Caveats



- Audit criteria vary by jurisdiction and entity and are continually evolving
- Disclaimer: None of our remarks are intended to be legal advice

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## Who's in the room...



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### Upping the Hospice Compliance Ante

- OIG Hospice Compliance Program Guidance (1999)
- 59% increase in hospice length of stay (2000-2010)  
=> calls for greater accountability and quality data collection
- Medicare/Medicaid Contractors incentivized by recoupments (RACs, ZPICs, MICs)
- LCDs evolve from guidelines to requirements
- Patient Protection and Affordable Care Act – return of “overpayment” within 60 days . . . is an obligation as defined in the False Claims Act
- Zone Program Integrity Contractors turn attention to pre-payment reviews
- Open Access
- Changing interpretations (LCDs)
- Poor documentation +

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### What We’re Seeing – Tip of the Iceberg

Orlando Area Hospice to Pay \$3 Million to Resolve Allegations That It Billed Medicare for Patients Not Terminally Ill

Hospice of Arizona and Related Entities Pay \$12 Million to Resolve False Claims Act Allegations

**\$112 million claim filed against San Diego Hospice...Feds cite 2012 whistleblower case but provide few additional details**

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### What We’re Seeing – Top Denials

Palmetto GBA 4Q2013

- Hospice Appropriateness
  - Legible signature
  - Clear evidence of initial and ongoing prognoses of 6 months or less
  - Documentation supports LCDs
  - Documentation of co-morbidity
- Plan of Care
  - Individualized
  - Documentation of review no less than every 15 days

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## What We're Seeing - Palmetto GBA 4Q2013

- Face to Face Encounters
  - Present and within time period
  - Signed, dated and in correct format
- Valid Election Statement
  - Within required timeframes
  - Complete beneficiary notices, data and signed/dated

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## Coming Down the Pike

- Quality Reporting Fraud
  - QRP – Hospice Quality Reporting Program (2013 data by April 2014 for FY2015 payment determination)
    - Structural Measure
    - NQF #0209 Pain Measure
  - Hospice Information Set (Jul 2014)
- Diagnoses Specificity (Concurrent with ICD-10 transition - Oct 2014)
  - Multiple Related Diagnoses (LCDs/Limitations to Unrelated Costs )
  - RTP of non-specific symptom diagnoses (AFTT, Debility, others)

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Taking Hospice Care to the Next Level

## HOW TO MITIGATE RISK

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## Communication

- Open
  - Evaluate potential barriers
  - Allow direct access to the Compliance Department
  - Encourage questions and reports of concerns
- Effective
  - Address multi-generational workforce needs
  - Careful consideration to determine what needs to be communicated and how it should be communicated

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## Monitoring/Auditing

- Monitoring
  - Upper management monitors compliance activity and develops internal controls
  - Lower and middle management monitor compliance with policies/procedures and other governing documents, and implements internal controls
- Auditing
  - Determine if internal controls are effective
  - Independent of operations
  - External reviews and consultants
  - Attorney/Client privilege

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## Training/Education

- Engage your workforce – “What’s in it for me?”
- Address multi-generational workforce needs
- Measure effectiveness – Kirkpatrick Model
  - Reaction
  - Learning
  - Behavior
  - Results

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### Case Example

- The hospice was notified of DOJ/FBI visits to former employees
- Engaged counsel and outside consultants under ACP
  - Litigation Hold
- Contacted State AG
- Letter sent outlining compliance program and prior government audit results
- Declined to intervene
  - *Qui Tam* unsealed
  - Relator counsel elected not to move forward

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Hospice Enforcement and Compliance

### When a Regulator Shows Up at Your Door

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### Tips – The New Era Of Hospice Enforcement

- LCDs – Enforcing the speed limit
- Retrospective audits; documentation
- Administrative/civil subpoenas
- FCA *qui tams*
- Electronic production
- CIAs; Implementation report; IRO
- Permissive exclusion
- Responsible Corporate Officer Doctrine
- Criminal prosecution
- Employment claims; retaliation, defamation
- Public relations nightmare; referrals; census

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### Case Example

- ADR; Medical review process
- Internal dispute; Board control
- FCA *qui tam*; Retaliation claim
  - Press conference; seal; sanctions
- DOJ; Cooperation; audit & medical review
  - Consultant costs
  - Costs of electronic discovery
- DOJ Intervention; Financial (in)ability to pay
- Management Agreement; Acquisition

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### Case Example Cont.

- Settlement negotiations (the time cost)
  - DOJ
  - HHS-OIG
  - Relator (FCA & personal claims; fees & costs)
- Litigating fairness, adequacy & reasonableness
  - A “travesty of justice”
- Retaliation claim; IRS lien(s); fees & costs; Realtor’s share
- CIA; Education & training; Implementation report
- What’s next???

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### Tips – “prevention is the best cure” (Epictetus)

- Education
  - OIG guidance
  - ADR; Medical reviews
- Prospective audits
- Voluntary disclosure (HPH)
- Emphasis on compliance
- “Minding the ship”; “Buck stops here”
  - Responsible Corporate Officer Doctrine
- Employment issues; retaliation
- “The Richest Man in Babylon” (George Clayson)

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### Questions...



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### Contact Information

Cat Armato, Associate, The Corridor Group

cathleenarmato@gmail.com  
(706) 745-7362



Latour "LT" Lafferty, Holland & Knight

lt.lafferty@hklaw.com  
(813) 227-6361

**Holland & Knight**

Bill Musick, Senior Associate, The Corridor Group

bmusick@corridorgroup.com  
(888) 942-0405 (toll-free)



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**Anatomy of an OCR Breach Investigation**

HCCA 18<sup>th</sup> Annual Compliance Institute  
San Diego, CA  
April 1, 2014

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**Objectives**

- Learn key steps involved in responding to an incident
- Understand timeframes and review key documentation requirements
- Learn best practices to enhance oversight

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**Breach Scenario**

Contractor from Temp Agency

Abuses weak security access controls

Downloads and takes screen prints of member information

Information emailed to personal account

Names were used to file credit card applications and false 2012 tax returns; both listed addresses other than the member's residence. Most of the elderly members were no longer filing tax returns for the 2013 Tax Season and were unaware of the fraud.

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Could this happen at your organization?

What would you do?

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The OCR Investigation

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Timeframe

Breach      CE Notification      OCR Investigation      CE Response      OCR Finding      OCR Settlement

60 Days      Months      20 Days      Months      Many Months

OCR Investigation and multiple responses may be required over many months

Case cleared or moved to settlement proceedings

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### Immediate Next Steps

1. Assess situation to stem further disclosure
2. Complete an Incident Report
3. Determine if incident is a breach
4. Gather documentation
  - Try to obtain signed attestation from employee/temp
  - Ensure file is deleted, if possible
5. Mobilize incident response team
  - Privacy Office, Information Security, Human Resources, Member Services/Customer Service, Security, Breach Response specialist

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### Stakeholders

- Department Involved and contingency agencies
- Customer Service
- Finance
- IT
- Human Resources
- Consultants
- Legal Counsel
- Credit Monitoring Services
- Corporate Communications / PR Team

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### Notification Process

1. Notify impacted members, patients
2. Place ad in local paper
3. Notify OCR, CMS, if applicable and State Attorney General (depending on your State law requirements)
4. Train customer service, develop FAQ
5. Contact Business Associates, vendors if involved

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### The waiting begins....

- ❑ Gather documentation to build your case file – training materials, Privacy & Security policies and procedures, disciplinary action policies
- ❑ Further assess risks
  - Consider whether you have adequate resources to do risk analysis or hire consultant with expertise in HIPAA Privacy & Security
- ❑ Finalize risk assessment, if needed
- ❑ Consult with HIPAA counsel

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### Case Study – OCR Request

- ❑ Within 4 months, OCR responded to the online breach notification with a request for the following items:
  - Press Release
  - List of complaints received from members and resolution of complaints
  - List of staff participating in training in response to the breach
  - Risk Assessment as a result of the breach
  - P&Ps
- ❑ Response due within 20 days

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### Additional Requests & additional details

- ❑ Follow-up requests may not be directly related to incident
- ❑ Requests may extend back many years
- ❑ Every response requires corresponding documentation
- ❑ Example of requests:
  - Incident Report – internal documentation or tracking of what occurred
  - Evidence of regular system activity and audit log reviews
  - Risk Analysis
  - Vulnerability scan results
  - Corrective action plans
  - Disciplinary Action
  - Safeguards for the transmission of ePHI
  - Privacy & Security Awareness Reminders

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### System activity and log review

- ❑ Evidence of regular system activity and audit log reviews
  - Must be able to demonstrate that logs are captured and reviewed
  - Configuration and log samples for the systems
  - Procedure documents for monitoring logs and following up on incidents
  - Signed document by administrators that logs are reviewed

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### Risk Analysis

- ❑ Risk Analysis – Included a detailed review of Security process including

- |                                  |  |
|----------------------------------|--|
| P&Ps                             | Password and Account Management                    |
| End Point Security               | Access Control & Management                        |
| Mobile Media and Device Security | Remote Access & Authentication                     |
| Wireless Security                | Training and Awareness                             |
| Malware Protection               | Incident and Breach Response                       |
| Configuration Management         | Third Party Security Management and hosted systems |
| Vulnerability Management         | Business Continuity Management                     |
| Secure Disposal                  | Risk Management                                    |
| External Breach Protection       | Physical Security                                  |
| PHI Transmission Protection      |  |

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### Corrective Action Plan

- ❑ OCR may request prior risk assessments to better understand unresolved issues over the years
- ❑ A corrective action plan associated with findings from a risk assessment must be documented
- ❑ Building a corrective action on short notice is costly and may commit you to security strategies and timelines that are onerous and not completely necessary

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### Security Rule Policies & Procedures (P&Ps)

- Must be approved and dated and include the following:
  - Sanctions
  - Termination Procedures
  - Contingency Plan
  - Facility Security Plan
  - Password Management
  - Data Backup
  - Device & Media Controls
  - Authorization & Supervision

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### Other Safeguards

- Disciplinary Action – demonstrate that immediate action was taken to sanction the employee/contractor
  - Ensure safeguards for the transmission of ePHI
- Privacy & Security Awareness Reminders offered to workforce members including contingent workers regarding the protection of ePHI and industry best practices
- Conduct regular site audits

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### What's Next?

- OCR accepts evidence and documentation as a Corrective Action Plan (CAP) and closes breach investigation
  - or
- OCR moves the investigation over to the settlement phase:
  - Possibly more data requests to solidify the government's case
  - Offer to settle through resolution agreement and corrective action plan (possibly through meeting)
  - May indicate potential civil monetary penalties (CMP) that may be exposed, which may be tens of millions due to multiple alleged violations over multiple years
  - May be some room for negotiation, but high potential CMPs may limit health care provider's leverage

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## Settlement

- ❑ Recent settlements have had less stringent corrective action plans (e.g., shorter and no independent monitoring)
- ❑ If you do not agree to resolution agreement:
  - Letter of opportunity providing 30 days to provide affirmative defenses and mitigating factors
  - Notice of proposed determination indicating proposed CMP and providing 90 days to appeal to administrative law judge (ALJ)
  - If appeal to ALJ judge, can appeal ALJ decision to HHS Departmental Appeals Board, and can appeal DAB decision to U.S. Court of Appeals
  - If no appeal, HHS imposes the CMPs

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## How Much Does A Breach Cost?

1. OCR sends organization letter, requesting evidence to a list of questions. 20 days to respond.

2. OCR sends a 2<sup>nd</sup> letter asking for more details.

| Steps  | Approx. Cost  |
|--|---|
| <b>Internal discovery</b>                        | a. \$5,000 – 10,000<br>b. \$10k – 15,000<br>c. \$15k – 20,000             |
| <b>Breach Notification &amp; Response</b>        | a. \$10k – 20,000<br>b. \$20k – 30,000<br>c. \$40k – 50,000               |
| <b>OCR LETTER RECEIVED</b>                       |   |
| <b>OCR Response #1 and #2</b>                    | a. \$10k – 20,000<br>b. \$20k – 30,000<br>c. \$40k – 50,000               |
| <b>OCR negotiates a settlement</b>               | a. \$50k – 100,000<br>b. \$100k – 250,000<br>c. \$250k – 1 Million        |
| <b>OCR requires Org to perform annual audits</b> | a. \$5k – \$25,000<br>b. \$25 – \$50,000<br>c. \$50k – \$100,000          |
| <b>Approx. Total?</b>                            | a. \$80k - \$165,000<br>b. \$165k - \$355,000<br>c. \$395k - \$1.2Million |

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## Costs add up

| Steps   | Approx. Cost                 |
|---|------------------------------|
| Internal discovery                            | \$10-15k                     |
| Breach Notification & Response                | \$20-30k                     |
| OCR Response #1 and #2                        | \$40-50k                     |
| OCR negotiates a settlement for Company       | \$250k- 1 million            |
| OCR requires Company to perform annual audits | c. \$50-100k                 |
| <b>TOTAL</b>                                  | <b>\$370,000-1.2 million</b> |

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## How May a Breach Affect You?

