Don't Gamble With Your DMEPOS Business; Compliance Tips and Tactics to Help Beat the Dealer

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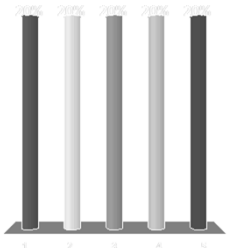
Objectives

- Tips ,tools and internal controls for dealing with the RAC , pre-payment audits and working with payers.
- Review civil and criminal healthcare fraud enforcement involving manufacturers and suppliers.
- Define government's quality care emphasis/focus on overpayments and how it impacts compliance programs
- Avoid hot pockets and still grow your business.
- Discuss direct to beneficiary marketing, lead generation services, orthotics, and ventilators

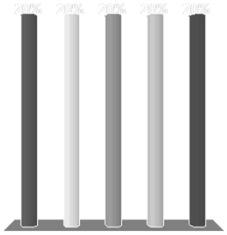
What type of company do you represent?

1. Hospital/Health system
2. Private/Family owned DME
3. Publically held DME
4. Insurer
5. Other



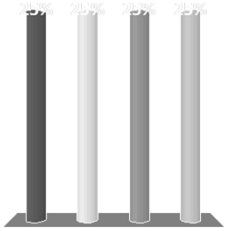
How long have you worked in DME?

1. <1 year
2. 1-5 years
3. 6-10
4. >10
5. DME? I'm in the wrong room!!



How many employees in your operation?

1. <20
2. 20-50
3. 51-100
4. >100



The Business of DMEPOS

- Historical background
- When did it blow up?
- CMS overreaction

DMEPOS Customers

Think outside the box

- 23 million of the Greatest Generation
- 20 million of the Korean War generation
- 78 million Baby Boomers (those born between 1946 and 1964).

DMEPOS facts

- Retiring at the rate of 10,000 per day.
- Living to be 85 years old
- Do not expect to be living in long term care
- Will need what industry has to offer.
- Demand will only increase exponentially.

Fun Facts About Customer Activities

- The first Senior Olympics took place in 1987 and attracted 2,500 people.
- 2015 attendance had over 10,000 competitors and 20,000 spectators, with the 4 oldest competitors each over 100 years old.

More Fun Facts

- Ages 50-and-over athletes representing all 50 states and the District of Columbia.
- Top 10 competitions: Softball, Basketball, Track & Field, Volleyball, Tennis, Swimming, Cycling, Golf, Road Racing and Archery

Industry Boom = Increase Payer Scrutiny = Increased Need for Regulatory Attention

Karen Johnson

- Tips ,tools, and internal controls for dealing with the RAC , pre-payment audits and working with payers.

DMEPOS – A Complex World!

- Many rules and regulations
- Constant changes
- Varying interpretations

Feeling Overwhelmed?

You're not alone!

Resources at Your Fingertips!

- Web-based workshops
- Self-paced tutorials
- DME sessions on demand
- In-person seminars
- Live Chats/Online Q&A sessions
- CMS Events: Ask the Contractor Teleconferences (ACT)
- RAC Monitor Mondays
- Supplier Manual
- Medicare Listserves
- YouTube videos - https://www.youtube.com/user/NGSMedicare/videos

Government Policies

- Know the Rules
  - National Coverage Determinations (NCD)
  - Local Coverage Determinations (LCD)
  - Policy Articles (PA)
- Medicaid Policies

Who is Auditing?

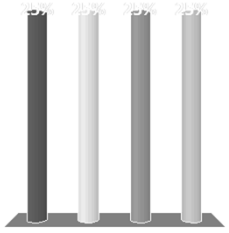
- MAC
  - Probe, Pre & Post-payment reviews
- CERT
- OIG
- RAC
- ZPIC
- State Medicaid

Benefits of Medical Review

- Initiatives designed to:
  - Identify errors
  - Reduce payment error rate
  - Decrease denials
  - Increase educational opportunities

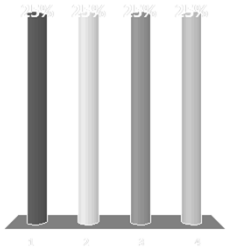
How prepared for MAC, RAC, & OIG reviews are you?

1. Not prepared
2. Somewhat prepared
3. Very prepared
4. What reviews?



What has the scrutiny been like on your supplier?

1. Minimal
2. Moderate
3. Major
4. Horrendous!



How Can You Ensure Safety?

Simple….

