Survival of the Fittest!

Navigating the DMEPOS Jungle

Barb Stockert, Government and Payer Relations, Sanford Health
Jeanne Folmer, Lead Auditor, Compliance, Sanford Health
Thomas W. Beimers, Counsel, Faegre Baker Daniels LLP
Ruth Krueger, Regional Director, Compliance, Sanford Health

Objectives

- Identify risk areas, record keeping, and audit priorities for durable medical equipment companies
- Review OIG information request, subsequent investigations/enforcement actions
- Provide tool kit of resources for auditing and monitoring and discuss those risky scenarios that get folks in trouble
How long have you worked with DME regulations?

A. 0-3
B. 4-7
C. >7

General Coverage Requirements

DMEPOS (Durable Medical Equipment Prosthetic Orthotic and Supplies) must be:

1. Prescribed by a physician or other recognized medical professional
2. Eligible for a designated Medicare benefit category
3. Meet Medicare’s statutory and regulatory requirements
Do You Know What is Covered and Not Covered?

Non-covered items (not all inclusive)
- Convenience Items
- Diapers
- Most Bathroom Items
- Hearing Aides
- National Coverage Determination (NCD) for Durable Medical Equipment Reference List (280.1)

Classifying a DME Benefit Category

To meet the Category of DME Benefit a product must:
- withstand repeated use,
- serve a medical purpose,
- not be useful in absence of illness or injury.
Prosthetic Benefit Category

- Replace all or part of an internal body organ, or to replace all or part of the function of a permanently inoperative or malfunctioning internal body organ.

Braces (Orthotics)

- A brace is a rigid or semi-rigid device that supports a weak or deformed body member.
Surgical Dressings

- Therapeutic and protective coverings that are applied to surgical or debrided wounds.

Immunosuppressive Drugs

- Oral Anti Cancer Drugs
- Oral Antiemetic Drugs
Therapeutic Shoes for Diabetics

- Custom molded or extra depth shoes and inserts for patients with diabetes.

What is a National Coverage Determination?

- A national coverage determination (NCD) is a United States nationwide determination of whether Medicare will pay for an item or service.
Who Can Request an NCD?

- Beneficiaries, manufacturer’s, providers, suppliers, medical associations, or health plans.
  - Has to be considered a potential benefit for Medicare beneficiaries

How to Request an NCD

Submit on line:

Or mail to:
Centers for Medicare Medicaid Services
Director, Coverage and Analysis Group
7500 Security Blvd; Baltimore, MD 21244.

Local Coverage Determinations

In the absence of a NCD a service is covered at the discretion of the Medicare contractors based on a Local Coverage Determination (LCD).

Relationship of NCD’s and LCD’s

○ NCD’s always TRUMP!

○ NCD’s are binding for all Medicare contractors

○ LCD policy MAY be more restrictive than the NCD but NEVER less restrictive.

○ LCD’s can be developed when contractor sees a number of errors in their jurisdiction.

○ Medicare Coverage Database:
  http://www.cms.gov/medicare-coverage-database/
Getting It Right the First Time

Patient Demographics
Insurance Verification
  ● Always remember to CCC (Copy Customer Card)
Understand the Coverage Criteria
Use Recommended Intake Forms and Documentation Checklists:
https://www.noridianmedicare.com/dme/coverage/checklists.html

Dispensing Orders

Equipment and Supplies may be delivered with a dispensing order except those items that require a WOPD (written order prior to delivery).
  ● May be written or verbal
  ● Description of item
  ● Beneficiary name
  ● Ordering Physician
  ● Date of the order and/or start date
  ● Physician signature (or supplier signature if verbal)
Detailed Written Orders

Ordering physician must review content of order, sign, and date the form. **Order must include:**
- beneficiary name,
- physician name (and NPI if subject to F2F),
- date of the order and/or start date,
- detailed description, AND
- physician signature and date.

Prescription pads have a date field located in the upper right corner. This is sufficient to use as a start and signature date.

