DME Compliance and Regulatory Issues

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BREAKING NEWS

CMS JUST ANNOUNCED THE DME COMPETITIVE BID PROGRAM WILL BE TERMINATED

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

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

DME MACS WILL BE KINDER, GENTLER

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OMG

APRIL FOOL!
Overview

- 2014 DME Documentation & Reimbursement Issues
  - F2F
  - PECOS
  - WOPO
  - ICD-10
  - New CMS Form 1500
  - OMHA Appeal Problems
  - Competitive Bid Program Status

Overview (cont’d)

- DME Issues in OIG 2014 Work Plan
  - Overview
  - New DME Projects
- 2014 DME Business Arrangements
  - Lead Generation vs. Referrals
  - Telemarketing
  - Closets
- Case Studies
- Q&A
- Resources/Handouts

2014 DME Documentation & Reimbursement Issues: Face to Face Requirement

- Enacted as part of Affordable Care Act (Section 6407).
- Under the face to face requirement, a physician must document that a physician, Nurse Practitioner, Physician Assistant, or Clinical Nurse Specialist has had a face to face encounter with the patient.
- The face to face encounter must document that the beneficiary was evaluated and/or treated for a condition that supports the DME ordered.
- For list of covered items, see MM8304 (face to face rule does not apply to power mobility devices as the Local Coverage Determination already requires a face to face).
- The encounter must occur within the 6 months before the order is written for the DME.
Physicians can obtain extra payment using HCPCS G0454 for signing/co-signing the face to face encounter of the Nurse Practitioner/Physician Assistant/Clinical Nurse Specialist. CMS will start actively enforcing and will expect full compliance with the face to face rule beginning on a date that will be announced in CY 2014. (per CMS 9/9/13 announcement) Question remains on when enforcement begins if it will be enforced effective July 1, 2013 or some later date.

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

Generally, DWOs must also include the following (per DME MAC and LCD requirements):
- Physician’s Name;
- Start date of the order (if different from the date of the order);
- Signature date personally entered by the ordering practitioner;
- Dosage or concentration, if applicable;
- Route of administration, if applicable;
- Frequency of use;
- Duration of infusion, if applicable;
- Quantity to be dispensed; and
- Number of refills, if applicable.

Failure to obtain a WOPD may result in the item being denied as excluded by statute.
Enacted as part of Affordable Care Act (Section 6405).

PECOS denial edits (Phase 2) effective Jan 6, 2014 – DME items now included.

Under the PECOS rule, a physician must be enrolled in Medicare to order or refer items or services for beneficiaries.

But many docs, not enrolled in Medicare, order DME items for beneficiaries. Now, the supplier won’t get paid for those items, even if med necessary and properly documented.

For DOS on/after Jan 6, 2014, if the ordering/referring provider:
- Is on the claim, Medicare will verify that the ordering/referring provider is in PECOS and eligible to order and refer.
- Is not in PECOS (or is in PECOS but is not of the specialty to order or refer), the claim will not be paid. It will be denied.
- If the name submitted on the claim does not match the provider’s name in PECOS, the claim will be denied.

Consider a “dear patient” letter when provider is not enrolled in PECOS

CMS guidance states that an ABN is not appropriate for use with claims where the provider is not enrolled in PECOS. See MLN SE1305.

ICD-10

Will be required beginning on October 1, 2014

What’s the big deal?
- ICD-9 is 30 years old which means has outdated and obsolete terms. It’s codes are mostly numeric and have 3 to 5 digits.
- ICD-10 will accommodate new diagnoses, procedures and technological innovations. Its codes are alphanumeric and contains 3 to 7 characters. It will be more descriptive and result in more streamlined and efficient billing process.

Will not affect CPT coding for outpatient procedures and physician services
CMS HCFA 1500

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

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

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

It is here to stay and is not going away any time soon.

- It is anti-competitive.
- It reduces access to patient care, patient choice and quality of care.
- It has forced HME companies to lay off employees or worse close their doors.