1. **Patient Loyalty**
2. **Financial loss**
  - o Average cost of a breach is **\$194/ record**
  - o OCR can fine an organization up to **\$1.5 million per incident**
3. **Reputational damage**
4. **System downtime**
5. **Litigation**

Table: Categories of HIPAA Violations & Penalty Amounts

| Violation category                | Each violation   | Violations of an identical provision (in a calendar year) |
|-----------------------------------|------------------|---|
| Did Not Know                      | \$100- 25,000    | \$1.5 million   |
| Reasonable Cause                  | \$1,000- 100,000 | \$1.5 million   |
| Willful Neglect—<br>Corrected     | \$10,000-250,000 | \$1.5 million   |
| Willful Neglect—<br>Not Corrected | \$50,000-1.5M    | \$1.5 million   |

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## Lessons Learned

- Established HIPAA Governance Committee – confirm that CAP and risk analyses are current
  - Created a 'watch list' of employees who could send ePHI externally
  - HIPAA Security & Training for contingent workers
  - Limited temp access to certain websites and personal email
- Ongoing Risk Analyses and evaluation of HIPAA Privacy and Security program effectiveness.
- Stronger communication with and oversight of temp agencies; regularly evaluate contract terms.

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Clinical Documentation and ICD-10  
Presented by: Altegra Health

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### ICD-10 CM/PCS

ICD-10 will be the official HIPAA-transaction set to communicate all patient conditions and all inpatient treatments, beginning on **October 1, 2015**

- **ICD-10-CM**
  - US clinical modification of the World Health Organization's ICD-10
  - Diagnostic coding system (no procedure codes)
  - Approximately **68,000 ICD-10-CM alpha and numeric diagnosis codes**
  - Current **ICD-9-CM has 14,000 numeric diagnosis codes**
- **ICD-10-PCS**
  - Developed under contract by CMS specifically to replace the ICD-9-CM procedural coding system.
  - Approximately **70,000 ICD-10-PCS alpha and numeric codes**
  - Current **ICD-9 Volume 3 has 4,000 numeric procedure codes**

ALIGNED RESOURCES INTEGRATED SOLUTIONS 2

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### Benefits to ICD-10

- Fewer queries and/or requests for additional clarification
- Fewer denials based on medical necessity
- Financial impact for VBP, ACO and other quality driven incentives
- Improved clinical outcomes
  - Patient-related risk factors
  - Treatment effectiveness
  - Quality of care rendered (metrics)
    - Death, Complications, Readmissions, Length of Stay
  - Predictors
    - Resource Intensity, Severity of Illness, Risk of Mortality, Risk of Complications, Risk of Readmission

ALIGNED RESOURCES INTEGRATED SOLUTIONS 3

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CDI 

- Clinical Documentation Improvement (CDI) programs began in the late 1980s in response to the Federal Government's implementation of Diagnosis-Related Groups (DRGs) in 1983.
- Programs started as "DRG optimization" are now known as CDI. The programs emphasized concurrent inpatient chart review by nurses/coders to collaborate with physicians to clarify their documentation.

ALIGNED RESOURCES  
INTEGRATED SOLUTIONS 4

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The Importance of Documentation 

- Coders need clear documentation to accurately tell the story of the patient's visit/admission. The story reflects the severity of illness, potential length of stay, diagnoses that were POA (present on admission) or HAC (hospital acquired condition)
- Queries and Clarifications
  - Follow Trends
  - Use consistent templates and feedback format
  - Query the correct specialty

ALIGNED RESOURCES  
INTEGRATED SOLUTIONS 5

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Osteoarthritis 

- **This is a 52-year-old male who presented with left knee pain and swelling for 1 to 2 months. He has a history of right total knee arthroplasty done in the past, twice; one 6 years ago and second was done recently in the beginning of 2013.**

1. History of Right total knee arthroplasty
2. Osteoarthritis  
(ICD-10-CM "Left Osteoarthritis")

ALIGNED RESOURCES  
INTEGRATED SOLUTIONS 6

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**Asthma** 

- ICD-9-CM
  - Indicate Status of Disease
    - Acute Exacerbation/Chronic/Status Asthmaticus
- ICD-10-CM
  - Indicate Severity of Disease
    - Mild Intermittent or Mild Persistent
    - Moderate Persistent or Severe Persistent

ALIGNED RESOURCES  
INTEGRATED SOLUTIONS 7

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**Urosepsis** 

- He has been at the rehab facility and apparently at some point, he was determined to have a urinary tract infection for which he received Levaquin. At any rate, he had fevers and chills and had generalized malaise. He has been having some general decline and most recently got a little worse with altered mental status and was therefore sent to the ER. He had a high-grade fever and low blood pressure and was admitted initially into the intensive care unit with some sepsis. He was placed empirically on vancomycin and cefepime.
- Urine culture is growing greater than 100,000 colonies of enterococcus.

**IMPRESSION:**

1. Urosepsis  
(ICD-10 "Sepsis due to enterococcus")

**PLAN:**

1. Continue vancomycin for 7 days for urinary tract infection.

ALIGNED RESOURCES  
INTEGRATED SOLUTIONS 8

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**Respiratory Failure** 

- ICD-9-CM
  - Status of Disease
    - Acute/Chronic/Acute on Chronic
- ICD-10-CM
  - Severity of Disease
    - With Hypercapnia or Hypoxia

ALIGNED RESOURCES  
INTEGRATED SOLUTIONS 9

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**Pneumonia** 

- She was found to have a fever on admission as well as a large right-sided infiltrate. Also, she was noted to have elevated troponin, evidence of urinary tract infection, renal failure, anemia and hypoxemia. She was also noted on an arterial blood gas to have evidence of acute hypoxic and hypercarbic respiratory failure. She has since been placed on BIPAP with improvement of her hypercarbic and hypoxic respiratory failure, although requiring high amounts of oxygen.

**ASSESSMENT:**

The patient is a pleasant 66-year-old female who presents with healthcare-associated pneumonia

(ICD-10 "Suspect Gram Negative, or Resistant to Gram Positive")

**RECOMMENDATIONS:**

- 1. Continue antibiotics intravenously.

ALIGNED RESOURCES  
INTEGRATED SOLUTIONS 10

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**Hemiplegia** 

- This is a 69-year-old patient who presented with slurred speech. Went from Mesa Christian Healthcare Center, also have altered mental status. The patient was being treated for a femur fracture, status post fall. The patient was admitted and was seen by neurology, had MRI, PT, OT. The patient slowly improved. Doing better. She is back to her normal baseline. The patient will continue her PT, OT. Okay by neurology to be transferred.

**FINAL DIAGNOSES:**

- Cerebrovascular accident
- Multiple sclerosis
- Spastic hemiplegia

(ICD-10-CM- Indicate affected side and dominant side)

ALIGNED RESOURCES  
INTEGRATED SOLUTIONS 11

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**Renal Failure** 

- Acute:**
  - With cortical necrosis, medullary necrosis, tubular necrosis
  - Acute kidney injury (non-traumatic)
- Chronic:**
  - Stage?
  - Due to hypertension? Due to diabetes?

ALIGNED RESOURCES  
INTEGRATED SOLUTIONS 12

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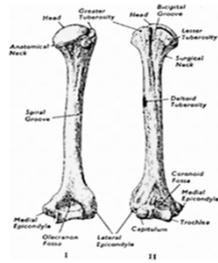
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Fractures



- specific area of bone
- laterality
- type of fracture
- severity of fracture
- episode of care
  - Initial encounter
  - Subsequent
  - Sequela




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Tobacco Use or Dependence



- ICD-9-CM
  - Tobacco Use
- ICD-10-CM
  - Tobacco Use
  - Tobacco Dependence

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Compliance and CDI Partnership



- Routine involvement in partnering committees
- Track Query trends and response time
- Coder/CDI feedback on EHR template builds
- Enhanced Documentation does not have to be restricted to ICD-10 implementation!!
- Continue our efforts

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Thank You 

QUESTIONS?

ALIGNED RESOURCES  
INTEGRATED SOLUTIONS

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It's Not Child's Play  
Children's Hospitals  
Compliance Issues

HCCA Compliance Institute  
San Diego, California  
April 1, 2014

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DISCLAIMERS

- Remarks are Personal Opinions Only.
- We Do Not Speak for DLA Piper LLP, Miami Children's Health System, or Any Current or Former Clients.
- Not to Be Construed as Legal Advice. Each Case is Different. Consult Your Own Legal Counsel.

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AGENDA

1. Trends in Medicaid Enforcement
  - Effects of Exchanges and Enrollment
  - Principles of Medicaid Policy
  - Enforcement Basic Principles
  - Drug Program Enforcement
  - Lessons Learned and Best Practices

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AGENDA

2. Patient Consent and Bioethical Issues

- Minor Consent Issues Related to EMR
- End of Life Decision Making
- Case Studies
- Items to Consider

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AGENDA

3. Stark and Medicaid

- Overview of Stark
- Application to Medicaid through 3 cases:
  - All children's
  - Halifax
  - Toumey
- Penalties
- Compliance and Prevention Activities

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Trends in Medicaid Enforcement

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**MEDICAID DYNAMICS**

- ACA Exchanges are Operational
- CMS Anticipates Increases in Medicaid or CHIP Enrollment
- Twenty-Six States and D.C. Participating in Medicaid Expansion in 2014
- Three States Considering Post-2014 Expansion
- Other States have Rejected or Narrowly Defeated Expansion

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**MEDICAID DYNAMICS**

- Medicaid Clients
  - Exchanges expected to capture 4.3 million currently eligible but not enrolled
  - Expansion may result in 11.4 million newly-eligible clients
- Projected Increases of over 15 million.
- Enforcement Will Follow the Money
  - Example: 2013 Texas Legislature authorized 127 new FTEs

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**RAPIDLY-CHANGING ISSUES**

- Each of these areas is being reassessed and certain deadlines have been extended. Need to monitor for developments
  - Quality measures as conditions of payment
  - Observation stays and two-midnight rule
  - DSH calculations

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**FEDERAL MEDICAID PRINCIPLES**

- State Medicaid policies may be equal to or more stringent than federal or CMS Medicaid policy
- State Medicaid policies cannot be less restrictive than federal or CMS Medicaid policy
- Federal findings are generally against the State, not the provider

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**FEDERAL EXCEPTIONS**

- Alternatively, State policies may differ through a number of vehicles:
  - 1115 demonstration project or research waivers
  - 1915(b) managed care waivers
  - 1915(c) home and community-based service waivers
  - Other Exceptions
  - State nonadherence

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**STATE MEDICAID PRINCIPLES**

- States do not enforce federal law – only state law.
- States must enact statutes or adopt rules that incorporate federal or CMS Medicaid laws and regulations.
- This can result in delays, inconsistencies, and loopholes. It is important to review each State's laws and policies.

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**FEDERAL-STATE COORDINATION**

- Federal Funding of Approximately 60%
- Recaptured from the State once a payment is Identified
- Whether or not State Recoups from Provider
- Pressures to Show ROI on Resources and FTEs
- Pressures to contain costs; subsidize ACA
  - Examples: DSH Calculations, FWA Recoveries

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**STATE MEDICAID ENFORCEMENT**

- Types of Review
  - Investigations'
  - Utilization Review
  - Audits
  - Enrollment Site Inspections
- Trends, Issues
  - RAC Audits
  - Data Analytics
  - Incentive Program Audits

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**FEDERAL MEDICAID ENFORCEMENT**

- Issues on HHS OIG 2014 Work Plan
  - Health-Acquired Conditions Billed to Medicaid
  - Provider-Preventable Conditions Billed to Medicaid
  - Atypical Antipsychotic Drugs to Children
  - Drug Manufacturer's Rebates
  - State Oversight, Collection, and Reporting of Manufacturer Rebates

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**340B ENFORCEMENT**

- First 20 years, Little Enforcement by Government
- 2011 OMB and HHS OIG Reports
- Now a Large 340B Audit Initiative
  - 51 Audits in FY 2012
  - 2013 HHS OIG Audit Report on Contract Pharmacies
  - January 2014 Budget Bill Allocated an Additional \$ 6 million for Program Integrity
- Medicaid Component Needs to be Addressed in These Audits

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**340B OMNIBUS RULE**

- Omnibus Proposed Rule Expected June 2014
  - Codify Miscellaneous Guidance and Agency Publications
- Issues To Be Addressed in Rule
  - Definition of Eligible Patient
  - Contract Pharmacy Requirements
  - Hospital Eligibility, Possibly GPOs
  - Off-Site Facility Eligibility

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**340B AUDITS**

- HRSA Audits
  - 51 in FY 2012
    - 26 Had No Findings or No Sanctions; 9 To Be Determined
    - 16 Resulted in Sanctions
- HRSA May Begin Auditing Manufacturers
- State Vendor Drug Audits may Also Implicate 340B issues

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**CASE STUDY – STATE AUDITS**

- Initial Findings of Hospital Pharmacy Noncompliance and Questioned Costs.
- Hospitals Claimed 340B Inventory Systems as a Defense.
- Series of Discussions Between Pharmacies, Medicaid Staff, and OIG.