A. True  
B. False
The **start date or initial date of service** must be the date the supplier was contacted by the physician.

A. True  
B. False

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**When Do I Need a New Order?**

- When there is a change in the order
- For items that are replaced, worn, lost, stolen, or irreparably damaged
- If/when beneficiary’s condition changes
- Change of supplier
Periodic Basis Prescriptions

All items provided on a recurring basis must include all the components of a regular order and the following:

- route of administration,
- frequency of use,
- number of refills,
- length of need for rental items, AND
- dosage & concentration or duration of infusion, if applicable.

Prescription Additional Information

- Date of the order is considered the date the supplier is contacted by the physician.
- *PRN* or *As Needed* are not acceptable
- Signature and date stamps are not allowed.
- Prescriptions are NOT considered a part of the medical record
If a beneficiary has equipment prior to becoming Medicare eligible, the required documentation must meet all requirements for a new order.

A. True  
B. False

Written Orders Prior to Delivery

Items that require a WOPD
- Support Surfaces
- Transcutaneous Nerve Stimulators (TENS)
- Seat Lift Mechanisms
- Negative Pressure Wound Therapy (NPWT)
- Power Mobility Devices (PMD)
- Wheelchair Seating
- Items subject to Face-to-Face requirement
WOPD Requirements

- Must meet all written order requirements
- If an item requires a WOPD and it is not obtained, the claim will deny as excluded by statute.

Face-to-Face Requirement

- Included in the Affordable Care Act (ACA)
  - ACA 6407 Federal Register
- Med Learn Matters Article CR 8304
- Effective sometime in 2014 at CMS discretion
Face-to-Face Requirement

Who cannot order DME?

A. MD
B. DO
C. Oral surgeon
D. Chiropractor
E. Podiatrist
F. Optometrist
Nurse Practitioner and Clinical Nurse Specialist

Nurse Practitioners and Clinical Nurse Specialists may also order DMEPOS if they meet the following requirements:

- they are treating the beneficiary for the condition of which the item is needed
- they are permitted to practice independently of a physician
- they have their own NPI and
- they are licensed to practice in the state where services are rendered.

Physician Assistants:

- Must meet the definition of a Physician Assistant in Section 1861 of the Social Security Act
- Can practice under the supervision of an MD or Doctor of Osteopathy
- Must have their own NPI and
- Are permitted to perform services in accordance with State law
Which of the following are **not** considered part of the beneficiary’s medical record for DME payment purposes?

A. CMN’s
B. Hospital records
C. Supplier made forms

### Continued Use

Ongoing utilization of supplies or a rental item by a beneficiary.

- Suppliers are responsible to monitor usage of rental items and supplies.
- Supplier records that document a refill or replacement is needed.
Continued Need

Medical Need is determined at time of initial order.

- All of the following verifies continued need:
  - A recent order for refills, or change in prescription
  - Length of time documented on CMN, DIF, or Detailed Order
  - Timely documentation in the medical record showing usage of the item.

The definition of timely documentation is:

- A. 3 months
- B. 6 months
- C. 12 months
Refill Documentation

Delivered to Beneficiary

- Must have documentation of a request for a refill. Must be either a written document or a written record of a phone conversation between the supplier and beneficiary.

- Must be documented before shipment. A retrospective attestation by either the supplier or beneficiary is not sufficient.

More on Refill Documentation

- A new prescription is needed with:
  - change of supplier
  - change in the order: item(s), frequency of use, etc.
  - change in the length of need
  - State law requires a renewal
Required Forms

Certificate of Medical Necessity (CMN) is required for:
- oxygen, pneumatic compression device, osteogenesis stimulator, transcutaneous electrical nerve stimulator (TENS), and seat lift mechanisms.

DME Information Form (DIF) is required for:
- external infusion pump
- parental/enteral nutrition

Completing CMN’s & DIF’s*

- CMN’s:
  - Sections A & C completed prior to sending to physician by supplier
  - Sections B & D completed by ordering physician
  - Signature and date stamps are not acceptable.
  - Must accompany initial claim.
  - CMN can be used as written order if sufficiently detailed.