- Accurate and complete documentation and coding
- Developing proactive & sound internal controls

Intake & Assessment

- Helpful in collecting required documentation
- Assists in accurate claim submission
- Intake form
  - Customize your own
  - Handout

Successful Tips for Responding to an Audit

Tip #1 – Pay Attention To Deadlines

- If no deadline is specified -ask
- Respond promptly (ADRs– within 45 days)
- Methods for record submission
  - Endeavor Portal
  - Fax
  - Postal Hardcopy
  - CD

Tip #2 – Designate Individual(s) Responsible to

- Gather documentation
- Respond
- Ask for an extension if timeline can't be met
- Consequences for not responding
  - Delayed/no payment

Tip #3 – Documentation Prep

- Read the Directions in the Letter
  - Match claim info to letter
  - Return documentation with letter
  - Number pages
  - Documentation is legible, signed by the author and is a clear copy
  - Send current /pertinent copies
  - Don't highlight info
  - Don't staple info together
  - Send to correct requestor
  - Send once per ADR letter

Tip #4 – Ensure Complete Medical Records

- Additional documentation not permitted
- Legible records
- Verify no information has been cut off in copying
- *Don't alter the medical record*
- Include explanation/support for any unusual services/tests

Tip #5 – Good Record Keeping

- Make copies of information sent
- Note date when info sent
- Record all communication
  - Emails
  - Phone calls
  - Responses
  - Reasons for denials
- Monitor findings/outcomes
- Share results

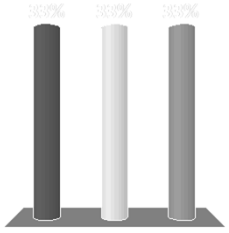
Tips for Working with Payers

- Keep lines of communication open
- Provide as much information as possible
- Ask questions
- Ask for clarification
- Give explanation where needed

Performing Internal Reviews

Does your company perform internal service reviews?

1. Yes
2. No
3. Don't know



Approach to Internal Review

- Annual review of OIG Work Plan
- Identify areas of High Risk
- Perform a Self-Assessment
  - Internal controls in place?
  - Policies and procedures in place?
  - Are they consistent across the practice?

Next Steps

- Determine who needs to be involved?
  - Compliance, Management/Billing/Coding staff, HIM
- Identify type of DME at highest risk
  - How far to look back?
  - Random selection of claims
- Obtain samples from all locations
- Identify any internal policies and controls already in place
- Determine accuracy threshhold (accuracy rate)

Develop Effective Audit Tool

- DMEPOS Supplier Manual
- CMS/Medicare Articles
- LCDs & Policy Articles
- Documentation Checklists

https://med.noridianmedicare.com/web/jddme/policies/documentation-checklists

- Yes/No questions
- Check boxes

General Documentation Checklist Example

- ❑ Face-to-Face Examination (F2F)
- ❑ Written Order Prior to Delivery (WOPD)
- ❑ Dispensing Order (if applicable)
- ❑ Detailed Written Order (DWO)
- ❑ Beneficiary Authorization
- ❑ Proof of Delivery (POD)
  - o Method1
  - o Method 2
  - o Method 3
- ❑ Continued Need
- ❑ Continued Use
- ❑ Medical Records Supporting Coverage Criteria

Review Billing Claim Form

- Identify any errors on the claim form
  - HCPCS codes
  - Modifiers
  - Correct Physician UPIN
  - Diagnosis
  - Place of Service

Perform the Audit

Discuss Preliminary Findings

- Share findings with DME Staff and Management
- Get input
- Clarify questions
- Come to consensus

Write an Executive Report

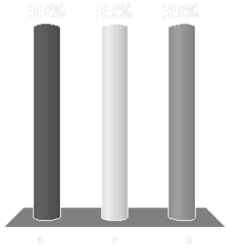
- Provide background information
- Define objective/purpose
- Scope and method of claim selection
- Results - define errors identified & accuracy %
- Incidental findings
- Education provided
- Corrective action (if required)

Corrective Action Plan (CAP)

- Include steps for corrective action
- Define who is responsible
- Expected date for completion
- CAP Template
  - Handout

Does your office use a CAP when errors are found?

1. Yes
2. No
3. NA



Corrective Action Plan

Audit Name
Date CAP due to Compliance:

Facility/Dept/Clinic	Main Contact	Compliance Contact

Findings requiring correction	Corrective Action Items (*education, process improvement/resolution, etc*)	Person Responsible	Expected Completion Date	Completion Validated
	1.			

Date sent to Compliance_____by_____

Overpayments

- Report and refund overpayment errors
- 60 days to refund Medicare/Medicaid
- Follow MAC/Medicaid instructions

Monitoring

- Assures education was effective
- Validates internal controls are working
- Periodic spot checks

How to Prevent Future Errors?

- Monitor quarterly MAC Medical Reviews
- Cert Reviews
  - CERT Quick Look Documentation Chart (Handout)
- Share info with:
  - Supplier staff
  - Ordering providers

Pre-Payment Common Errors

- Requested information not received
- Insufficient/no clinical documentation
- Basic coverage criteria not supported
- Improper Coding
- Incomplete/Outdated Detailed Written Orders (DWO)
- Invalid/no proof of delivery received
- Missing/illegible Signatures

Education Review Requests (ERR)

- Voluntary educational program
- Focus on certain DME policies
- Suppliers submit documentation & receive feedback
- Reviewed by a Clinician

Benefits of ERR

- Personalized educational support
- Timely feedback for areas of:
  - Proficiencies
  - Deficiencies
- Improved future outcomes
- *NOTE* – does not guarantee payment

Appeals Won

Ultimate Goals

- Compliant/Sound Processes
- Develop Good Relationships
- Satisfied Customers
- Payment