Medicare DMEPOS Market Pricing Program Act of 2013 (H.R. 1717)

- Introduced by Rep Tom Price, M.D. (R-GA) and Rep. John Larson (D-Conn)
- 169 Co-sponsors

Change of Ownership/Novation Agreements

- Must have Competitive Bidding Implementation Contractor ("CBIC") approval to assume a Competitive Bid Contract
- Contract cannot be subdivided
- 60 days advance Notice

Commonly Owned Suppliers Ownership

- Suppliers with 5% or more common ownership can be added to each other's competitive bid contact;
- Accomplished by completing the Contract Supplier Location Update form with the CBIC

Issued Jan 31, 2014

- 12 DME Medicare projects (down from 16 in 2013) and 1 DME Medicaid project
- 5 new projects; 7 continuing projects
Reasonableness of Medicare’s Fee Schedule for DME Compared to Amounts Paid by Other Payors. Prior OIG studies contended that Medicare overpays for various types of DME. If CMS determines that the fee schedule methodologies result in fees that are "grossly deficient or excessive," CMS can replace the current fee schedule amounts with special payment limits. This OIG review will compare the Medicare fee schedule amount for various DME (including commode chairs, folding walkers, and transcutaneous electrical nerve stimulators) with payments made for various DME by non-Medicare payers, such as private insurance companies and the Department of Veterans Affairs.

Nebulizer Machines and Related Drugs – Supplier Compliance with Payment Requirements. Prior OIG work contended DME suppliers were overpaid $6 million for nebulizer inhalation drugs on the grounds the drugs were not medically necessary. Under this project, OIG will review Part B payments for nebulizer machines and drugs to assess medical necessity.

Power Mobility Devices – Lump-Sum Purchase Versus Rental. OIG will determine whether cost savings can be realized by Medicare if certain power mobility devices are rented over a 13-month period rather than acquired through a lump-sum purchase.

Power Mobility Devices – Add-On Payment for Face-to-Face Exam. Medicare requires the treating physician to conduct a face-to-face exam of the beneficiary to determine medical necessity for power mobility devices, and the physician may bill Medicare for an E/M service, receiving an add-on payment for this work. OIG will review Part B payments for power mobility devices to determine if the face-to-face exam requirements were met.

Competitive Bidding for Diabetes Testing Supplies – Mandatory Market Share Review. OIG will determine the market share of different types of diabetic test strips following Round 2 of the DME Competitive Bidding Program. The Program statutes require that contracts for mail order test strips be awarded to suppliers that provide at least 50%, by volume, of all types of diabetic test strips.
Lead generation companies have been around for years in the non-health care space where there is little regulation and as a result are not often familiar with the multiple federal anti-fraud laws in the health care market, such as the Medicare anti-kickback statute and the telephone solicitation statute.

It is acceptable to purchase a lead; however, it is a violation of the anti-kickback statute to pay for referral. The line between the two can be blurry. In the eyes of the OIG, there is a distinction between:

1. A “raw” or “unqualified” lead and
2. A “qualified” lead or a referral.

Most Common way to Pay for Leads:
- Per Lead
- Flat Fee

The telephone solicitation statute prohibits suppliers from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of a covered item, except in three specific situations:

1. The beneficiary has given written permission to the supplier to make contact by telephone;
2. The contact is regarding a covered item the supplier has already furnished the beneficiary; or
3. The supplier has furnished at least one covered item to the beneficiary during the preceding fifteen months.

It is also a violation of Supplier Standard Number 11 to do indirectly that which they are prohibited from doing directly which means a supplier is responsible for verifying that marketing activities performed by third parties do not involve prohibited activity and that information purchased from such third parties was neither obtained, nor derived, from prohibited activity.

The telephone solicitation statute also specifically prohibits payment to a supplier that knowingly submits a claim generated pursuant to a prohibited telephone solicitation. Accordingly, such claims for payment are false and violators are potentially subject to criminal, civil, and administrative penalties, including exclusion from federal health care programs.
Not per se illegal but the government does not like loan closet arrangements.

An HME company may place inventory in an office or facility that is not owned by a physician or non-physician practitioner.

The inventory must be for the convenience only of the office's/facility's patients and the office/facility cannot financially benefit, directly or indirectly, from the inventory.

It is important that the office/facility ensure patient choice.

Technically, the HME company can pay rent to the office/facility so long as the rental agreement complies with the Space Rental safe harbor and takes into consideration the February 2000 Special Fraud Alert on Rental of Space In Physician Offices by Persons or Entities to Which Physicians Refer.

CASE STUDIES

Questions?

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