- DIF’s:
  - Completed by the supplier
  - Must receive prior to claim submission.

*CMN is certificate of medical necessity – DIF DME information Form
Advanced Beneficiary Notice of Non-Coverage (ABN)

- Written notice of potential non-coverage
- Informs beneficiary
- Allows them time to make a decision whether they want an item or not.
- Valid for 1 year for continued supplies or usage of an item.

When Should You Use an ABN?

- Medical necessity not met
- Overutilization
- When an ADMC* denial is received
- No Medicare supplier number
- Unsolicited telephone calls
- Non-contract supplier providing DMEPOS to a beneficiary that lives in a CBA**
- Upgrades

*Advanced Determination of Medical Coverage **Competitive Bidding Area
When to use an ABN

An item does not meet the definition of a Medicare benefit:

- enteral nutrition for a beneficiary that is able to drink orally
- therapeutic shoes for a non-diabetic beneficiary
- wheelchair for a beneficiary that can ambulate
- seat lift mechanism for a beneficiary that cannot walk

Additional ABN Information

- Must list the “specific” reason Medicare will not pay
- An ABN is valid for one year
- Must list an estimate of the charge
- Provide a copy of completed ABN to the beneficiary
Proof of Delivery (POD)

- Must keep POD documentation for seven years
- Can be signed by the beneficiary or the authorized representative
- Proof of delivery must be dated

Three Methods of Delivery

- Directly to the beneficiary or their representative
- Via shipping or delivery service
- Directly to a nursing facility on behalf of the beneficiary
Information on all records must include:

- Beneficiary name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered
- Quantity delivered
- Date delivered
- Beneficiary or authorized representative **AND**
- Date and signature

POD Reminders

- Date of service is **ALWAYS** the date of delivery
- A shipping or delivery service must have a tracking slip.
Documentation of a request for a refill must be a written document completed after delivery.

A. True  
B. False

Refill information must be kept on file and available upon request.

A. True  
B. False
Contact with the beneficiary or designee regarding refills must take place no sooner than_____ calendar days prior to the delivery/shipping date.

A. 12  
B. 14  
C. 21

Consumable supplies are functional supplies and can only be replaced when supply is no longer able to function.

A. True  
B. False
For delivery of refills, the supplier must deliver the DMEPOS product no sooner than ___ calendar days prior to the end of usage for the current product.

A. 10  
B. 15  
C. 20

Beneficiary Authorization

- Sign and date #12 on a CMS 1500 claim form
- Sign and date a supplier generated signature on file
- Future claims for the same services (rentals) can be filed without obtaining a new signature
If you bill as “non-assigned” for DME rentals, you will need to obtain the beneficiary’s authorization every month.

A. True  
B. False

Nationwide DME Audits

CERT: AdvanceMed or Livanta

- Established by CMS to monitor and report the accuracy of Medicare Fee for Service payments.
- Calculates paid claims error rate for DME MAC’s
Nationwide DME Audits

RAC: Performant Recovery, CGI Federal, Connolly, Inc. and Health Data Insights

- Detects and corrects improper payments so CMS claims processing contractors and suppliers can implement actions that will prevent future improper payments.

More DME audits

- Medical Review (performed by the Contractors):
- Supplemental Study Strategic Health Solutions:
- ZPICS and PSC’s:
Self Help Tools

- Do not audit by insurance carrier
- Focus on the product
- Have a staff person review documentation before filing the claim
- Use intake sheets
- Learn from the competition

Resources

- Medicare Program Integrity Manual
  Chapter 5- Items and Services Having Special DME Review Consideration

- Noridian Healthcare Solutions Supplier Manual
  Chapter 3- Documentation Requirements
Let’s talk about enforcement.