Consequences for Non-Compliance

George Breen

- Civil and criminal healthcare fraud enforcement
- Quality care emphasis/focus on overpayments and how it impacts compliance programs

"*IN THE NEWS*"

- Department of Justice, May 27, 2015, "*Durable Medical Equipment suppliers to Pay $7.5 Million to Resolve False Claims Act Allegations*".
- The United States Attorney's Office, District of Columbia, Department of Justice, May 4, 2015, "*Durable Medical Equipment Supplier to Pay United States $300,000 To Resolve False Claims Allegations*".
- US Department of Justice, March 21, 2015, "*Washington: Owner of Medical Equipment Supply Company Convicted for $3.5 Million Medicare and Medical Fraud Scheme*"

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"*IN THE NEWS*"

- The U.S. Attorney for the Western District of Michigan, February 25, 2015, "*United States Recovers One Million Dollars in Connection with False Claims Act Allegations Relating to Skilled Therapy Services and Durable Medical Equipment*".
- US Federal Bureau of Investigation, February 25, 2015, "*Washington: Former Owner of Durable Medical Equipment Company Pleads Guilty in $5 Million Health Care Fraud Scheme*".
- Department of Justice, November 6, 2014, "Device Company Resolves FCA Case Alleging Physician Kickbacks for $4.9 Million.

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Federal Laws and Key Players

- U.S. Department of Justice (DOJ)
  - United States Attorneys' Office (USAO)
  - Federal Bureau of Investigation (FBI)
- U.S. Department of Health and Human Services (HHS)
  - Office of Inspector General (OIG)
  - Centers for Medicare and Medicaid Services (CMS)
- State Attorneys' General Offices
  - Medicaid Fraud Control Units (MFCUs)

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The Enforcement Environment

Government Investment in Fraud Enforcement Activities

- Investments and Increased Collaboration
  - **Health Care Fraud Prevention and Enforcement Action Team (HEAT):** Coordinates the increased tools and resources available across government to help prevent, investigate and prosecute Medicare and Medicaid fraud.
  - **Medicare Fraud Strike Force:** Interagency teams of analysts, investigators, and prosecutors from CMS, DOJ, HHS-OIG, FBI state and local law enforcement.
  - **Healthcare Fraud Prevention Partnership (HFPP):** Public-Private partnership between federal government, states, private insurers and associations to improve fraud-fighting capabilities across payers.

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The Enforcement Environment

- Department of Justice 2015 Recoveries:
  - DOJ recovered **$3.5 billion** from FCA cases (settlements and judgments).
    - **$1.9 billion** from the health care sector.
  - Average 3-year ROI (FYs 2011-2013) is **$8.10** per dollar invested.
- OIG/HHS FY 2015 Recoveries
  - **$3.35 billion**
    - $1.13 billion from program audits.
    - $2.22 billion from investigative work.
  - 4,112 individuals and entities excluded.
  - 925 criminal actions brought.
  - 682 civil and administrative cases brought.

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The False Claims Act: The Weapon of Choice

The Government's primary weapon against health care fraud has been the False Claims Act ("FCA"), 31 U.S.C. §§3729 et seq., because:

- it imposes potentially ruinous civil penalties; and
- actions under the FCA can be initiated by whistleblowers.

The FCA imposes liability for:

- (A) knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval;
- (B) knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim; and
- (C) conspiring to commit a violation of [the False Claims Act].

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Knowing and Knowingly

- Have "actual knowledge of the information";
- Act "in deliberate ignorance of the truth or falsity of the information"; or
- Act "in reckless disregard of the truth or falsity of the information".

Does not require proof of specific intent to defraud

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The Consequences Of Losing An FCA Case Are Great

- Treble damages
- Civil penalties of up to $11,000 per claim *.
- Program suspension, debarment and exclusion for entities, officers, directors and employees and related parties.
- *The "Bipartisan Budget Act of 2015," will require significant increase in penalties mandated by the FCA. Initial "catch up adjustment" – followed by further, automatic annual adjustments.
  - Must take effect no later than August 1, 2016.

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Qui Tam Relators

- The federal False Claims Act is a *qui tam* statute, meaning that private citizens ("relators") may file complaints alleging violations of the FCA under seal on behalf of the U.S. Government and receive at least 15%, but not more than 25%, of any amount recovered.
- Once a whistleblower files a suit, the Department of Justice must decide whether to "intervene" (i.e., take over and prosecute the suit).
- If the government does not intervene, the case is unsealed and the whistleblower may proceed on his/her own.

31 U.S.C. §3730(b)

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Whistleblowers Setting The Agenda

(Current) Assistant Attorney General for the Civil Division, Joyce R. Branda, May 15, 2014:

- "Amendments to the False Claims Act in 2009 and 2010 have radically shifted the civil-fraud landscape; since then, the number of qui tam complaints has increased to the point where they dominate the focus of the DOJ's civil commercial branch."