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**MEDICAID vs. 340B**

| <b><u>MEDICAID</u></b>  | <b><u>340B</u></b>  |
|---|---|
| <ul style="list-style-type: none"><li>▪ Hospitals are required to track and bill State at actual acquisition cost.</li><li>▪ State uses invoices to determine AAC and purchasing patterns.</li><li>▪ State required invoice to link to specific inventory.</li><li>▪ Each pharmacy location had a separate contract and billing account with the State.</li><li>▪ State did not refer to Medicaid Exclusion File to identify 340B covered entities.</li></ul> | <ul style="list-style-type: none"><li>▪ Hospitals had rolling, automated pricing system. No historical acquisition costs.</li><li>▪ Pricing system did not link invoices to specific inventory.</li><li>▪ 340B does not prohibit commingling of inventory.</li><li>▪ May use centralized system for all pharmacies on cost report.</li><li>▪ Each affiliated pharmacy should be entered into the Medicaid Exclusion File.</li></ul> |

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**LESSONS LEARNED**

- The Same Words may Have Different Definitions in Medicaid and 340B Contexts.
- Need for Updating and Clarifying 340B Hospital Rules. State Proposed a Rule Amendment and Issued New Written Policies.

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**LESSONS LEARNED**

- State Agency may not be Familiar with 340B Program:
  - Different divisions and silos
  - Limited resources
  - Other risks, priorities, legislative direction
- Legacy Agency Regulations may Conflict Internally or with 340B Requirements.

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**LESSONS LEARNED**

- State Thinks in Terms of Overpayments and Recoupments. It may Disallow the Amount of the Entire Claim.
- Need for Developing Appropriate Method to Quantify 340B Drug Claim Findings.

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**LESSONS LEARNED**

- If rules and policies don't align, bill conservatively.
- Be sure to list billing numbers of all affiliated pharmacies on the Medicaid Exclusion File or other State master list.

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**LESSONS LEARNED**

- 340B policy allows commingling of inventory but State policy may not.
- Make sure any resolution squares with a written rule or policy. Cannot depend upon verbal or written communications that differ from published policy, regulation, or law.

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**BEST COMPLIANCE PRACTICES**

- Monitor HRSA/OPA Website for Proposed Rule
- Review and Update all Policies and Procedures
- Update all Databases
  - OPA Database and Medicaid Exclusion File
  - Physician and Provider Credentials
  - Contracts with Pharmacies, Governments

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**BEST COMPLIANCE PRACTICES**

- Review Internal Operations
  - Purchasing
  - Patient Eligibility Determination
  - Distribution of Drugs
- Staff Training of Updated Policies
- Annual Certification
  - Compliance with Regulations
  - Ensuring Contract Pharmacy Compliance, Including Audits

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Patient Consent and Bioethical Issues

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MINOR CONSENT ISSUES RELATED TO EMR

- Patient Portal - Access
  - Meaningful Use requirements
  - Protection of Data
- Record Retention Requirements
- Psych/Behavioral Health records within the EMR
  - What do parents have the right to access?
  - State specific – ex. Florida

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END OF LIFE DECISION MAKING

- State dependent (know your state statutes)
  - Futility of Treatment – ex. Texas
- Withdrawal versus Withholding
- Brain Death – Ex: Texas
- AND versus DNR

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**CUSTODY - CASE STUDY**

- Two parents are divorced, and have an existing custody order. The custody order states Mother had right to make medical decisions for child (including the booking of medical appointments for the child).
- Father calls the cardiology office and make appointments for the child. Mother would call the same office, upset, and forbid the office from allowing Father to make appointments for the child.
- As the compliance officer, an employee of the office comes to you, asking how to handle the parents. What do you advise?

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**GUARDIANSHIP - CASE STUDY**

- A child is admitted to hospital at age 17, with the parents making joint decisions about the child's medical care. During the child's stay, becomes comatose.
- Child turns 18 while an inpatient at the hospital.
- When the child was admitted, they could not appoint a healthcare surrogate, and now they are of age, parents no longer able to make medical decisions for the child.
- Clinician comes to you as the compliance officer and asks for your advice. What do you advise?

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**GUARDIANSHIP - CASE STUDY CONT.**

- What do you in your institution when a child turns 18 while admitted, and their parent has been previously making medical decisions?
- Do you want to get guardianship in this instance?

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**MATURE MINOR - CASE STUDY**

- A child, age 16, presents at your hospital's emergency department with a broken foot. Upon being admitted, she then complains of pain in her abdomen, and discloses to the treating clinician that she is pregnant.
- What medical treatment can the child consent for, if any?
  - State specific – ex. Florida
  - Emancipated Minor (including auto-emancipation) versus Mature Minor

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**CONSENT BY FAMILY MEMBERS – CASE STUDY**

- Uncle presents child to the hospital emergency department. Can he consent to the child's treatment?
  - History and Physical
  - Surgery
  - Anesthesia
  - Psych
- Is it a true emergency?

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**ITEMS TO CONSIDER**

1. Best Interests of the Child
2. Voluntary/involuntary admissions for psych treatment
  - State specific, most states have an involuntary psych treatment statute that would allow certain identified individuals to involuntarily admit a minor who would be harmful to themselves or others.
  - Voluntary psych admissions may be more complicated, as your state may require a hearing.
3. Adolescent patient and their use of social media (i.e. friend requesting the caretaker)
  - Be sure your institution has very specific social media policies policing these activities.

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## Stark and Medicaid

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### STARK LAW - OVERVIEW

- Section 1877 of the Social Security Act (the Act) (42 U.S.C. 1395nn), also known as the physician self-referral law and commonly referred to as the “Stark Law”:
  - Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership, investment, or compensation), unless an exception applies.
  - Prohibits the entity from presenting or causing to be presented claims to Medicare (or billing another individual, entity, or third party payer) for those referred services.
  - Establishes a number of specific exceptions and grants the Secretary the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse.

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### 3 QUESTIONS

1. Is there a referral by a physician for DHS payable by Medicare?
2. Does the physician have a financial relationship with the entity furnishing the DHS?
3. Does the financial relationship fit in an exception?

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**WHAT ARE DHS?**

- The following items or services are DHS:
  - Clinical laboratory services.
  - Physical therapy services.
  - Occupational therapy services.
  - Outpatient speech-language pathology services.
  - Radiology and certain other imaging services.
  - Radiation therapy services and supplies.
  - Durable medical equipment and supplies.
  - Parenteral and enteral nutrients, equipment, and supplies.
  - Prosthetics, orthotics, and prosthetic devices and supplies.
  - Home health services.
  - Outpatient prescription drugs.
  - Inpatient and outpatient hospital services.

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**STARK AND MEDICAID – ALL CHILDREN’S**

- **Background:** Qui tam action filed by former Director of Operations for Pediatric Physician Services, Inc., wholly owned by All Children’s.
- **All Children’s:** Argued that the Stark Law referral prohibitions do not apply to the Medicaid program because CMS never finalized a rule regarding the Stark Law’s applicability to the Medicaid program.
- **Government:** Alleged that All Children’s financial relationships with 17 employed physicians violated the Stark Law and in turn, that the claims for payment that All Children’s submitted to the Florida Medicaid program as a result of referrals from those 17 physicians were false claims that violated the False Claims Act as well as Florida state law.

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**STARK AND MEDICAID – ALL CHILDREN’S (cont.)**

- **Ruling:** U.S. District Court for Middle District of Florida concluded that the failure to finalize that rule did not mean that the Stark Law does not apply to Medicaid claims, and held that the referral prohibitions of the Stark Law do apply to Medicaid through 42 USC 1396b(s). Since the Stark Law is in subchapter XVIII, the District Court reasoned that “the substantive prohibitions contained in the Stark Amendment are therefore applicable to claims submitted to Medicaid.
- *“In other words, CMS cannot pay [federal financial participation or “FFP”] for services provided under Medicaid if the payment would be prohibited under Medicare due to an illegal referral in violation of the Stark Amendment. Certifying compliance with the Stark Amendment to ensure that CMS pays FFP for Medicaid claims that violate the Stark Amendment would be a violation of the False Claims Act in the same manner that certifying compliance for full reimbursement under Medicare would be.”*

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**STARK AND MEDICAID – HALIFAX**

- **Background:** Qui tam action filed by a member of the compliance department of a corporate affiliate of Halifax.
- **Halifax:** Argued that the statutory language of Stark called only for the denial of FFP to a state Medicaid program for self-referred services, and therefore, created no obligation on behalf of the provider.
- **DOJ/Government:** Countered, stating that since the state was not entitled to claim FFP from the federal government based upon the allegedly prohibited referrals, Halifax had caused a false claim to be submitted. Further, the government purported the false claim was the state Medicaid program's claim to the federal government for FFP.
- **Ruling:** Because of the prohibition of FFP for services provided pursuant to allegedly improper referrals under Stark, the court sided with the government.

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**STARK AND MEDICAID – TOUMEY**

- **Background:** Qui tam lawsuit alleging that certain employment arrangements were in question, characterizing such arrangements as prohibited financial relationships under Stark.
- **Toumey:** Claimed FMV analysis was obtained, as well as favorable legal opinions which analyzed the arrangement, and therefore supported the application of Stark exception.
- **Government:** Because Toumey performed the billing for the services provided at the outpatient surgery center, the government alleged the claims Toumey submitted to Medicare and Medicaid as a result of the prohibited contractual relationships amounted to false claims.
- **Ruling:** In September 30, 2013 decision, the court agreed with the government's assessment of the statutory minimum civil penalty of \$5,500 per claim, or \$119.5 million. Combining this with treble damages and fines from the previous jury verdict means Toumey owes a total of more than \$237.5 million for its non-Stark-compliant billing practices.

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**PENALTIES**

- Civil Sanctions
- Exclusions from federal programs
- Recoupment of payments
- Bootstrap of False Claims Act violation
- State's "Baby Stark"

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**COMPLIANCE AND PREVENTION**

- **Compliance activities:**
  - Great uncertainty – should we treat Medicaid claims the same as Medicare claims when performing a stark analysis?
  - Although very few pediatric services qualify for Medicare payments, keep in mind ESRD services.
  - Always consider your physician financial arrangements.

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**SPEAKER CONTACT INFORMATION**

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| <p><b>Karen Nelson</b><br/>Of Counsel</p> <p>T +1 512.457.7048<br/>F +1 512.721.2209<br/>M +1 512.954.7275<br/>E karen.nelson@dlapiper.com</p> <p>401 Congress Avenue,<br/>Suite 2500<br/>Austin, Texas 78701-3799<br/>United States<br/>www.dlapiper.com</p> | <p><b>April Andrews-Singh, Esq.</b><br/>General Counsel, Senior Vice<br/>President of Legal &amp; Public Affairs<br/>Miami Children's Hospital</p> <p>Office (786) 624-2233<br/>Cell (305) 298-5517<br/>Fax (305) 663-8436<br/>april.andrews@mch.com</p> <p>3100 S.W. 62nd Avenue<br/>Miami, FL 33155</p> | <p><b>Rory Brecker</b><br/>Associate</p> <p>T +1 305.423.8566<br/>F +1 305.503.6866<br/>E rory.brecker@dlapiper.com</p> <p>200 South Biscayne<br/>Boulevard,<br/>Suite 2500<br/>Miami, FL 33131-5341<br/>United States<br/>www.dlapiper.com</p> |
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It's Not Child's Play  
Children's Hospitals  
Compliance Issues

HCCA Compliance Institute  
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
**OFFICE FOR CIVIL RIGHTS**

**OCR Audits of HIPAA Privacy, Security and Breach Notification, Phase 2**

Linda Sanches, MPH  
 Senior Advisor, Health Information Privacy

HCCA Compliance Institute  
 March 31, 2014

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**Agenda**

- Background
- Audit Phase 1
  - Design
  - 2012 Findings
  - Evaluation—major recommendations
- Audit Phase 2
  - Approach
  - Size
  - Timing
  - Focus
  - Entity selection
- Guidance

Office for Civil Rights, DHHS March 2014  
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**Program Mandate**

**HITECH Act, Section 13411 - Audits**

- This section of The American Recovery and Reinvestment Act of 2009, requires HHS to provide for periodic audits to ensure covered entities and business associates are complying with the HIPAA Privacy and Security Rules and Breach Notification Standards.

