

# **DME Compliance and Regulatory Issues**

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

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

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

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

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

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

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

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

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

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REVISED products from the Medicare Learning Network® (MLN)

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

MLN Matters® Number: MM8304 **Revised**

Related Change Request (CR) #: CR 8304

Related CR Release Date: May 31, 2013

Effective Date: July 1, 2013

Related CR Transmittal #: R468PI

Implementation Date: July 1, 2013

## Detailed Written Orders and Face-to-Face Encounters

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

## Provider Types Affected

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

## What You Need to Know

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

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

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

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

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

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

## Background

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

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

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

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

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

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

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

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

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

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

## Additional Information

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

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

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## Appendix A

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

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

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

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

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

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

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

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

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

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## **5.1 – Home Use of DME**

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

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

## **5.2 – Rules Concerning Orders**

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

### **5.2.1 - Physician Orders**

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

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

### **5.2.2 - Verbal and Preliminary Written Orders**

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

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

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

### **5.2.3 – Detailed Written Orders**

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

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

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

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

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

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

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

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

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

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

### **5.2.3.1 - Written Orders Prior to Delivery**

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

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

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

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

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

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

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

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

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

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

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



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

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

### **5.2.3.2.3 – Detailed Written Order for Covered Items** **(Rev. 468; Issued: 05-31-13; Effective: 07-01-13; Implementation: 07-01-13)**

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

### **5.2.4 – Requirement of New Orders** **(Rev. 242; Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)**

A new order is required in the following situations:

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

### **5.2.5 - Billing for Refills of DMEPOS Items Provided on a Recurring Basis** **(Rev. 378, Issued: 07-01-11, Effective: 08-02-11, Implementation: 08-02-11)**

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Medicare & Medicaid Services



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

MLN Matters® Number: SE1305 Revised

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

Related CR Release Date: N/A

Effective Date: N/A

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

Implementation Date: N/A

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

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

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

## Provider Types Affected

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This MLN Matters® Special Edition Article is intended for:

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

## Provider Action Needed

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

## What Providers Need to Know

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

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

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

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

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

## Background

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

Below are examples of some of these types of claims:

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

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

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

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

CMS would like to highlight the following limitations:

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

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## Questions and Answers Relating to the Edits

### 1. What are the ordering and referring edits?

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

### 2. Why did Medicare implement these edits?

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

### 3. How and when will these edits be implemented?

These edits were implemented in two phases:

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

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

<b>N264</b>	Missing/incomplete/invalid ordering provider name
<b>N265</b>	Missing/incomplete/invalid ordering provider primary identifier

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

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

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

<b>N272</b>	Missing/incomplete/invalid other payer attending provider identifier
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For adjusted claims the CARC code 16 and/or the RARC code N272 was used.

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

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

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

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

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

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

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

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

<sup>1</sup> NPIs were added only when the matching criteria verified the NPI.

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

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

## Effect of Edits on Providers

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

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

**a. You have a current Medicare enrollment record.**

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

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

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- eligible to order or refer in the Medicare program. If you are not sure that the physician or non-physician practitioner who is ordering or referring items or services meets those criteria, it is recommended that you check the Ordering Referring Report described earlier in this article.
- Ensure you are correctly spelling the Ordering/Referring Provider's name.
  - If you furnished items or services from an order or referral from someone on the Ordering Referring Report, your claim should pass the Ordering/Referring Provider edits.
  - The Ordering Referring Report will be replaced twice a week to ensure it is current. It is possible that you may receive an order or a referral from a physician or non-physician practitioner who is not listed in the Ordering Referring Report but who may be listed on the next Report.

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

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

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

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

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

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

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

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

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

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

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

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

## Additional Guidance

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

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

## Additional Information

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For more information about the Medicare enrollment process, visit <http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html> or contact the designated Medicare contractor for your State. Medicare provider enrollment contact information for each State can be found at [http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/Contact\\_list.pdf](http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/Contact_list.pdf) on the CMS website.

The Medicare Learning Network® (MLN) fact sheet titled, "Medicare Enrollment Guidelines for Ordering/Referring Provider," is available at [http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedEnroll\\_OrderReferProv\\_factSheet\\_ICN906223.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedEnroll_OrderReferProv_factSheet_ICN906223.pdf) on the CMS website.