  "It's a clear and unmistakable result of the statute," Branda said. "There's no question it has brought cases of complex corporate wrongdoing we otherwise wouldn't know about."*

- FY 2015
  - 638 FCA cases filed by whistleblowers
    - $2.8 billion recovered from whistleblower cases.
    - $597 million paid in whistleblower awards.
    - $1.1 billion recovered from whistleblower cases declined by the Government.

* (http://www.law360.com/articles/538432/health-fraud-whistleblowers-drive-doj-agenda-official-says)

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Types of False Claims Allegations in the DME Space

- Inadequate documentation of services performed.
- Billing for services that are of such poor quality they are deemed "worthless."
- Billing for goods or services not provided.
- Billing for goods or services that lack medical necessity.

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"Reverse" False Claims - Health Reform and Overpayments

- The Patient Protection and Affordable Care Act ("ACA") requires any person who has received "an overpayment" to return it, and report the reason for the overpayment, to the payor within 60 days after the overpayment was "identified," or the date the any corresponding cost report is due, whichever is later.
- Overpayment is defined as "any funds that a person receives or retains . . . to which the person, after applicable reconciliation, is not entitled."
- Penalties can be imposed on anyone who "knows of an overpayment" and fails to report and return it.
- Under this law, the retention of an overpayment beyond 60 days constitutes an "obligation" within the meaning of the FCA.
- Became effective upon enactment of ACA on March 23, 2010.

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Overpayments: Final Rule Published February 12, 2016

– In Parts A & B:

1. Report and Return Overpayments with 60 days of "Identification"
   - The 60 day clock does not start to run until after reasonable diligence and quantification of the alleged overpayment.
     - Presumptive Period – 6 Months.
2. 6 year look back period for retrospective overpayment reviews.

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How To Demonstrate Reasonable Diligence?

- Create a record to demonstrate that your organization collected or attempted to address allegations of overpayments in timely manner.
  - Develop standard form to document disclosure.
  - Document interviews and steps taken.
  - Document evidence and means to determine credibility.
  - Record employees involved in deliberations and decisions.
- Keep an ongoing record of overpayment refunds made by your organization (federal, state, private payers).

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Overpayments: One Court Speaks

United States ex rel. Kane v. Healthfirst, Inc., et al., No. 1:11-cv-02325 (S.D.N.Y. Aug. 3, 2015)

- First reported decision on FCA reverse false claim provision and when an overpayment is "identified"
  - The FCA's statutory 60-day clock for repaying "identified" overpayments begins ticking "when a provider is *put on notice of a potential overpayment*, rather than the moment when an overpayment is conclusively ascertained.

    Suggested that the appropriate exercise of "prosecutorial discretion" would be an ameliorating antidote to the apparent rigidity and "unforgiving" nature of the 60-day rule

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Select Criminal Statutes Applicable to Health Care

Health Care Fraud 18 USC § 1347

- Prohibits the knowing and willful execution of a scheme to defraud any health care benefit program (defined as any public or private plan or contract, affecting commerce, under which a medical benefit, item or service is provided to any individual).
- Prohibits obtaining by false and fraudulent means any money or property owned, or under custody or control of any health care benefit program.

Penalties:

- Fine up to the greater of $500,000, twice the gross gain or twice the gross loss caused by the offense.
- Imprisonment up to 10 years.
- Both

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Select Criminal Statutes Applicable to Health Care

Mail and Wire Fraud 18 USC § 1341, 1343

- Prohibits schemes to defraud and use of interstate mails or wires for purposes of executing the scheme.
- Does not require conduct to occur in connection with delivery of payment for health care benefits in order for liability to attach.

Penalties:

- Fine up to the greater of $500,000, twice the gross gain or twice the gross loss caused by the offense.
- Imprisonment up to 20 years.
- Both

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Select Criminal Statutes Applicable to Health Care

False Statements Relating to Health Care Matters
18 USC § 1035

In connection with a health benefit program, this statute prohibits the knowing and willful:

- Falsification, concealment or cover up of material fact.
- Making materially false, fictitious or fraudulent statements or representations.
- Making or using any materially false writing or document, knowing it contains a materially false, fictitious or fraudulent statement or entry.

Penalties:

- Fine up to the greater of $500,000, twice the gross gain or twice the gross loss caused by the offense.
- Imprisonment up to 5 years.
- Both

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Select Criminal Statutes Applicable to Health Care

Fraud Relating to Federal Health Care Programs
42 USC § 1320?b(a)

Prohibitions include:

- Knowingly and willfully making a false statement or representation of a material fact in application for any benefit or payment under a federal health care program.

Penalties:

- Fine up to $25,000.
- Imprisonment up to 5 years.
- Both

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Select Criminal Statutes Applicable to Health Care

Anti-Kickback Statute 42 USC § 1320a-7b

- Prohibits knowing and willful solicitation of payment (1) in return for referring an individual for an item or service which may be paid in whole or in part by a federal health care program or (2) in return for leasing, ordering or arranging any good, item or service which may be paid for in whole or in part by a federal health care program.
- Prohibits making or offering payment to induce such referrals or purchases.

Penalties:

- Fine up to $25,000.
- Imprisonment up to 5 years.
- Both

ACA

- Knowledge of and specific intent to violate the statute are not necessary elements for a conviction.