**Program Opportunity**

- OCR sought a comprehensive, flexible process for analyzing entity efforts to provide regulatory protections and individual rights.
- Identify best practices and uncover risks and vulnerabilities not identified through other enforcement tools
- Encourage consistent attention to compliance activities

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| U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES<br><b>OFFICE FOR CIVIL RIGHTS</b> |                     |                  | Multi-year Phase 1  |  |
|--|---------------------|------------------|---------------------|--|
| Description  | Vendor              | Status/Timeframe | March 2014<br>( 4 ) |  |
| <b>Audit program development study</b>   | Booz Allen Hamilton | Closed 2010      |                     |  |
| <b>Covered entity identification and cataloguing</b>                           | Booz Allen Hamilton | Closed 2011      |                     |  |
| <b>Develop audit protocol and conduct audits</b>                               | KPMG                | Closed 2011-2012 |                     |  |
| <b>Evaluation of audit program</b>   | PWC, LLP            | Closed 2013      |                     |  |

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|---|--|--|-------------------------|--|
| <ul style="list-style-type: none"> <li>• Comprehensive audit protocol and associated set of audit program work papers</li> <li>• Databases of covered entities</li> <li>• Methodology for entity selection</li> <li>• Survey of entity attributes for audit planning</li> <li>• Program evaluation</li> <li>• Other foundational materials –Include templates for notification letters, final reports, document requests</li> </ul> |  |  | March 2014<br>( 5 )     |  |

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| U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES<br><b>OFFICE FOR CIVIL RIGHTS</b>  |  |  | Phase 1, Pilot 2011 -- 2012 |  |
|---|--|--|-----------------------------|--|
| <b>Audit Protocol Design</b> <ul style="list-style-type: none"> <li>• Created a comprehensive, flexible process for analyzing entity efforts to provide regulatory protections and individual rights</li> </ul>   |  |  | March 2014<br>( 6 )         |  |
| <b>Resulting Audit Program</b> <ul style="list-style-type: none"> <li>• Conducted 115 performance audits through December 2012 to identify findings in regard to adherence with standards. Two phases:                             <ul style="list-style-type: none"> <li>• Initial 20 audits to test original audit protocol</li> <li>• Final 95 audits using modified audit protocol</li> </ul> </li> </ul> |  |  |                             |  |

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## Protocol—11 Modules

**Breach Notification**

**Privacy**

- Notice of Privacy Practices
- Rights to Request Privacy Protection of PHI
- Access of Individuals to PHI
- Administrative Requirements
- Uses and Disclosures of PHI
- Amendment of PHI
- Accounting of Disclosures

**Security**

- Administrative Safeguards
- Physical Safeguards
- Technical Safeguards

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## Overall Findings & Observations

**No findings or observations for 13 entities (11%)**

- 2 Providers, 9 Health Plans, 2 Clearinghouses

**Security accounted for 60% of the findings and observations—although only 28% of potential total.**

**Providers had a greater proportion of findings & observations (65%) than reflected by their proportion of the total set (53%).**

**Smaller, Level 4 entities struggle with all three areas**

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## Audit Findings & Observations By Level

AUDIT FINDINGS AND OBSERVATIONS BY LEVEL OF ENTITY

| Level   | Percentage |
|---------|------------|
| Level 1 | 41%        |
| Level 2 | 20%        |
| Level 3 | 20%        |
| Level 4 | 19%        |

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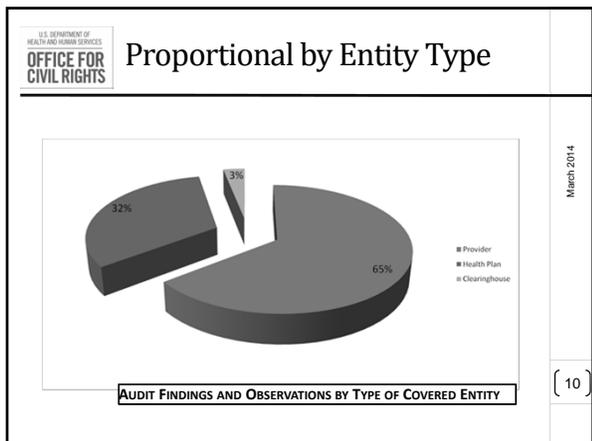
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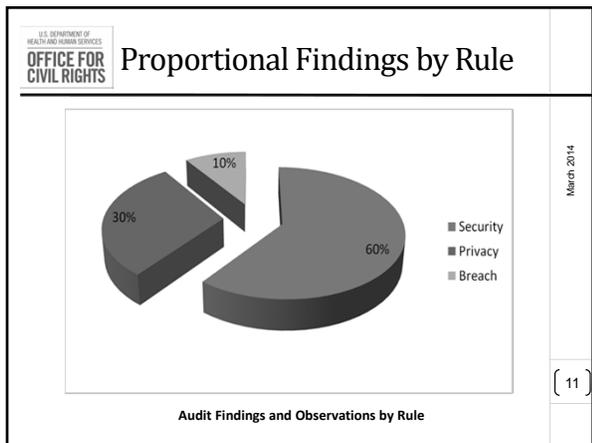
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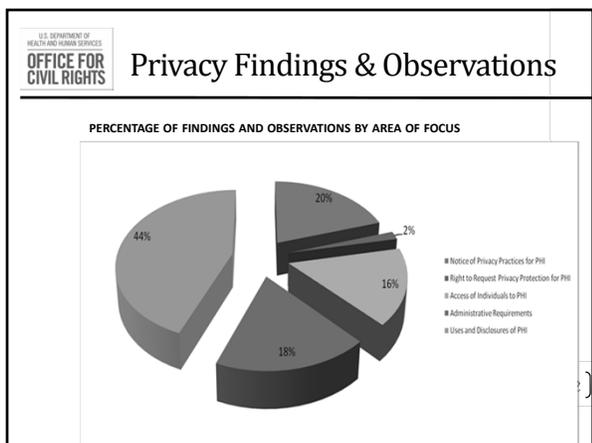
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## Security Results

March 2014

**58 of 59 providers** had at least one Security finding or observation

**No complete & accurate risk assessment in two thirds of entities**

- 47 of 59 providers,
- 20 out of 35 health plans and
- 2 out of 7 clearinghouses

Security addressable implementation specifications: most entities without a finding or observation met the standard by fully implementing the addressable specification.

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## Security Elements

Percentage of Audit Findings and Observations by Area of Focus

| Area of Focus                    | Percentage |
|----------------------------------|------------|
| Risk Analysis                    | 22%        |
| Access Management                | 14%        |
| Security Incident Procedures     | 14%        |
| Contingency Planning and Backups | 7%         |
| Workstation Security             | 14%        |
| Media Movement and Destruction   | 8%         |
| Encryption                       | 9%         |
| Audit Controls and Monitoring    | 14%        |
| Integrity Controls               | 6%         |

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## Breach Notification by Entity Type

Audit Findings and Observations by Requirement and Type of Entity

| Requirement                         | Providers (%) | Health Plans (%) | Clearinghouses (%) |
|-------------------------------------|---------------|------------------|--------------------|
| Notifications to Individuals        | 58%           | 42%              | 0%                 |
| Timeliness of Notification          | 57%           | 43%              | 0%                 |
| Methods of Individuals Notification | 43%           | 37%              | 20%                |
| Burden of Proof                     | 55%           | 44%              | 2%                 |

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## Overall Cause Analysis

- For every finding and observation cited in the audit reports, audit identified a "Cause."
- Most common across all entities: **entity unaware of the requirement.**
  - in 30% (289 of 980 findings and observations)
    - **39% (115 of 293) of Privacy**
    - **27% (163 of 593) of Security**
    - **12% (11) of Breach Notification**
  - Most of these related to elements of the Rules that explicitly state what a covered entity must do to comply.
- Other causes noted included but not limited to:
  - Lack of application of sufficient resources
  - Incomplete implementation
  - Complete disregard

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## Cause Analysis – Top Elements *Unaware of the Requirement*

| Privacy  | Security  |
|--|---|
| <ul style="list-style-type: none"> <li>• Notice of Privacy Practices;</li> <li>• Access of Individuals;</li> <li>• Minimum Necessary; and,</li> <li>• Authorizations.</li> </ul> | <ul style="list-style-type: none"> <li>• Risk Analysis;</li> <li>• Media Movement and Disposal; and,</li> <li>• Audit Controls and Monitoring.</li> </ul> |

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Objectives  
 Communications  
 Entity Selection  
 Protocols

## PHASE ONE PROGRAM EVALUATION

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|--|-------------------------------|--|
|   | <h2>Evaluation Objective</h2> | <small>Office for Civil Rights, DHHS March 2014</small>                            |
| <p>To determine if the implementation objectives of the audit plan and program were achieved. The assessment:</p> <ul style="list-style-type: none"> <li>• Looked at the effectiveness of the protocol &amp; auditing process in identifying compliance challenges;</li> <li>• Methods applied included:             <ul style="list-style-type: none"> <li>• the review of audit data;</li> <li>• surveys of the audited covered entities; and,</li> <li>• interviews with audited covered entities</li> </ul> </li> <li>• Focused on what activities and resources facilitated the audit program, and understanding the barriers and/or problems that may have been encountered in the program.</li> </ul> |                               | <span style="border: 1px solid black; border-radius: 50%; padding: 2px;">19</span> |

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|---|---|--|
|    | <h2>Communication &amp; Outreach Results</h2> | <small>Office for Civil Rights, DHHS March 2014</small>                            |
| <p>Audited covered entities generally felt positive about communications during the course of the audit:</p> <ul style="list-style-type: none"> <li>• <b>90%</b> agreed that communications prior to the onsite visit clearly explained the purpose of the audit</li> <li>• <b>71%</b> agreed that communications prior to the onsite visit clearly explained what would happen during the audit process</li> <li>• <b>56%</b> became aware of additional HIPAA regulations which apply to their organizations</li> </ul> <p>However, 59% of responding covered entities were <i>not</i> aware of the audit program prior to receiving notification of selection. Most of these entities were also not aware that the audit protocol was available on the OCR website</p> |   | <span style="border: 1px solid black; border-radius: 50%; padding: 2px;">20</span> |

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|--|---|--|
|   | <h2>Communication and Outreach Recommendations</h2> | <small>Office for Civil Rights, DHHS March 2014</small>                            |
| <p><b>Ongoing Publicity of the Audit Program</b></p> <ul style="list-style-type: none"> <li>• OCR should continue to widely publicize the audit program and overall results to prompt covered entities to proactively attempt to identify and correct potential compliance issues.             <ul style="list-style-type: none"> <li>• For smaller entities, OCR may want to focus additional attention on forums and journals</li> </ul> </li> <li>• After each year of audits, OCR should evaluate areas of high risk and pervasive non-compliance and consider the creation and delivery of training on leading practices</li> </ul> |   | <span style="border: 1px solid black; border-radius: 50%; padding: 2px;">21</span> |

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## Selection Process

**Results**

- Some surveyed audited entities indicated that the selection methodology should be published so that entities can understand the selection criteria.

**Recommendation**

- OCR should consider this request.



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## Recommendations: Protocol Modifications

Consider updating the protocol to include test procedures that specifically address the review of specific types of documentation needed to meet the audit objective

Add steps to guide auditors in tailoring the protocol to the specific covered entity type

Revise the protocol to include the Omnibus Final Rule and reassess priority areas based on program audit results and industry feedback

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## Selection of Requirements to Audit-- Recommendations

**Implement a Risk-Based Approach**

- A risk-based approach for applying audit protocols would allow OCR to determine areas of the Rules which require implementation of controls which, if not implemented effectively, pose the greatest risk to the protection of PHI.
- OCR should consider a multi-tiered audit approach which can be tailored based on entity type, area or a hybrid.

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### Requested Documentation Results

Survey results from responding covered entities regarding the documents and data requested of them:

|   |   |  |
|---|---|--|
| <ul style="list-style-type: none"> <li>• <b>87%</b></li> </ul> <p>The documents and data requested were communicated clearly <b>during the onsite visit</b></p> | <ul style="list-style-type: none"> <li>• <b>82%</b></li> </ul> <p>The documents and data requested were clearly <b>outlined in the original request</b></p> | <ul style="list-style-type: none"> <li>• <b>79%</b></li> </ul> <p>The documents and data requested <b>were sufficient for assessing compliance</b> at their type of entity</p> |
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### Requested Documentation

#### Results

- Survey comments and follow-up interviews also indicated some inconsistency in the document collection process:
  - Electronic vs. hard copy submission
  - Issues with the document repository causing resubmission
  - Misdirection of audit notification letters

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### Timing and Staffing Levels

Recommendation--Implement a Centralized Staffing Tracker

Benefits:

- Captures historical data to identify the appropriate number of staff required for an audit
- More even distribution of man hours, which would likely decrease the range in time of testing
- Staff assigned based on the nature of the entity being reviewed
- Assign people with proper backgrounds
- Plan for and complete audits more easily
- Enhanced program oversight

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## Work Papers Recommendations

- **Use an Electronic Work Paper System (EWPS)**
- An EWPS system would provide a centralized mechanism for capturing documentation to support standards related to audit planning, fieldwork, reporting, and monitoring. This includes documentation for the following areas:

|  |  |
|--|--|
| Independence, both on an organizational and individual level             | Professional judgment and competence (ex. auditor resumes)   |
| Support for conclusions (ex. Documentation provided by covered entities) | Planning (ex. agreed upon protocols, sampling methodologies) |
| Quality Control and Assurance  | Clear supervisory review evidence                            |
| Audit work papers/narrative  | Audit reports and referencing                                |

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## Work Paper Recommendations

- **Use Representative Sampling Methods**
- Representative sampling will help OCR to understand the degree to which an entity is compliant for a given focus area.
- *Yellow Book section 6.64: random sampling* is the preferred method when a representative sample is needed. This method produces unbiased estimates of the population, as each unit has an equal probability of being chosen.