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

## Additional Article Updates

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

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

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

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

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

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

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

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

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## Memorandum to OMHA Medicare Appellants

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

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

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

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

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

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

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

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

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

Sincerely,



Nancy J. Griswold  
Chief Administrative Law Judge

# Hospital - DMEPOS supplier arrangements and the Anti-kickback Statute

By *Richard Rifenbark, Esq. and Nathaniel Lactman, Esq., CCEP*

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

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

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

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

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

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

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

## Overview of applicable laws

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

The AKS prohibits any person from knowingly and willfully



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

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

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

### **DMEPOS suppliers as hospital affiliates**

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

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

### **Compliance concerns and potential safeguards**

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

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

*Continued on page 48*

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

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

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

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

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

### **DMEPOS suppliers that provide items to hospital patients**

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

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

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

### **Compliance concerns and potential safeguards**

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

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

the following requirements must be met:

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

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

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

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

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

*Continued on page 50*

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

### **DMEPOS supplier convenience and consignment closet arrangements**

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

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

### **Compliance concerns and potential safeguards**

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

consignment closets in physicians' offices are suspect."<sup>16</sup>

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

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

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

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

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

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

## Conclusion

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

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

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

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

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

# DMEPOS reimbursement appeals and the compliance officer

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

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

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

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

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

## Hot reimbursement issues

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



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

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

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

### **DMEPOS claims appeals process**

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

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

#### **First level — Redetermination**

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

#### **Second level — Reconsideration**

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

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

### **Third level — Administrative law judge**

The third level of appeal is a hearing before an administrative law judge (ALJ) in the Office of Medicare Hearings and Appeals. If at least \$130 remains in controversy, a supplier may seek an ALJ hearing by filing a written appeal using form CMS-20034A/B (and may also file supplemental legal briefs). A supplier that wants to appeal an unfavorable reconsideration decision must file the request for an ALJ hearing within 60 days from the date of receipt of the unfavorable reconsideration decision. A supplier can request an in-person hearing, but hearings typically occur by videoconference or telephone. Suppliers can also forgo a hearing and instead ask the ALJ to issue a decision on the written record. Generally, the ALJ will issue its decision within 90 days of receiving the supplier's hearing request, but this deadline is often extended. If the ALJ does not issue a decision in that timeframe, the supplier may escalate the appeal to the fourth level.

### **Fourth level — Medicare Appeals Council**

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

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

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

### **Fifth level — Judicial review in federal district court**

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

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

### **Benefits of compliance officer involvement**

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



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

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

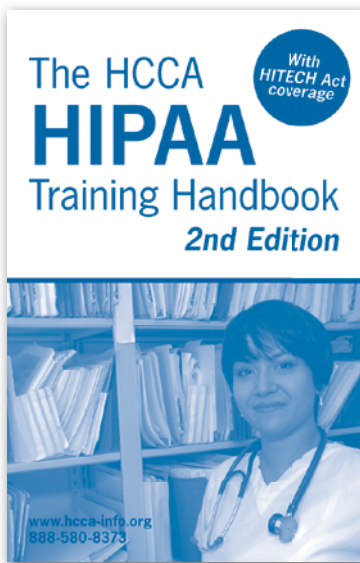
It is important that suppliers keep their compliance officers involved in the appeals process because compliance officers can track and trend claim denials and assist in efforts to demonstrate the frequency of the varying interpretations of Medicare regulations across the four DME MACs. By doing so,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

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

### Conclusion

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

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

# Proposed overpayment regulations issued for 60-day refund rule

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

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

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

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



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## Background

Prior to the enactment of the 60-day refund rule, there was a long history of disagreement between the health care bar, regulators, prosecutors, and the industry regarding whether or not there was a duty to affirmatively disclose overpayments. Some providers argued there was no duty to refund innocent overpayments, but the government disagreed and made efforts to pursue *qui tam* cases and settlements on the reverse false claim theory (i.e., where an obligation to pay or transmit money to the government is fraudulently evaded).

Much of this debate was settled with the enactment of Section 1320a-7k(d) on March 23, 2010. Specific to overpayments, PPACA included the following three interrelated provisions:

- ▶ Providers have an obligation under the False Claims Act (FCA), including an express duty to refund and report Medicare and Medicaid overpayments by the later of 60 days after the overpayment is identified or the date the corresponding cost report is due. Failure to report and return the overpayment is an obligation for purposes of the FCA.
- ▶ Enhancements to the Civil Monetary Penalties (CMP) Law now provide CMPs for failing to report and return known overpayments within 60 days or when the cost report is due.
- ▶ Expanded exclusion authority under the Medicaid program for failure to report and return known overpayments.

Section 1320a-7k(d) itself states, in pertinent part, as follows:

**(d) REPORTING AND RETURNING OF OVERPAYMENTS. —**

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

- (A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and
- (B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

(2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS. —

An overpayment must be reported and returned under paragraph (1) by the later of —

- (A) the date which is 60 days after the date on which the overpayment was identified; or
- (B) the date any corresponding cost report is due, if applicable.

(3) ENFORCEMENT.—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.

(4) DEFINITIONS. — In this subsection:

(A) KNOWING AND KNOWINGLY. — The terms ‘knowing’ and ‘knowingly’ have the meaning given those terms in section 3729(b) of title 31, United States Code.