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Select Criminal Statutes Applicable to Health Care

Obstruction of Justice – Health Care 18 USC § 1518

- Prohibits preventing, obstructing, misleading or delaying communication of information or records to a criminal investigation where the information or records relate to a violation of the federal health care laws, or to attempt to do so.

Penalties:

- Fine up to the greater of $500,000, twice the gross gain from or twice the gross loss caused by the offense.
- Imprisonment up to 5 years.
- Both

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DOJ's Civil and Criminal Divisions Working Together

- Assistant Attorney General for the Criminal Division, Leslie Caldwell, September 17, 2014:

> "[e]xperienced prosecutors of the Fraud Section are immediately reviewing the *qui tam* cases when we receive them to determine whether to open up a parallel criminal investigation. Those prosecutors then coordinate swiftly with the Civil Division and U.S. Attorneys Office as to the best ways to proceed in parallel investigations ". "The Justice Department "encourages you to reach out to criminal authorities in appropriate cases, even when you are discussing the case with civil authorities. The sooner we on the criminal side learn about potential criminal conduct, the sooner we can investigate and the earlier we begin our investigation, the more legal tools and investigative techniques we will have available to us. Working together, and along with our civil fraud counterparts, U.S. Attorney's Offices, and investigative agencies, we can bring more cases and hold more companies and individuals responsible for the crimes they commit."

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The Yates Memorandum

- On September 9, 2015, Deputy U.S. Attorney General Sally Quillian Yates issued a memorandum to all DOJ attorneys entitled "Individual Accountability for Corporate Wrongdoing" (the "Yates Memo").
- Addresses "how the Department approaches corporate investigations, and identified areas in which it can amend its policies and practices in order to most effectively pursue the individuals responsible for corporate wrongs."

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The Yates Memorandum – Key Provisions

- Corporations must provide all relevant facts about individuals involved;
- *Both* criminal and civil corporate investigations should focus on individuals from inception;
- Criminal and civil attorneys should be in routine communication;
- Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for individuals;
- Corporate cases should not be resolved without a clear plan to resolve related individual cases; and
- Civil attorneys should consistently focus on individuals as well as the company.

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The Yates Memo In Action?

- *U.S. v. Berkley Heartlab, Inc., et. al.*, No. 9:14-cv-00230 (D.S.C.).
- DOJ intervened.
- United States alleges that the defendants paid $80 million in kickbacks to physicians in the form of improper "process and handling fees" to induce physicians to refer blood samples to three different laboratories, including Health Diagnostics Laboratory ("HDL").
- Among defendants sued : Tonya Mallory, co-founder and former Chief Executive Officer of HDL.
- HDL settled in March 2015 for $47 million.
- Government continues to pursue Ms. Mallory; named her as a defendant in its August 2015 Complaint in Intervention.

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The Yates Memo In Action?

- 10/29/15 - DOJ announces Warner Chilcott's agreement to pay $125 million to resolve criminal and civil liability arising from alleged illegal marketing of certain drugs.
- Same day, DOJ announces the indictment of a former Warner Chilcott president with conspiring to pay kickbacks to physicians to induce them to prescribe the company's drugs.
- DOJ Press Release: "Today's enforcement actions demonstrate that the government will seek not only to hold companies accountable, but will identify and charge corporate officials responsible for the fraud."

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OIG Exclusion Authority

- §1128 and 1156 of the Social Security Act.
- Effect of Exclusion:
  - No Federal health care program payment may be made for items or services:
    - Furnished by an excluded individual.
    - Directed or prescribed by an excluded individual, where person furnishing the item or service knew or had reason to know of the exclusion.
- Excluded individual also subject to Civil Monetary Penalty of $10,000 for each violation, plus potential treble damages.
- 20 statutory bases for exclusion.
  - 4 bases for mandatory exclusion.
  - 16 bases for permissive exclusion.

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OIG Exclusion Authority

OIG Mandatory Exclusion

- § 1128 (c) of the Social Security Act.
- 5 year minimum.
- Resulting from:
  - Felony convictions relate to health care fraud or controlled substances.
  - Felony or misdemeanor convictions for program related crimes or patient neglect or abuse.

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OIG Exclusion Authority

OIG Permissive Exclusion

Select Bases Including:

- Submission of false or fraudulent claims to a federal healthcare program.
- Engaging in unlawful kickback arrangements.
- Performance of unnecessary or substandard services.
- § 1128 (b)(15) permits exclusion of the following individuals within a "sanctioned entity" based on the entity's conviction of certain offenses or exclusion:

  Owners – if they know or should have known of the wrongful conduct leading to the sanction.

  Officers and Managing Employees – based solely on their position with the sanctioned entity, regardless of their knowledge.

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OIG Exclusion Authority

OIG Guidance for Implementing Permissive Exclusion

The OIG may consider:

- Circumstances of misconduct.
- Seriousness of offense.
- Individuals roles in sanctioned entity.
- Individuals response to misconduct.
- Information about the entity.
- OIG currently considering revisions to Guidance.