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## Final Report: Results

Survey results from responding covered entities regarding the audit report issued to them:

|  |  |   |
|--|--|---|
| <p>• <b>80%</b></p> <p>The report was clear and easy to read</p> | <p>• <b>79%</b></p> <p>The report provided an actionable basis for bringing the entity into HIPAA compliance</p> | <p>• <b>71%</b></p> <p>The report adequately identified gaps between HIPAA requirements and entity operations</p> |
|--|--|---|

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Who will be audited & selection  
What will be audited  
Approach  
Timeline  
Outreach  
Electronic management system

**PHASE 2 2014 -- 2015**

March 2014

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### Who Can Be Audited?

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graph TD; A[Who Can Be Audited?] --- B[Any Covered Entity]; A --- C[Any Business Associate]; B --- D[Health plans of all types]; B --- E[Health care clearinghouses]; B --- F[Individual and organizational providers]; C --- G[Selection through covered entities];
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### Phase 2 Covered Entity Pool

- Have selected a pool of covered entities eligible for audit
- Used resources developed through Booz Allen Hamilton contract
  - Health care providers selected through NPI database
  - Clearinghouses & Health Plans from external databases (e.g., AHIP)
- Random selection used when possible w/in types
- Wide range (e.g., group health plans, physicians and group practices, behavioral health, dental, hospitals, laboratories)

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Pre-audit Survey

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- Available entity databases lack data for entity stratification
- Survey currently going through the Paperwork Reduction Act clearance process
- Questions address size measures, location, services, best contacts
- OCR will conduct address verification with entities this spring
- Entities will receive link to on-line screening "pre-survey" this summer
- Expect to contact 550-800 entities
- OCR will use results of survey to select a projected 350 covered entities to audit

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Audit Phase 2 Approach

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- Primarily internally staffed
- Selected entities will receive notification and data requests in fall 2014
- Entities will be asked to identify their business associates and provide their current contact information
- Will select business associate audit subjects for 2015 first wave from among the BAs identified by covered entities
- Desk audits of selected provisions
- Comprehensive on-site audits as resources allow

DHHS, OCR April 2014

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Phase 2 Audit Distribution Projections

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| Entity Type                                | Privacy | Breach | Security |
|--|---------|--------|----------|
| <b>Covered Entities</b>                    | 100     | 100    | 150      |
| • <b>Health Plans</b>                      | 33      | 31     | 45       |
| • <b>Providers</b>                         | 67      | 65     | 100      |
| • <b>Clearinghouses</b>                    | -       | 4      | 5        |
| <b>Business Associates</b>                 | 0       | 0      | 50       |
| • <b>IT Related</b>                        | -       | -      | 35       |
| • <b>Non-IT Related (eg, TPAs, claims)</b> | -       | -      | 15       |
| <b>Total Audits by Protocol</b>            | 100     | 100    | 200      |

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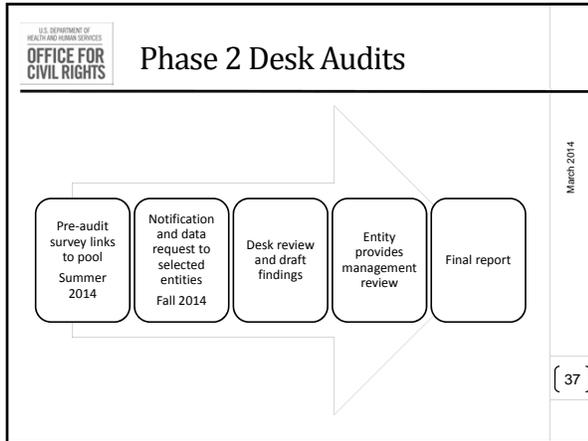
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## Phase 2 Timing

| Period                    | Activity   |
|---------------------------|--|
| Spring 2014               | CE address verification                                    |
| Summer 2014               | Pre-audit surveys link sent to covered entity pool         |
| Fall 2014                 | Notification and data request letters to selected entities |
| Two weeks                 | Period for entity response                                 |
| October 2014 -- June 2015 | CE Audit Reviews   |
| 2015                      | Business Associates  |

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- U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
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- ## Desk Audit Expectations
- Data request will specify content & file organization, file names, and any other document submission requirements
  - Only requested data submitted on time will be assessed.
  - All documentation must be current as of the date of the request.
  - Auditors will not have opportunity to contact the entity for clarifications or to ask for additional information, so it is critical that the documents accurately reflect the program.
  - Submitting extraneous information may increase difficulty for auditor to find and assess the required items.
  - Failure to submit response to requests may lead to referral for regional compliance review
- March 2014
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### Electronic Management System

- All communication electronic—entities will receive and respond to pre-audit survey, notification and document requests through email, or other electronic media (eg, CD)

Audit management system for

- Document retention
- Auditor assignments
- Work papers
- Audit manager review
- Referral for regional compliance review

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### Phase 2 Protocol Criteria

March 2014

- Auditors will assess entity efforts through an updated protocol; new criteria reflect omnibus rule changes and more specific test procedures
- Uses sampling methodology in a number of provisions to assess compliance efforts
- Desk audits will target particular provisions that were the source of a high number of compliance failures in the pilot audits
- Updated protocol will be available on web site so that entities can use it for internal compliance assessments

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### Phase 2 Audit Focus

March 2014

**2014 – Covered Entities**

- Security—Risk analysis and risk management
- Breach—Content and timeliness of notifications
- Privacy—Notice and Access

**2015**

*Round 1 Business Associates*

- Security—Risk analysis and risk management
- Breach—Breach reporting to CE

*Round 2 Covered Entities (Projected)*

- Security—Device and media controls, transmission security
- Privacy—Safeguards, training to policies and procedures

**2016 (Projected)**

- Security: Encryption and decryption, facility access control (physical); other areas of high risk as identified by 2014 audits, breach reports and complaints

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|    | <h2>EHR &amp; HIPAA on Medscape</h2> | <p style="writing-mode: vertical-rl; transform: rotate(180deg);">March 2014</p> |
| <ul style="list-style-type: none"> <li>• New! 6<sup>th</sup> module EHRs and HIPAA: Steps for Maintaining the Privacy and Security of Patient Information."</li> <li>• For physicians, nurses, and other healthcare professionals; free Continuing Medical Education (CME) and Continuing Education (CE) credits. Steps to safeguard patient data on electronic health records (EHRs), to plan appropriate communication for patients about how their data will be stored and used on EHRs, and to evaluate Meaningful Use criteria related to data security and privacy required as part of the EHR Incentive Program.</li> <li>• OCR's Medscape destination page at <a href="http://www.medscape.org/sites/advances/patients-rights">http://www.medscape.org/sites/advances/patients-rights</a>.</li> </ul> |                                      |   |

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|   | <h2>Medscape Education Tools</h2> | <p style="writing-mode: vertical-rl; transform: rotate(180deg);">March 2014</p> |
| <ul style="list-style-type: none"> <li>• <i>Patient Privacy: A Guide for Providers</i><br/><a href="http://www.medscape.org/viewarticle/781892?src=ocr2">http://www.medscape.org/viewarticle/781892?src=ocr2</a></li> <li>• <i>HIPAA and You: Building a Culture of Compliance</i><br/><a href="http://www.medscape.org/viewarticle/762170?src=ocr2">http://www.medscape.org/viewarticle/762170?src=ocr2</a></li> <li>• <i>Examining Compliance with the HIPAA Privacy Rule</i><br/><a href="http://www.medscape.org/viewarticle/763251?src=ocr2">http://www.medscape.org/viewarticle/763251?src=ocr2</a></li> <li>• These Medscape modules offer free Continuing Medical Education (CME) credits for physicians and Continuing Education (CE) credits for health care professionals.</li> </ul> |                                   |   |

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|    | <h2>Security Rule Compliance Aides</h2> | <p style="writing-mode: vertical-rl; transform: rotate(180deg);">March 2014</p> |
| <ul style="list-style-type: none"> <li>• New! Risk Analysis tool for small providers from ONC, find at <a href="http://healthit.gov">http://healthit.gov</a></li> <li>• HHS Mobile Device Security Resource Kit             <ul style="list-style-type: none"> <li>• <a href="http://healthit.gov/mobiledevices">http://healthit.gov/mobiledevices</a></li> </ul> </li> <li>• Vast Array of Guidance Material             <ul style="list-style-type: none"> <li>• <a href="http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html">http://www.hhs.gov/ocr/privacy/hipaa/administrative/securityrule/securityruleguidance.html</a></li> </ul> </li> </ul> |   |   |

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| <small>U.S. DEPARTMENT OF<br/>HEALTH AND HUMAN SERVICES</small><br><b>OFFICE FOR<br/>CIVIL RIGHTS</b>   | <h2>More Information</h2> | <small>March 2014</small> |
| <p><b>HIPAA Audit Webpage</b><br/><a href="http://www.hhs.gov/ocr/privacy/hipaa/enforcement/audit/index.html">http://www.hhs.gov/ocr/privacy/hipaa/enforcement/audit/index.html</a></p> <p>Wide range of other information about health information privacy including educational resources, FAQ's, rule text and guidance for the Privacy, Security, and Breach Notification Rules<br/><a href="http://www.hhs.gov/ocr/privacy/">http://www.hhs.gov/ocr/privacy/</a></p> |                           | ( 46 )                    |

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### The Dance of Compliance Program Oversight: Building a Successful Board & Compliance Officer Partnership

Mike Roosevelt, Esq.  
Chair, Audit Committee and Board Member  
Sutter Health  
San Francisco, CA

Steve Ortquist, JD, CHC-F, CCEP, CHRC  
Managing Director,  
Aegis Compliance & Ethics Center, LLP  
Chicago, IL



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### Compliance Program Oversight The Governing Body's Role



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### Development of the "Duty to Monitor"

Directors' duty of care includes a duty to attempt in good faith to assure that:

1. A corporate information and reporting system exists, and
2. The reporting system is adequate to assure the board that appropriate compliance-related information will come to its attention in a timely manner, in ordinary course.

*In re Caremark International Inc. Derivative Litigation*, 698 A.2d 959 (Del. 1996)



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### Development of the "Duty to Monitor"

To prevail on a breach of the "duty to monitor" a plaintiff must show either that

- (a) "the directors utterly failed to implement any reporting or information system or controls" to monitor the business, or else
- (b) "having implemented such a system or controls, [the directors] consciously failed to monitor or oversee its operations thus disabling themselves from being informed of risks or problems requiring their attention."

Scienter Element: "[i]n either case, imposition of liability requires a showing that the directors knew that they were not discharging their fiduciary obligations," that is, that they were "demonstrating a conscious disregard for their responsibilities."

*Stone v. Ritter*, 911 A2d 362, 370 (Del. 2006)




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### Expansion of the Delaware "Duty to Monitor?"

#### *Citigroup*

Plaintiff shareholders attempted to hold Citigroup's directors personally liable (*Caremark duty of oversight theory*) because of their failure to be fully informed regarding Citigroup's business risk in the subprime mortgage market.




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### Expansion of the Delaware "Duty to Monitor?"

#### Classic *Caremark* cases

Theory: Directors should be liable for their failure to monitor employee misconduct or violations of law.

#### *Citigroup*

Theory: Directors should be liable for their failure to be informed about and monitor the organization's business risk.




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**Federal Sentencing Guidelines**  
Sentencing of Organizations § 8B2.1.(b)(2)(A)  
Board's leadership obligations:

- Be knowledgeable about the content and operation of the compliance and ethics program;
- Exercise reasonable oversight with respect to the implementation and effectiveness of the compliance & ethics program



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**Federal Sentencing Guidelines**  
*Ad Hoc Advisory Group Report (2004)*

Knowledgeable about the content and operation of the program

*"The knowledge about program features and operations that members of a governing authority should gain includes:*

- practical management information about the major risks of unlawful conduct facing their organization;
- the primary compliance program features aimed at counteracting those risks; and
- the types of problems with compliance that the organization and other parties with similar operations have encountered in recent activities."

*(Report of the Ad Hoc Advisory Group leading to the 2004 Sentencing Guidelines amendments, October 7, 2003)*



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**Federal Sentencing Guidelines**  
*Ad Hoc Advisory Group Report (2004)*

Exercise reasonable oversight

*"The provisions of this proposal describing the oversight duties of governing authority members recognize that effective management requires that governing authorities be proactive in*

- seeking information about compliance problems,
- evaluating that information when received, and
- monitoring the implementation and effectiveness of responses when compliance problems are detected."