Current Enforcement Priorities

- Record FCA Numbers
  - Both Number of Cases and Dollar Amounts Are At Record Highs
- More Follow-On Investigations
  - Consulting Arrangements
  - Cooperation Obligations – DPAs/CIAs
- More Criminal Enforcement
  - Responsible Corporate Officer Doctrine
  - Individuals Named As Defendants In False Claims Act Cases
- More Auditors – More Referrals
- Medicare Fraud Strike Forces
- State AG Offices
By The Numbers – FY 2013

- 274 New Criminal Cases (HEAT only)
- Nine Medicare Fraud Strike Forces Active
- 3,214 Exclusions
- 1,023 Civil Cases Pending - End of FY 2012
- 885 New Cases in FY 2012
- $2.6 Billion In Civil FCA Recoveries - Health Care Fraud
- $5.8 In Total DOJ-HHS Recoveries
  - $25 Billion Total Returned To Medicare Since 1997
- Return on Investment: $8 Returned to Medicare Trust Fund for Every $1 Spent (DOJ Statistics)

Sources of Risk – Key Fraud and Abuse Authorities

- Health Care Fraud Statute, 18 U.S.C. § 1347
- Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)
- Stark Law, 42 U.S.C. § 1395nn
- False Claims Act, 31 U.S.C. §§ 3729-3733
- Exclusion, 42 U.S.C. § 1320a-7
- Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a
- Other Criminal Laws, 18 U.S.C. §§ 287, 1001, 1035
Anatomy of an Investigation

- **Qui Tam Complaints**
- **Criminal or Civil – How Does DOJ Decide?**
- **Role of Agencies**
  - FBI
  - OIG
  - Auditors
  - State AGs
  - FDA
- **DOJ Use of Contractors and Experts**
- **OIG Enforcement Actions**

Examples of Recent FCA Cases

- **RS Medical – $1.2 Million – D.S.C. (2013)**
  - Submitted claims for DME (TENS units; back braces; knee braces; stimulators) without physician orders, proper supporting documentation, or medical necessity
  - Suit filed by former RS employee
  - Five-Year CIA
Examples of Recent FCA Cases

- **Hill-Rom – $41.8 Million – E.D. Tenn. (2011)**
  - Submitted claims for bed support surfaces for patients who did not qualify, or for whom DME was not medically necessary
  - Suit filed by then current and former Hill-Rom sales reps
  - Five-Year CIA

- **Pinnacle Medical – $1.8 Million – N. D. Ala. (2012)**
  - Complaint alleged lack of medical necessity and proper documentation for blood glucose monitoring strips and lancets
  - Suit filed by two former billing department employees
  - Five-Year CIA
Civil Monetary Penalties Law (CMPL)

Key Points
- Section 1128A of Social Security Act, 42 U.S.C. § 1320a-7a, is the Civil Monetary Penalties Law, containing many of the OIG’s CMPs as well as CMP enforcement procedures.
- Many CMPs codified other than in CMPL incorporate the CMPL intent standards and procedures.
- Enacted in 1981, CMPL is most often used by OIG as an alternative to civil action under False Claims Act (“FCA Light”).
- DOJ Authorization Required For OIG CMPL Action - § 1320a-7a(c)(1); Case Initiated by OIG.

Civil Monetary Penalties Law

Key Points (cont.)
- OIG Has to Prove Elements of CMPL action by Preponderance of the Evidence/Respondent Has Burden on Mitigating Factors and Affirmative Defenses.
- Six Year Statute of Limitations, § 1320a-7a(c)(1).
- CMP, Assessment, and Exclusion available in most CMPL cases; although most CMPs are up to $10,000 for each item or service improperly claimed, different CMPs are applicable for specific violations.
- ALJ Proceeding, § 1320a-7a(c)(2).
- CMPL Regulations at 42 CFR Parts 1003, 1005 and 1006.
CMP Intent Standard

- Intent varies in CMPs
  - e.g., Late price reporting is strict liability
- Generally must prove “Knew or Should Have Known”
  - Actual Knowledge
  - Deliberate Ignorance
  - Reckless Disregard
- Similar to FCA Standard - More than Negligence