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CMS Revocation Authority

- CMS issued a Final Rule for safeguards to reduce Medicare fraud on December 3, 2014

  Under authority of the ACA, CMS can and will deny or revoke enrollment of entities and individuals that pose a program integrity risk to Medicare:

  » "… providers and suppliers that have a pattern and practice of billing for services that do not meet Medicare requirements. This is intended to address providers and suppliers that regularly submit improper claims in such a way that it poses a risk to the Medicare program."

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HOW CAN YOU PROTECT YOURSELF AND YOUR BUSINESS? Mandatory Compliance

- Section 6401 of ACA (Medicare/Medicaid/CHIP suppliers/providers)
  - Mandates compliance programs for Medicare/Medicaid/CHIP providers and suppliers as condition of enrollment.
  - Compliance program must contain "core elements" to be determined by Secretary.
  - Implementation date for providers/suppliers required to have compliance program in place to be determined by Secretary.
  - Secretary to determine scope of requirement for particular industry sector.

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Compliance and DOJ

- On 11/3/15, DOJ announced the hiring of a full-time compliance expert to assist DOJ in:
  - determining whether corporations subject to DOJ investigation have maintained a good faith compliance program.
  - developing benchmarks for evaluating corporate compliance and remediation measures.

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Establishing An Effective Program: Nuts & Bolts

- Look to OIG's Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry 64 FR 36368 (July 6, 1999)
- Federal Sentencing Guidelines -- 7 elements:
  1. Written standards and procedures
  2. Governance and infrastructure
  3. Education and training
  4. Effective lines of communication / reporting
  5. Disciplinary guidelines
  6. Auditing, monitoring reporting systems
  7. Corrective action

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Establishing Effectiveness: Nuts & Bolts

- Extra credit for:
  - Data analytics
  - Integrity surveys
  - 3rd party reviews
  - Return on investment consideration
  - Repayments, self-disclosures, corrective action plans
  - Compliance rewards

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Compliance and DOJ – Compliance Metrics

- Does the corporation ensure that its directors and managers offer strong support for corporate compliance policies?
- Do compliance program staff have stature within the company?
  - Are the compliance teams adequately funded and able to access needed resources?
- Are compliance policies clear and in writing?
  - Are they easily understood by employees?
- Are the compliance program guidelines effectively communicated to employees?
  - Are they easy to find and do employees get repeated training, including as to who to contact with concerns?

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Compliance and DOJ – Compliance Metrics

- Are the compliance policies subject to periodic review and updating as to evolving risks and circumstances?
- Do mechanisms exist to enforce the compliance policies, is compliance incentivized, and are violators likely disciplined on an even-handed basis?
- Are third parties (e.g., vendors, agents, consultants) informed of (and held accountable for) compliance expectations?

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Establishing Effectiveness: Key Concepts

- Seek Out and Utilize Resources to Promote Compliance
  - Strengthen relationships with associations.
  - Create "thought leadership".
  - Utilize webinars, regional and national conferences.
  - Increase visibility through speaking opportunities.
  - Utilize or create contacts within the industry to increase visibility and focus upon accomplishments.
- https://oig.hhs.gov/compliance/101/index.asp (Compliance Education Materials)
- http://exclusions.oig.hhs.gov/ (OIG Exclusion Database)
- http://sam.gov (GSA Exclusion Database)
- https://oig.hhs.gov/reports-and-publications/workplan/index.asp (OIG 2015 Work Plan)
- http://www.hhs.gov/ocr/office/faq/index.html (OCR FAQs)

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What Are The Hot Issues For DME In 2016?

- Frequently replaced supplies.
- Power Mobility Devices.
- Orthotic Braces – reasonableness of Medicare payments compare to payment by other payors and compliance with payment requirements.
- Review of Part B payment for claims for lower-limb prosthesis for billing compliance.
- Diabetic Testing Supplies.
- Competitive Bidding:
  - Beneficiary Access
  - Post Award Auditing
- Nebulizer Machines
- Ventilators

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Protect Your Organization and Yourself

- One size does not fit all.
- Zero-tolerance policy for prohibited conduct.
- Independence of Compliance Officer and direct Board/Management reporting.
- Foster a "Culture of Compliance".
- Comprehensive and effective compliance policies and procedures.
- Effective internal monitoring systems.
- Orientation and reorientation in relevant laws.
- Training and re-training.
- Toll-free hotline for confidential reporting.
- Background and exclusion checks.
- Conduct A Privileged Compliance Effectiveness Review.

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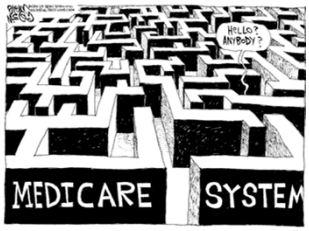
Wayne H. van Halem

Avoiding Hot Pockets While Still Growing Your Business



Data Analysis

- Potential errors that pose the greatest risk
- *Recognition of* trends, changes, schemes to inappropriately maximize reimbursement
- LCD needs
- Targeted education efforts
- Claim review strategies that efficiently prevent or address potential errors

Purpose

- Utilization / billing patterns that illuminate potential errors
- High volume/cost services that are being widely over-utilized
- Identify possible fraud investigations
- RACs, CERT, and CMS effect on DMAC's jurisdiction.