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## Federal Sentencing Guidelines

### Other board obligations

- Receive periodic reports from the compliance officer and/or other persons responsible for the compliance program about its implementation and effectiveness
- Compliance personnel must have "reporting obligations" to the board to get full credit for the compliance & ethics program (2011 amendments)
- Participate in periodic compliance training
- Accessible to the compliance officer



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## Corporate Integrity Agreement Requirements

Tenet, Novartis, Wellcare, AstraZeneca, etc.

- Quarterly review and oversight by board/committee, including of executive compliance committees and compliance officers
- Annual effectiveness reviews
- Compliance expert to advise board
- Committee resolution/certification (signed by each board committee member)



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## Freeh Report (Penn State)

Citing *Stone v. Ritter*, Special Counsel found that the Board failed in its fiduciary duties because:

- In 1998 and 2001 the Board did not have regular reporting procedures or committee structures in place to ensure disclosure to the Board of major risks; and
- In 2011 because, after becoming aware of the Grand Jury investigation of Sandusky, Board members did not independently assess the information provided by Spanier (President) and Baldwin (General Counsel) or demand detailed reporting from the same.
- The Board failed to create a "Tone at the Top" environment that Sandusky and other University officials believed they were accountable to.
- The Board's failure to insist on thorough reporting led to an environment where President Spanier did not feel accountable for keeping the Board immediately informed on serious developments.
- "The Board allowed itself to be marginalized by not demanding 'thorough and forthright reports on affairs of the University'



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### Makeup of the Board or Oversight Committee

Should oversight committees include a member(s) with compliance & ethics expertise?

See, e.g., SEC Disclosure Rule re: "Audit Committee Financial Expert"

- Understanding of financial statements and GAAP
- Ability to assess general application of such principles in connection with accounting for estimates, accruals and reserves
- Expertise in preparing, auditing or evaluating financial statements
- An understanding of internal controls
- An understanding of the audit committee functions.

See, e.g., Dodd Frank requirement that banks establish risk committees with "at least one risk management expert having experience in identifying, assessing, and managing risk exposures of large, complex firms."



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### Compliance Program Management The Compliance Officer's Role



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### Federal Sentencing Guidelines

Sentencing of Organizations § 8B2.1.(b)(2)(B)

(B) High-level personnel of the organization shall ensure that the organization has an effective compliance and ethics program, as described in this guideline. Specific individual(s) within high-level personnel shall be assigned overall responsibility for the compliance and ethics program.

*"High-Level Personnel" means individuals who have substantial control over the organization or who have a substantial role in making policy within the organization. (e.g., a director; an executive officer; an individual in charge of a major business or functional unit such as sales, administration, or finance; a person with a substantial ownership interest.)*



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**Federal Sentencing Guidelines**  
Sentencing of Organizations § 8B2.1.(b)(2)(B)

(C) Specific individual(s) within the organization shall

- be delegated day-to-day operational responsibility for the compliance and ethics program
- report periodically to High-Level Personnel and, as appropriate, to the governing authority (or an appropriate subgroup) on the effectiveness of the program.

To carry out such operational responsibility, such individual(s) shall be given

- adequate resources,
- appropriate authority, and
- direct access to the governing authority (or an appropriate subgroup).



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**The Compliance Officer: OIG Compliance Program Guidance**

At a minimum every compliance program should include . . .

“designation of a chief compliance officer . . . charged with the responsibility of operating and monitoring the compliance program, and who report[s] directly to the CEO and the governing body.”



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**Compliance Officer Duties - OIG CPGs**

Compliance Officer's primary responsibilities should include:

- Overseeing and monitoring implementation of the compliance program;
- Reporting on a regular basis to the governing body, CEO and compliance committee on progress and effectiveness;
- Assisting [the governing body, CEO and management] in improving quality and reducing vulnerability to fraud, waste and abuse;



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### Compliance Officer Duties - OIG CPGs

- Periodically revising the compliance program to address changes in the organization and in the laws and policies of government and private payors;
- Developing and participating in training programs focused on elements of the compliance program and on assuring that employees and management understand legal and policy requirements;
- Ensuring that contractors and agents are aware of the requirements of the compliance program;



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### Compliance Officer Duties - OIG CPGs

- Coordinating personnel issues with HR and ensuring appropriate screening of employees, medical staff and independent contractors;
- Assisting in coordination of internal compliance reviews and monitoring activities;
- Independently investigating and acting on matters related to compliance, including coordination of corrective action with responsible management;
- Developing policies and programs to encourage reporting of suspected impropriety without fear of retaliation.



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### Compliance Officer Resources – OIG CPGs

#### Compliance Officer should/must have:

- Authority to review all documents and other information relevant to compliance activities;
- Sufficient finding and staff to perform his or her responsibility fully;
- Direct access to the governing body and to the CEO.



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### NOTE: Responsible Corporate Officer Doctrine

- *U.S. v. Dotterweich and U.S. v. Park* (1975) originally established Responsible Corporate Officer Doctrine
  - The individual's position of responsibility allows the individual to influence corporate policies or activities;
  - There is a connection between the individual's position and the violation such that the individual could have influenced the corporate actions; and
  - The individual's action or inaction facilitated the violation.

*Individual defendants can be found guilty of a criminal violation without any proof that they knew of the criminal activity in their organization.*



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### NOTE: Responsible Corporate Officer Doctrine

#### *U.S. v. Purdue Frederick Co., Inc.*

- Misbranding of OxyContin
- President, CMO and GC pled to misdemeanor misbranding charges & paid \$34.5M in fines/penalties

#### *U.S. v. Norian Corp.*

- Promotion of bone cement for unauthorized uses
- President, COO and Dir. of Regulatory and Clinical Affairs pled to misdemeanor and serve prison terms of 5 to 9 months



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### OIG's Expanded Use of Exclusionary Authority

"Liability as a responsible corporate officer does not turn upon a corporate officer's approval of wrongdoing, but rather on whether the officer had, by reason of his or her position in the corporation, responsibility and authority either to prevent, or promptly correct, the violation at issue, and the officer failed to do so."

Inspector General Levinson announcing expanded use of exclusion authority at 2010 HCCA Compliance Institute.



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**OIG's Expanded Use of Exclusionary Authority**

**OIG's *Guidance for Implementing Permissive Exclusion Authority Under Section 1128(b)(15) of the Social Security Act***

- Exclusionary authority can be used against:
  - compliance officers – traditional responsible corporate officer doctrine;
  - board members who "knew or should have known" about the misconduct in question.



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**Oversight Considerations LEADERSHIP**

- Does the compliance officer have the right reporting obligations and access to the board/audit & compliance committee?
- Is the compliance officer positioned correctly in the organization?
  - seniority (*specific individual(s) within High-Level Personnel assigned overall responsibility; High-Level Personnel = substantial control over the organization or a substantial role in policy making. E.g., director, executive officer, in charge of a major business unit or function.*)
  - reporting relationship
- Is management meeting its obligations and supporting the program?



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**Oversight Consideration RISK AREAS**

- What are the organization's primary compliance risks/risk areas?
  - Stark and/or Anti-kickback?
  - privacy & security?
  - billing/coding/false claims?
  - other?
- How can board members maintain a basic understanding of
  - legal & regulatory requirements in these risk areas?
  - what other organizations are experiencing?
  - their organization's prior experience?
  - what causes most significant risk for your organization?



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**Oversight Consideration  
COMPLIANCE PROGRAM  
STRUCTURE**

- Does the compliance program's structure align with the "seven elements?"
- Does the compliance program's structure address what is called for by applicable industry guidance? (E.g., OIG CPGs; DOJ *Principles of Prosecution*)
- Does the compliance & ethics program address organizational risks?
- Does the compliance & ethics program have adequate resources?
- Does the compliance & ethics program work? What is provided by management/compliance officer to illustrate that the program is effective?
- Has there been an external evaluation of the effectiveness of the compliance & ethics program?



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**Importance of External Effectiveness Evaluation**

"On February 8, 1993, the Ethics Committee of Caremark's Board received and reviewed an outside auditors report . . . which concluded that there were no material weaknesses in Caremark's control structure."  
*In re Caremark*

"The [external firm's compliance program evaluation] Report reflects that the directors not only discharged their oversight responsibility to establish an information and reporting system, but also proved that the system was designed to permit the directors to periodically monitor AmSouth's compliance with . . . regulations."  
*Stone v. Ritter*



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**Oversight Considerations  
STRUCTURE – REPORTING  
MECHANISMS**

- Are reporting mechanisms (e.g., hotline) working properly (e.g., confidential, trusted by workforce?)
- Do reporting and response mechanisms assure that appropriate concerns are raised to board's/committee's attention?
- Does the organization take appropriate steps to respond to problems (remediation, prevention, etc.)



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### Board/Audit Committee Report Considerations

- Reporting mechanism/hotline calls
- Risk assessment
- Annual workplan and progress
- Significant investigations
- Compliance audit results
- Corrective action plans



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### Board/Audit Committee Report Considerations

- Internal effectiveness metrics
  - scorecards
  - overpayment returns
- Periodic external effectiveness Reviews
- Other?



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### Compliance Resources

United States Sentencing Commission's *Sentencing Guidelines for Organizations* (see particularly § 8B2.1, *Effective Compliance & Ethics Program*)  
[http://www.ussc.gov/Guidelines/Organizational\\_Guidelines/guidelines\\_chapter\\_8.htm](http://www.ussc.gov/Guidelines/Organizational_Guidelines/guidelines_chapter_8.htm)

U.S. DHHS OIG compliance program guidances  
<http://oig.hhs.gov/compliance/compliance-guidance/index.asp>

American Health Lawyers Association/Office of Inspector General Governance Resources  
<http://www.healthlawyers.org/hiresources/PI/InfoSeries/Pages/CorporateResponsibilityCollection.aspx>

Free Report (Penn State) <http://progress.psu.edu/the-free-report>

U.S. Department of Justice *Principles of Federal Prosecution of Business Organization's*  
[www.justice.gov/opa/documents/corp-charging-guidelines.pdf](http://www.justice.gov/opa/documents/corp-charging-guidelines.pdf)



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**QUESTIONS &  
DISCUSSION**



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Mike Roosevelt  
[mike.roosevelt@fomlaw.com](mailto:mike.roosevelt@fomlaw.com)  
415-434-1363

Steve Ortquist  
[sortquist@aegis-compliance.com](mailto:sortquist@aegis-compliance.com)  
312-285-4850



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## Risk Rating Guidelines

| CRITERIA  | 1 - LOW  | 2 - MEDIUM  | 3 - HIGH   | 4 - Audit Committee  |
|---|--|---|--|--|
| Before opening/rating;<br>Down-grading <b>OR</b><br>Closing Cases | Affiliate Compliance Officer <b>without</b><br>review of RCO or VP/CCO   | <b>Requires</b> RCO or VP/CCO if RCO is<br>primary investigator approval  | <b>Requires</b> VP/CCO approval  | <b>Requires</b> VP/CCO approval  |
| Frequency   | Isolated or rare occurrence<br>No indication of system failure   | Pattern or repeated events that suggest<br>deficient practices or poorly designed<br>processes  | Pervasive or widespread activity that suggests<br>a systemic failure   |  |
| Position of Authority   | Allegation involves an individual without<br>supervisory authority   | Allegation involves an individual with<br>supervisory or middle-management<br>authority   | Allegation involves an individual with senior<br>management, executive management,<br>officer, or board-level authority.   | Allegation involving executive<br>management or board level<br>personnel, and involving<br>significant misconduct, appears<br>credible or is confirmed |
| Financial Risk  | Situation would not expose the affiliate<br>to significant financial risk  | Situation may expose the affiliate to<br>significant financial risk   | Significant financial risk is likely   | Confirmed facts may expose Sutter<br>Health to <i>material</i> financial risk  |
| Operational Risk  | Incident poses no risk to continued<br>operations or qualification to do<br>business   | Incident causes a tolerable delay in<br>some aspects of operations, but poses<br>no risk to continued qualification to do<br>business   | Incident has the potential to shut down<br>operations<br>Incident puts at risk permits, licenses or other<br>grants necessary to the ability to conduct<br>business  | Incident is likely to shut down<br>operations unless immediate<br>remediation steps are successful   |
| Reputational Risk   | No publicity is threatened or expected   | Publicity is unlikely to have significant<br>impact on Sutter's reputation or<br>operations   | Publicity is threatened, likely or has occurred<br>and could have significant or lasting impact<br>on Sutter's reputation or operations  | Publicity is threatened, likely or has<br>occurred and is of a nature that<br>the BOD should be made aware.  |
| Patient Safety Risk   | Error or condition was caught by a<br>control or error detection barrier<br>No actual or potential harm to patients  | Has caused or is likely to cause minimal<br>harm to patients  | Serious safety event<br>"Never Events"<br>Has injured or is likely to injure patients<br>Includes moderate to severe harm, either<br>temporary or permanent  | A pattern of conduct or failures<br>causing significant harm to<br>patients has been identified  |
| Control Framework Risk  | Nature of incident does not suggest<br>either a control weakness or a pattern<br>of behavior   | Nature of incident suggests a control<br>weakness, but not a pattern of<br>behavior   | Nature of incident suggests a <i>material</i> control<br>weakness or a pattern of behavior   |  |
| Legal Risk  | Allegation if true expose individuals to<br>potential liability, but not the<br>organization   | Allegations if true could expose the<br>organization to potential civil liability,<br>but not significant civil or criminal<br>liability  | Allegations if true could expose the<br>organization to significant civil or potential<br>criminal liability   | Verified facts as such that the<br>organization may be exposed to<br>significant civil or potential<br>criminal liability                              |
| Regulatory Risk   | Allegation, even if true, would not<br>require external reporting or third-<br>party investigation<br><br><b>Privacy Exception:</b> Based on HIPAA<br>risk assessment, report to DHHS not<br>required. | Allegation if true requires external<br>reporting, but would not prompt third-<br>party investigation.<br><br><b>Privacy Exception:</b> Based on HIPAA<br>risk assessment report to DHHS<br>required. Incident involves < 500<br>individuals. | Allegation if true requires external reporting<br>and would likely prompt third-party<br>investigation.<br>Exposes organization to potential loss of<br>license, Medicare certification, or<br>administrative fines.<br><b>Privacy Exception:</b> Incident involving >500<br>individuals, reports to DHHS and the media<br>required. |  |
| System Impact   | Affects few subsidiaries<br>No apparent pattern  | Affects a region or several subsidiaries<br>across more than one region   | Affects multiple regions<br>Affects the majority of medical groups or<br>hospitals   | Substantiated, systemic problems<br>that also potentially implicate<br>other BOD level rating guidelines   |