CMPs for Improper Claims

- False or Fraudulent Claims
- Items/services not provided as claimed
  - Including a pattern of up-coded claims
- Pattern of Medically Unnecessary items or services
- Billing while Excluded
  - Excluded Person
  - Employer or Contractor
Improper Claims Elements

- Knowingly Presents or Causes to be Presented
- Claims for Items or Services
- Under a Federal Health Care Program
- Knew or Should Have Known Were Improper
  - Cannot Rely on Third Party

Proving Knowledge

- Statute, Regulations, Contractor Guidance to Provider
- Internet – CMS/Contractor Guidance
- Witness Statements
  - Experts – Medical necessity/reimbursement rules
  - Employees, co-workers, outside billers
- Documentary Evidence of Knowledge
  - Certifications Signed by Provider
  - Prior notices to provider on same type of claims at issue in current case
CMP Remedies for Improper Claims

- Penalty up to $10,000 for each item or service improperly claimed
- Assessment up to 3 times the amount improperly claimed
- Exclusion

Improper Claims CMP Cases

- *Daniel Herrington, One Source Medical*
- Florida-based DME company
- OIG alleged billing for custom molded diabetic inserts when only prefabricated inserts were provided
- $124,000 payment
Improper Claims CMP Cases – cont.

- Cary Frounfelter/Kast Orthotics & Prosthetics, Inc.
- USAO Declined – Spin-off from HealthSouth fraud case
- Many O&P business were involved in fraud scheme developed by HealthSouth
- O&Ps exploited billing rules in exchange for preferred access to hospitals
- ALJ imposed $100,000 penalty, $42,220 assessment, and 7-year exclusion
- Affirmed by DAB

Improper Claims CMP Cases – cont.

- Owner of DME company agreed to be excluded for 10 years
  - Billed for DME that was never provided
  - Billed for 13 motorized wheelchairs when less expensive power scooters were actually provided
  - Billed in advance of DME actually being provided
CIAs and Penalty Avoidance

- In Civil Cases, Strength of Compliance Has Significant Effect on Scope of Resolution
- Assessment of Compliance Program – Government Attempts To Measure Risk of Recidivism
- OIG Role – Exclusion Authority and Individual Liability
- Compliance Officer Role
  - CCO Should Be Key Participant in Negotiations

Compliance Program Assessment

- Has Become a Standard Part of DOJ Inquiry
  - What was known, when; and when should it have been known?
  - Compliance Program Is Critical Source For “Knowledge” Issues
- Government Will Almost Certainly Request Compliance Program Materials
  - Early Decision Points
  - Audits, Hotline Logs, Complaints, Responses
- Best Foot Forward
- Be Aware of Privilege Issues (Self-Evaluative)
How Government Assesses Compliance Program Strength

- Interviews – Can Key Personnel Describe the Compliance Program?

- Are Audits and Internal Review Results Available?
  - Are Reviews Proactive or Exclusively Reactive?
  - Are There Corrective Action Plans? Have They Been Successful?

How Government Assesses Compliance Program Strength con’t

- How Does Company Handle Hotline Calls and Complaints?
- How Does Sales Force Interact With Compliance Function?
- Has the Program Evolved (Policies and Procedures)?
- How Does the Compliance Team Communicate to Management? What Is the “Tone at the Top”?
Compliance Department Role in Government Investigations

- Coordinate With In-House Counsel and Outside Counsel
- Put Company’s Best Foot Forward
- Communicate With Management

Should You Enhance Compliance Program During Investigation?

- Are Changes An Admission of Inadequate Procedures?
- Compliance Is Never Static – Enhancements Are Necessary
- Keep Legal Counsel In the Loop
  - Information May Be Relevant To Government Info Requests
Employee Interviews

- Preparation for Government Interviews
  - Scope of Issues
  - Use Relevant Documents To Prepare

- Role of Compliance in Internal Investigations
  - Participate in Interviews
  - Source of Expertise/Institutional Knowledge

Questions?
Scenarios that can put you in the fire!