Important

- Being an aberrancy does not mean you are doing anything wrong
- If it's legitimate, and you are prepared, you have no need for concern.

Audit Triggers

- Highest Reimbursed Codes within a product category
  - E0260 vs E0255 or E0250
  - K0004 vs K0001
  - Up coding

Audit Triggers

- Billing same day multiple mobility products i.e.
  - wheelchair (K0001 – K0007)
  - cane (E0100 – E0105)
  - walker (E0130 – E0149)
- Same or Similar

Audit Triggers

- Maximum Allowed Amount on Certain Codes
  - Albuterol, allows 465 mg/month (J7609 – J7611)
  - Urologicals allow 200 units per month (A4332, A4351 – A4353)
- Identify percentage of claims that meet or exceed maximum allowed amounts.

Audit Triggers

- Refill policies
  - Are suppliers regularly sending the max allowed amounts?
  - Are services reasonable and necessary?
  - Are refill requests documented properly?

Audit Triggers

Claims for High End Equipment

- Identify providers that provided power wheelchairs to a given patient.
  - Most patients would have received other types of equipment
    - manual wheelchair or a walker before needing a power wheelchair.

Audit Triggers

Diagnosis Code Data

- What diagnoses codes are you using?
  - ✓Medicare would not expect that your patient population all have the same diagnoses for the same equipment
- Medicare excludes diagnoses specific products
- Can get even more complex with ICD-10

Audit Triggers

- Peer Analysis
  - Medicare compares your data to other similar suppliers
  - Review utilization rates/guidelines
  - Be prepared if you have high utilization with specific equipment

Audit Triggers

- Unbundling
  - Base codes for certain products may include other components that are not separately payable
  - Wheelchairs
  - Prosthetics
  - Urologicals

Audit Triggers

- Accessories
  - Do all your patients who receive wheelchairs also receive the same accessories consistently?
  - Each separately billed code must be medically reasonable and necessary with documentation to support.

Audit Triggers

- Inpatient claims
  - Difficult to counter
  - RACs run this algorithm all the time
  - Patients must contact you if they are admitted to a hospital or facility
    - Check when doing refill requests or follow up
  - Recent Update: RACs limited to DME claims paid on or after April 1, 2015.

Audit Triggers

- Rule Changes
  - Changes in rules can lead people to change behavior in an effort to circumvent them
  - Group II vs. Group III PMDs after capped rental change
  - Vents being provided to avoid capped rental or competitive bid limitations
  - Increases in billing for non-competitive bid items

Audit Triggers

- High Dollar Volume Claims
  - Medicare high dollar volume set at $1000
  - High focus on prepayment review

Audit Triggers

- Cross-claims analysis
  - Compare your claims data with that of other provider types
  - Is there a relationship with the referring physician?
  - Is the patient on home health (homebound)
  - Inpatient claims

Audit Triggers

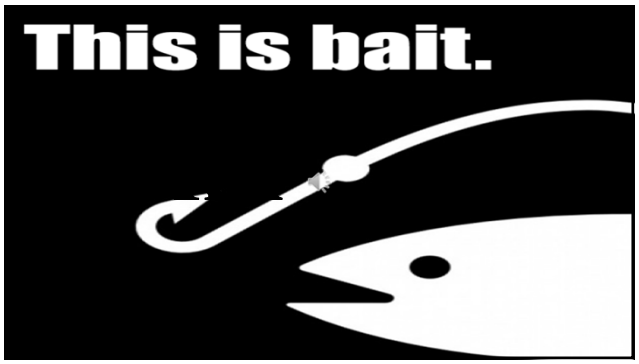
- Location of provider, beneficiary, and referral sources
  - Mail-order exclusion

Audit Triggers

- Date of Death
  - Algorithm regularly run on MACs, RACs, ZPICs etc
  - Denials are "red-flag" denials for Medicare

Audit Triggers

- Compromised HICNs
  - Medicare numbers sold on the black-market
  - Beneficiaries found guilty of fraud
  - HIPAA violations
  - Medical Identity Theft



What Does The KX Modifier Mean?

Improper Use of KX Modifier

- Must meet coverage criteria of policy
- Evidence of criteria in the supplier's files must be available upon request
- Add KX modifier to [Procedure Code] only if all criteria of policy are met.
- Misuse is subject to false claim violations
  - Penalty is $11,000 per violation

Audit Trigger

- Modifiers
  - What modifiers do you use consistently?
  - KX Modifiers
    - Are you using this one properly?
  - ABN modifiers
    - Are your ABNs valid?
  - Function-level modifiers

Target Business Practices

- New Provider Analysis
  - As a new provider is enrolled, their data is more heavily scrutinized
  - New providers are flagged based on various pieces of data obtained during the enrollment process and background checks

Target Business Practice

- Referring NPI concentrations
  - Compare the referring NPI field to identify situations in which some providers may have a significant relationship with a referring doctor because they account for a large percentage of their claims.