This tool is designed to help you evaluate and prioritize potential compliance issues based on a variety of risks. Potential issues could arise from EthicsPoint reports, risk assessment findings, monitoring activities, audit results, or other sources. The tool offers general guidelines for assessing different risks that could apply to a particular issue, but it is not designed as a quantitative scoring tool. Some of the criteria may be irrelevant to a given issue, and in some cases one or two aspects of a situation may be so serious that it deserves to be treated as a high risk overall, even if the other risk factors are low.

\**Material* means events, situations, or facts that are significant enough to influence decisions by an individual or group; capable of having a significant influence on outcomes. For a discussion of materiality in financial statements, and why numerical thresholds may be misleading, see *SEC Staff Accounting Bulletin 99*, available at <http://www.sec.gov/interps/account/sab99.htm>.

Adapted from *The Helpline/Hotline Handbook* (Open Compliance and Ethics Group, 2007)

# Compliance Program Accountability Scorecard

## Section 1 - Written Standards

| SCORING ITEM  | MAXIMUM POINTS/SCORING METHODOLOGY  | INSTRUCTIONS FOR SCORING   | COMMENTS  |
|---|---|--|---|
| <p><b>1. Timely Distribution and Review of New and Revised Compliance Policies.</b> New or revised compliance policies will be distributed to affected workforce members within 30 days of the policy's effective date. Affected workforce members will be required to acknowledge receipt and review of each new or revised policy within 60 days of the policy distribution.</p> <p><b>ALL DEPARTMENTS/BUSINESS UNITS</b></p> | <p>For each new or revised compliance policy that is distributed, up to 10 points will be awarded to the department/business unit, based on the percentage of workforce members who timely complete the review and acknowledgement.</p> <p><b>Maximum of 10 points per policy:</b><br/> <math>\geq 95\% = 10</math> points; <math>\geq 90\%</math> to <math>&lt; 95\% = 5</math> points; <math>\geq 85\%</math> - <math>&lt; 90\% = 2</math> points; <math>&lt; 85\% = 0</math> points.</p> <p>Total number of possible points for the year will depend upon the number of compliance policies distributed.</p> | <p><i>Once PolicyStat is implemented it will be utilized to track review and acknowledgement of new policies. Until PolicyStat is implemented, new policies will be assigned in HealthStream and HealthStream will be utilized to track review and acknowledgement by affected employees. If workforce members who are not employees are required to review and acknowledge new compliance policies, email or online survey tools will be utilized to distribute policies and to track timely review and acknowledgement. Scoring will be completed by [ORGANIZATION'S] compliance staff based on records found in PolicyStat or HealthStream, or (for non-employees) records provided by the department/business unit compliance officer.</i></p> | <p><i>This measure provides [ORGANIZATION'S] departments/business units with credit for maintaining sound processes for distributing and communicating new compliance policy requirements and enforcing compliance with adhering to the requirements for distribution, review, and acknowledgement.</i></p> |

| SCORING ITEM  | MAXIMUM POINTS/SCORING METHODOLOGY  | INSTRUCTIONS FOR SCORING   | COMMENTS  |
|---|---|--|---|
| <p><b>2. [ORGANIZATION'S] Standards of Business Conduct (SBC) Review and Acknowledgement – <u>New Employees</u>.</b> New employees will be required to acknowledge by electronic signature their receipt of, and agreement to abide by, the [ORGANIZATION'S] Code of Business Conduct. The CBC will be assigned as an element of 2013 annual compliance training for new employees in HealthStream, and will be due within 60 days of the employee's start date with [ORGANIZATION].</p> <p><b>ALL DEPARTMENTS/BUSINESS UNITS</b></p> | <p>HealthStream records will be used to monitor compliance with this requirement. Scoring will be based upon the number of employees, calculated as a percent of all new employees, who complete the required acknowledgement within 60 days of start date, as evidenced by HealthStream records.</p> <p><b>Maximum 100 points per year:</b><br/> <math>\geq 98\% = 100</math> points; <math>\geq 92\%</math> to <math>&lt; 98\% = 50</math> points; <math>\geq 85\%</math> to <math>&lt; 92\% = 25</math> points; <math>&lt; 85\% = 0</math> points.</p> | <p><i>Scoring will be completed by [ORGANIZATION'S] compliance staff based on records found in HealthStream.</i></p> | <p><i>This measure provides [ORGANIZATION'S] department/business units with credit for promoting timely receipt and acknowledgement of [ORGANIZATION]'s CBC by all new employees.</i></p> |

**Section 2 - Compliance Program Leadership**

| SCORING ITEM  | MAXIMUM POINTS/SCORING METHODOLOGY   | INSTRUCTIONS FOR SCORING   | COMMENTS  |
|---|--|--|---|
| <p>1. <b>Attendance at Department/business unit Compliance Committee Meetings.</b> Points will be awarded for each department/business unit Compliance Committee (CC) meeting for which at least 60% (a quorum) of appointed committee members are in attendance for the entire meeting.</p> <p><b>ALL DEPARTMENTS/BUSINESS UNITS</b></p> | <p>Scoring will be based on attendance at department/business unit Compliance Committee meetings by appointed members as recorded in final meeting minutes.</p> <p>Twenty-five points will be awarded for one CC meeting each quarter at which at least 60% of appointed committee members are in attendance for the entire meeting.</p> <p><b>Maximum 25 points per quarter.<br/>Maximum 100 points per year.</b></p> | <p><i>Scores will be assigned based on a review of minutes for CC meetings. Scores will be validated with each department/business unit compliance officer before being finalized.</i></p> <p><i>Attendance of appointed members who represent more than one department/business unit will be counted separately for each department/business unit that is represented.</i></p> <p><i>When a department/business unit holds more than one CC meeting during any given quarter, the meeting with the highest number of appointed members in attendance shall be used to calculate the scoring for this requirement.</i></p> | <p><i>This measure provides [ORGANIZATION'S] department/business units with credit for maintaining a functioning compliance committee and for participation by requisite appointed members.</i></p> |

### Section 3 - Compliance Training and Education

| SCORING ITEM   | MAXIMUM POINTS/SCORING METHODOLOGY  | INSTRUCTIONS FOR SCORING  | COMMENTS  |
|--|---|---|---|
| <p>1. <b>Compliance Training for <u>New Employees</u>:</b> Compliance training will be assigned to new employees in two modules.</p> <p>Module 1 will be in-person classroom training during new employee orientation, and will introduce the employee to the compliance program. (Session must be 60 minutes in length.)</p> <p>Module 2 will be provided via HealthStream, and will cover several common compliance risk areas in more depth.</p> <p>All new hires must complete both modules within 60 days of their start date with [ORGANIZATION].</p> <p><b>ALL DEPARTMENTS/BUSINESS UNITS</b></p> | <p>HealthStream records will be used to monitor compliance with this requirement. Scoring will be based upon the number of new employees (calculated as a percentage of total new employees) who complete required compliance training within 60 days of start date, as evidenced by HealthStream records.</p> <p><b>Maximum of 300 points per year:</b><br/>           100% = 300 points; <math>\geq 92\%</math> to &lt; 100% = 200 points; <math>\geq 85\%</math> to &lt; 92% = 100 points; &lt; 85% = 0 points</p> | <p><i>For in-person training, sign in sheets must be maintained by the department/business unit HealthStream Administrator and provided to the department/business unit compliance officer and employee attendance records must be entered into HealthStream by the department/business unit HealthStream Administrator for tracking purposes.</i></p> <p><i>New employees who timely complete compliance training as part of New Employee Orientation will be exempted from additional online Annual Compliance Training requirements (see 2. below) in the calendar year that New Employee training was timely completed.</i></p> | <p><i>This measure provides [ORGANIZATION'S] department/business units with credit for maintaining an effective compliance training program and promoting timely completion of compliance training for new employees.</i></p> |
| <p>2. <b>Annual Compliance Training for Existing Employees:</b> Annual compliance training will be completed by all employees via HealthStream. This training consists of two modules. Both modules are MANDATORY, and both must be completed by midnight on December 31, 2013.</p> <p><b>ALL DEPARTMENTS/BUSINESS UNITS</b></p>   | <p>HealthStream records will be used to monitor compliance with this requirement. Scoring will be based upon completion of online compliance training by the established deadline, as evidenced by HealthStream records.</p> <p><b>Maximum of 300 points:</b><br/>           100% = 300 points; <math>\geq 92\%</math> to &lt; 100% = 200 points; <math>\geq 85\%</math> to &lt; 92% = 100 points; &lt; 85% = 0 points</p>  | <p><i>Scoring will be completed by compliance staff using data obtained from Lawson and HealthStream. Score will be based on information as found in HealthStream.</i></p>  | <p><i>This measure provides [ORGANIZATION'S] department/business units with credit for promoting timely completion of annual compliance training by all employees.</i></p>  |

| SCORING ITEM  | MAXIMUM POINTS/SCORING METHODOLOGY   | INSTRUCTIONS FOR SCORING   | COMMENTS   |
|---|--|--|--|
| <p>3. <b>Specific Compliance Training:</b><br/> Role-based specific compliance training (<i>e.g., Physician Financial Arrangements/Stark Training</i>) will be assigned from time to time to individuals whose roles place them in a position of responsibility for managing or assisting with avoidance of compliance risks for the department/business unit or for [ORGANIZATION]. To receive credit for this metric, training must be completed by the due date assigned by the Executive Compliance Committee.</p> <p><b>ALL DEPARTMENTS/BUSINESS UNITS</b></p> | <p>Sign in sheets (for classroom sessions) and HealthStream records will be used as evidence of timely training completion. Scoring will be based upon completion of the training by the established deadline.</p> <p><b>Maximum 100 to 300 points per course (as determined by Executive Compliance Committee):</b></p> <p>100% = maximum points;</p> <p>≥ 92% to &lt; 100% = 66% possible points;</p> <p>≥ 85% to &lt; 92% = 33% possible points;</p> <p>&lt; 85% = 0 points</p> | <p><i>Sign in sheets will be made available until 15 minutes after the start of each classroom session. Individuals who are required to attend training must participate in the full session to receive credit.</i></p> <p><i>For classroom training, sign in sheets must be maintained by the department/business unit compliance officer and employees' attendance records must be entered into HealthStream by the department/business unit for tracking purposes.</i></p> <p><i>Scoring will be completed by compliance staff using attendance records as found in HealthStream.</i></p> | <p><i>This measure provides [ORGANIZATION'S] department/business units with credit for maintaining an effective compliance training program and promoting timely completion of specific compliance training by those to whom it is assigned.</i></p> |