Physician Relationships

	Customer 1	Customer 2	Customer 3	Customer 4	Customer 5
NPI 1	33.96%	32.88%	42.86%	38.63%	41.79%
NPI 2	19.37%	10.69%	11.55%	3.82%	3.43%
NPI 3	7.53%	10.21%	3.95%	3.52%	2.13%
NPI 4	2.99%	5.61%	2.57%	3.16%	2.00%
NPI 5	2.98%	4.02%	2.38%	3.08%	1.86%
NPI 6	2.75%	3.68%	1.78%	2.26%	1.58%
NPI 7	1.75%	3.33%	1.74%	1.91%	1.51%
NPI 8	1.71%	2.97%	1.33%	1.74%	1.23%
NPI 9	1.64%	2.70%	1.13%	1.67%	1.17%
NPI 10	1.33%	2.40%	0.92%	1.50%	1.10%
Total Contribution from Top10	76.01%	78.48%	70.20%	61.28%	57.79%

Do you have low back pain?

Target Business Practices

- Direct to Beneficiary Marketing
  - While perfectly legal, CMS does not like this business model
  - Expects the physician to be the one initiating care, not the patient or supplier.

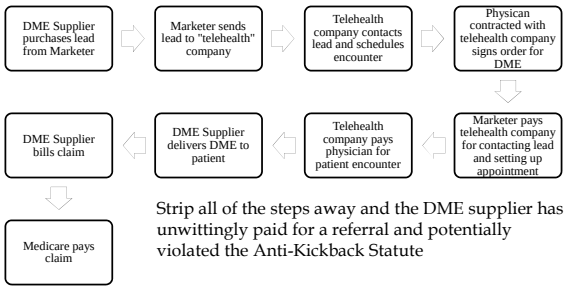
Target Business Practices

- Lead Generation Services
  - Aggressive and Misleading marketing materials
  - Manage contracts closely and discuss referrals with physicians
  - Often times, patients do not qualify

Telehealth

- Company contracts with, and is paid by:
  - Self-funded employers that pay a membership fee for their employees,
  - Health plans, and
  - Patients who pay a per visit fee
- Must be performed in an "approved" telehealth facility.

Scam Telehealth Relationships



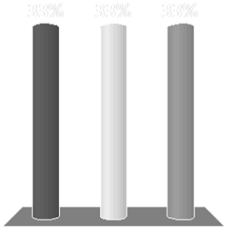
Strip all of the steps away and the DME supplier has unwittingly paid for a referral and potentially violated the Anti-Kickback Statute

Target Business Practices

- Orthotics
  - Back Braces
  - Knee Braces
  - Ankle Foot Orthotics
  - Multiple Orthotics on the same idea
  - "Arthritis Kits" or "Ortho Kits"
  - Are you familiar with the KX modifier requirements for AFOs and Knee Orthotics?

Do you provide /bill non-invasive ventilation?

1. Yes
2. No
3. NA



Target Business Practices

- Non-Invasive Ventilation (NIV)
  - Changes in technology and payment rules led to significant volume increase
  - CMS still views this product as a "life-saving" product
  - Pricing category put the "life-saving" constraints on coverage
    - Continuous rental, Generous fee
  - The CMS solution to increased availability for the technology is to change the pricing category
    - Remember the E0471

Non Invasive Ventilation

"Point being that it is theoretically possible to increase availability of non-invasive ventilation to a less seriously ill group of patients but that comes at a cost…Many manufacturers and suppliers want increased coverage but want to retain the high fee and continuous rental status. In Medicare, as in so many areas of life, you can't have your cake and eat it too."

- **LCD unlikely anytime soon -CMS is discussing the coverage gap**

Non Invasive Ventilation

- NCD
  - NIV covered for respiratory failure due to COPD and neurological diseases
  - life threateningly ill stage before the vent can be covered.
- No diagnosis code or specific lab test that allows for automation of that coverage.

Non Invasive Ventilation

- Amount of time patient off the ventilator has varied
- Documentation must include:

  (1) the underlying condition and

  (2) evidence that shows that without ventilator support =real risk of death

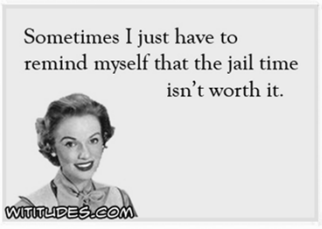
Understand Your Risk

- Audit preparation
  - Minimize impact of intense regulatory oversight
- Maintain compliance
  - Identify issues internally
  - Implement immediate and decisive corrective actions if necessary
- Streamline organization and increases efficiency
- Informed management
- Improves internal communication
- Improves overall quality (care, billing, reimbursement, services)

Supplier Benefits

- Informed supplier aware of their data = advantage in a competitive industry
- CMS only wants to do business with the most compliant of organizations
  - Accreditation
  - Surety Bonds
  - Competitive Bidding
  - Intense regulatory oversight
- Number of suppliers declining while numbers of consumers increasing = *A BUSINESS OPPORTUNITY* for the savvy supplier

Non-Compliance - It's not worth it!



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