## Section 4 - Auditing & Monitoring

| SCORING ITEM  | MAXIMUM POINTS/SCORING METHODOLOGY  | INSTRUCTIONS FOR SCORING  | COMMENTS   |
|---|---|---|--|
| <p>1. <b>Management of Identified Overpayments from Governmental Payers.</b><br/>Overpayments from government payers must be reported and returned within 60 days of being <i>identified</i> (Federal law), and must be recorded in the overpayment tracking database pursuant to ORGANIZATION policy.</p> <p><b>ALL DEPARTMENTS/BUSINESS UNITS</b></p> | <p>Score will be based on the percentage of overpayments (calculated as the amount in dollars repaid divided by the amount in dollars overpaid) that are timely recorded in the overpayment database, and are reported and repaid within 60 days of identification.</p> <p><b>Maximum 100 points per year:</b><br/> <math>\geq 98\% = 100</math> points; <math>\geq 92\%</math> to <math>&lt; 98\% = 50</math> points; <math>\geq 85\%</math> to <math>&lt; 92\% = 25</math> points; <math>&lt; 85\% = 0</math> points.</p> | <p><i>The overpayment tracking database will be used to score this metric. However, all government program overpayments identified within the department/business unit must be entered into the overpayment database and will be included in this calculation. Scores will be based on the percentage of government overpayments (calculated based on total dollars overpaid and repaid) that are reported and repaid within 60 days of being identified. In situations where repayment will occur in the form of a take-back by a government payer, the overpayment will be deemed repaid on the date when the department/business unit has completed all steps necessary to facilitate the take-back.</i></p> | <p><i>This measure provides [ORGANIZATION'S] department/business units with credit for maintaining an effective mechanism for promoting timely repayment of <u>identified</u> overpayments to Medicare.</i></p>  |
| <p>2. <b>Tracking Non-Monetary Compensation (NMC) to Physicians</b><br/>[ORGANIZATION'S] department/business units are required to track instances of NMC provided to referring physicians in the NMC tracking database to assure compliance with NMC requirements.</p> <p><b>ALL DEPARTMENTS/BUSINESS UNITS</b></p>                                    | <p>Scoring will be based on the percentage of NMC events that are timely recorded in the NMC tracking database, as required by policy titled <i>Tracking Non-Monetary Compensation Provided to Referring Physicians</i>.</p> <p><b>Maximum of 100 points per year:</b><br/> <math>\geq 98\% = 100</math> points; <math>\geq 92\%</math> to <math>&lt; 98\% = 50</math> points; <math>\geq 85\%</math> to <math>&lt; 92\% = 25</math> points; <math>&lt; 85\% = 0</math> points.</p>   | <p><i>Scoring will be based on outcomes of periodic reviews of the department/business unit's use of the NMC Database conducted by the department/business unit compliance officers.</i></p>  | <p><i>This measure provides [ORGANIZATION'S] department/business units with credit for maintaining a mechanism for ensuring that NMC offered to physicians is effectively tracked and monitored, in order to limit the risk of exceeding the annual limit.</i></p> |

| SCORING ITEM   | MAXIMUM POINTS/SCORING METHODOLOGY   | INSTRUCTIONS FOR SCORING   | COMMENTS   |
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| <p>3. <b>Proper Management of Short-Stay and Observation Cases (Hospitals Only)</b><br/> This monitoring process will be implemented by [ORGANIZATION'S] hospitals in to test and confirm adherence to Medicare rules that control proper billing for observation cases, and for cases that require a (condition code 44) status change from inpatient to outpatient.</p> <p><b>HOSPITALS ONLY</b></p> | <p>Scoring will be based on the outcome of monitoring processes for observation and short stay accounts completed quarterly by each hospital department/business unit. The monitoring process will require confirmation of compliance with metrics that are critical to assure appropriate billing of observation accounts, and short stay accounts with status changes (condition code 44) from inpatient to outpatient. Monitoring metrics will include: (1) appropriate order, (2) nursing documentation, (3) case management medical necessity (Interqual) review, (4) documentation of hours and (5) appropriate handling of condition code 44 requirements.</p> <p><b>Maximum 50 points per quarter.</b><br/> <b>Maximum 200 points per year:</b><br/> ≥ 98% = 200 points; ≥ 92% to &lt; 98% = 100 points; ≥ 85% to &lt; 92% = 50 points; &lt; 85% = 0 points.</p> | <p><i>Scoring will be calculated using monitoring/reporting templates developed by compliance. Scores will be computed by compliance staff using data found in monitoring reports.</i></p> | <p><i>This measure provides [ORGANIZATION'S] department/business units with credit for maintaining a mechanism for monitoring Medicare outpatient observation services, in order to limit the risk of inappropriate billing.</i></p> |
| <p>4. <b>Responding to Recovery Audit Contractor (RAC) Requests (Hospitals only)</b><br/> [ORGANIZATION'S] hospitals are required to record all RAC requests within 15 (calendar) days of receipt to facilitate appropriate and timely response, and to facilitate identification of trends in RAC requests and recoveries.</p> <p><b>HOSPITAL ONLY</b></p>  | <p>Scoring will be based on the percentage of RAC requests that are timely recorded.</p> <p><b>Maximum 100 points per year:</b><br/> ≥ 98% = 100 points; ≥ 92% to &lt; 98% = 50 points; ≥ 85% to &lt; 92% = 25 points; &lt; 85% = 0 points.</p>  | <p><i>Scoring will be performed based on periodic reviews conducted by the department/business unit compliance officers.</i></p>   | <p><i>This measure provides [ORGANIZATION'S] department/business units with credit for maintaining a mechanism for managing RAC requests.</i></p>  |

| SCORING ITEM  | MAXIMUM POINTS/SCORING METHODOLOGY  | INSTRUCTIONS FOR SCORING  | COMMENTS   |
|---|---|---|--|
| <p>5. <b>Monitoring Outpatient Infusion Therapy Coding/Billing</b><br/> This monitoring process has been implemented by [ORGANIZATION'S] hospitals, physician groups, and home health agencies to test and confirm adherence to Medicare rules controlling proper billing for infusion therapy services.</p> <p><b>HOSPITALS, PHYSICIAN GROUPS, HOME HEALTH</b></p> | <p>Scoring will be based on a monitoring tool that reviews eight critical elements of a correct infusion claim: (1) existence of valid order; (2) billed ICD-9 codes that match diagnosis codes in medical record; (3) properly appended modifiers; (4) documented start and stop times; (5) CPT codes billed on UB04 matching medical record; (6) CPT units of service billed on UB04 matching medical record; (7) medication units of service billed on UB04 matching medication administered; and (8) medications billed on UB 04 matching medications documented.</p> <p><b>Maximum 25 points per month.<br/> Maximum 300 points per year.</b><br/> [Scoring percentages TBD]</p> | <p><i>Each Department/business unit Review Team will perform monthly chart reviews utilizing the online monitoring tools and methodology created by [ORGANIZATION]'s compliance department. The database will create three levels of reports:</i></p> <ul style="list-style-type: none"> <li>■ <i>Monthly Summary and Detail Reports to be reviewed by the Review Team.</i></li> <li>■ <i>Monthly Summary and Detail Reports to be reviewed by compliance.</i></li> <li>■ <i>Quarterly Summary and Detail Reports and Matrix to be reviewed by compliance and shared with Committees and Boards.</i></li> </ul> | <p><i>This measure provides [ORGANIZATION'S] department/business units with credit for promoting accurate coding and billing for outpatient infusion therapy services.</i></p> |

| SCORING ITEM  | MAXIMUM POINTS/SCORING METHODOLOGY   | INSTRUCTIONS FOR SCORING   | COMMENTS   |
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| <p>6. <b>Physician Arrangement (Lease and Professional Service Agreement (“PSA”)) Monitoring:</b><br/> department/business unit compliance officers will conduct quarterly reviews of a sample (7.5%) of physician leases, call coverage agreements, medical director arrangements and other personal service arrangements to monitor for compliance with [ORGANIZATION'S] relevant policies and with applicable legal and regulatory requirements.</p> <p><b>ALL DEPARTMENT/BUSINESS UNITS</b></p> | <p>The Compliance Division has developed metrics that provide weighted scoring for findings of each lease and PSA review. Several factors are evaluated:<br/> (1) Is there a written agreement? (2) Was the arrangement subject to required legal review before it was initiated?<br/> (3) Was the writing signed by both parties before the arrangement was initiated? (4) Was the writing current (not expired) for the period of the review? (5) Was the signed writing entered into TractManager within 10 days of the start of the arrangement? and (6) Were all payments and/or charges reviewed consistent with the contract?</p> <p>Scoring is cumulative and will be adjusted on the scorecard each quarter as quarterly reviews are completed.</p> <p><b>Maximum 300 points per year:</b><br/> &gt;98% = 300 points; ≥ 95% to &lt; 98% = 200 points; ≥ 90% to &lt; 95% = 100 points; &lt; 90% = 0 points</p> | <p><i>Each compliance officer will perform quarterly physician lease and PSA reviews utilizing the review methodology and tools created by [ORGANIZATION'S] compliance department and will draft quarterly reports of the findings of the reviews.</i></p> | <p><i>This measure provides [ORGANIZATION'S] department/business units with credit for properly managing physician financial arrangements.</i></p> |

## Section 5 – Responding to Reported Issues

| SCORING ITEM  | MAXIMUM POINTS/SCORING METHODOLOGY  | INSTRUCTIONS FOR SCORING  | COMMENTS |
|---|---|---|----------|
| <p>1. <b>Timely Entry of Reports of Non-Compliance into EthicsPoint.</b> EthicsPoint is the primary repository of information on reports or findings of suspected or actual non-compliance and of the investigation and remedial measures that are taken to address them. All reports of <u>suspected non-compliance</u> that will take more than one hour to investigate and resolve must be entered into EthicsPoint pursuant to compliance policy. (Note, engagements with compliance that are purely consultative in nature are not entered into EthicsPoint.) Compliance and Privacy Officers must enter into EthicsPoint the date on which they determined (or should have determined) that entry into EthicsPoint was required by policy. EthicsPoint captures the date that an EP case is entered.</p> <p><b>ALL DEPARTMENTS/BUSINESS UNITS</b></p> | <p>Scoring will be calculated as a percentage equal to the number of compliance reports entered into EP within three calendar days of the compliance officer's determination that such entry is required divided by the total number of compliance investigations requiring entry into EP.</p> <p><b>Maximum 100 points per year:</b><br/> <math>\geq 85\%</math> entered within 48 hours = 100 points;<br/> <math>&lt; 85\% - \geq 80\% = 75</math> points;<br/> <math>&lt; 80\% - \geq 75\% = 50</math> point;<br/> <math>&lt; 75\% = 0</math> points</p> | <p><i>Scoring will be calculated for each department/business unit by [ORGANIZATION'S] compliance staff using data as found in EthicsPoint.</i></p> |          |

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| <p>2. <b>Compliance Investigations – Initial Investigation.</b> Initial investigation of reports of suspected non-compliance (including EthicsActionLine calls and emails, and reports directly to the compliance or privacy officer that are required to be recorded in EthicsPoint) will be completed within 30 days. Initial investigation will be deemed completed at the earliest of the following dates: (1) the date on which the EP investigation is fully and properly closed; (2) the date on which a corrective action plan is adopted to address all issues discovered in a complete investigation of the issue; or (3) the date on which the Chief Compliance Officer or an attorney representing [ORGANIZATION] determines based on findings of an initial investigation, that a more extensive investigation (generally one that will require external or extensive internal resources) is required.</p> <p><b>ALL DEPARTMENTS/BUSINESS UNITS</b></p> | <p>Scoring will be calculated as a percentage equal to the number of initial EP compliance investigations completed within 30 days of initial report divided by the total number of EP compliance investigations.</p> <p><b>Maximum 100 points:</b><br/> <math>\geq 85\%</math> completed within 30 days = 100 points; <math>&lt; 85\% - \geq 80\%</math> = 75 points; <math>&lt; 80\% - \geq 75\%</math> = 50 point; <math>&lt; 75\%</math> = 0 points</p> | <p><i>Scoring will be calculated for each department/business unit by [ORGANIZATION] compliance staff using data as found in EthicsPoint.</i></p> |  |
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| <p>3. <b>Timely Implementation/ Completion of Corrective Action Plans.</b><br/> [ORGANIZATION'S] compliance policies require formal written corrective action plans for all instances of discovered non-compliance that require corrective action and: (1) are risk rated at a level 3 or 4, or (2) for which corrective action will take more than 30 calendar days. This metric rewards department/business units for timely completion and closure of corrective action plans.</p> <p><b>ALL DEPARTMENTS/BUSINESS UNITS</b></p> | <p>Scoring will be calculated as a percentage equal to the number of formal corrective action plans that are timely completed and closed, divided by the total number of formal corrective action plan created pursuant to [ORGANIZATION'S] compliance policy.</p> <p><b>Maximum 300 points:</b><br/> <math>\geq 85\%</math> timely completed = 100 points;<br/> <math>&lt; 85\% - \geq 80\%</math> timely completed = 75 points;<br/> <math>&lt; 80\% - \geq 75\%</math> timely completed = 50 point;<br/> <math>&lt; 75\% = 0</math> points</p> | <p><i>Scoring will be calculated for each department/business unit by [ORGANIZATION's] compliance staff as a percentage equal to the number of corrective action plans timely completed divided by the total number of corrective action plans. The scheduled corrective action plan due date will be the date used for calculating this percentage.</i></p> |  |
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*Determinations regarding exceptions (e.g., employees who are on LOA) will be made in consultation with the Executive Compliance Committee. The Committee will have final approval authority.*