(B) OVERPAYMENT. — The term “overpayment” means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.

(C) PERSON. —

(i) IN GENERAL. — The term ‘person’ means a provider of services, supplier, Medicaid managed care organization (as defined in section 1903(m)(1)(A)), Medicare Advantage organization (as defined in section 1859(a)(1)), or PDP sponsor (as defined in section 1860D-41(a)(13)).

(ii) EXCLUSION. — Such term does not include a beneficiary.

As can be seen from the statutory language, a number of important definitions are omitted and the statute leaves open the critical question of when the 60-day period commences. Prior to the issuance of the proposed rule, organizations were required to interpret and apply the statute as best they could within their existing compliance structure. This is because the 60-day refund rule is currently in effect and a provider that fails to meet the reporting deadline faces damages and penalties under the FCA, CMPs, and potential

exclusion from participation in federal health care programs.

### Highlights of the CMS proposed rule

CMS's proposed rule explains when an overpayment is "identified" and how overpayments are to be reported and refunded. CMS's position on those two issues is largely consistent with the statutory language of Section 1320a-7k(d). CMS interpreted the statutory language in two important material ways:

- ▶ a "reasonable inquiry" principle offering a reasonable and measured approach to determining when the 60-day clock starts running; and
- ▶ a proposed 10-year look back period for retrospective overpayment reviews that significantly expands the potential liability of providers when refunding overpayments.

The proposed rule only applies to traditional Medicare Parts A and B, even though Section 1320a-7k(d) also includes Medicaid, managed care organizations, Medicare Advantage and Part D programs. The statutory 60-day refund rule with respect to those programs remains in effect, even without regulatory guidance, although health plans and Medicaid providers likely will look to the proposed rule and any final regulations for guidance as to how to apply the statutory requirements.

### When is an overpayment identified?

Under the proposed rule, an overpayment is "identified" when a person has actual knowledge of the existence of an overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. CMS acknowledged that the 60-day clock does not start running (i.e., an overpayment is not "identified") until after the provider has an opportunity to undertake a "reasonable inquiry" into the basis of the alleged overpayment.

### Reasonable inquiry

CMS did not detail what constitutes a "reasonable inquiry," but clearly CMS will allow some flexibility in light of the different levels of review needed to address the wide variety of potential overpayments—ranging from simple claims issues to complex regulatory analyses. CMS did not propose the 60-day clock start running on the first mere allegation or suspicion of an overpayment. CMS appeared to recognize that many sophisticated reimbursement questions require significant use of internal and external resources, due diligence, and document review. These important steps often cannot be completed within 60 days of the initial allegation of the overpayment.

Although the reasonable inquiry rule affords greater flexibility regarding the timing of refunds, CMS balanced it against the concept that providers or suppliers have a duty to promptly conduct this reasonable inquiry upon receipt of information of a potential overpayment. If a provider fails to make any reasonable inquiry, it may be found to have acted in reckless disregard or deliberate ignorance of the overpayment. In many respects, this is consistent with the practices of providers with effective compliance plans even prior to the implementation of PPACA.

According to CMS, defining "identification" in this way gives providers and suppliers an incentive to exercise due diligence to determine whether an overpayment exists. Without such a principle, CMS believes some providers and suppliers might avoid performing activities to determine whether an overpayment exists, such as self-audits, compliance checks, and other additional research.

CMS also stated that when a government agency informs a provider or supplier of a potential overpayment, the provider or supplier has an obligation to accept the finding or make a reasonable inquiry. At this point, the legal authority for such an obligation seems

unclear at best, as does what sort of government agency notice may trigger this obligation (e.g., remittance advice, general provider alert, RAC audits, informal letter to specific provider, preliminary audit report, or formal letter).

### 10-year look back period

The most dramatic change proposed by CMS is an expansion of the look back period for overpayments to 10 years. CMS chose this period to parallel the outside statute of limitations under the False Claims Act, but current Medicare reopening regulations permit look back periods of only 3 or 4 years for most situations (i.e., when there is no fraud, provider integrity issue, or similar fault). The proposed requirement to report and refund overpayments received during the prior 10 years represents a significant change to current overpayment and refund practices. Should the proposed rule go into effect as drafted, this change would result in materially increased liability for providers and suppliers.

Many providers and suppliers will find a 10-year look back period not viable, if only because that period extends beyond the current record retention rules and requirements under Medicare Conditions of Participation, Supplier Standards, and state laws on medical record retention (typically ranging from 5 to 7 years). The 10-year period represents a dramatic expansion of CMS's authority and reach into retrospective claims reviews.

### Self-reporting process

Under the proposed rule, the existing voluntary refund process in Chapter 4 of the Medicare Financial Management Manual will be renamed the "self-reported overpayment refund process." This is the process providers and suppliers will use to effectuate refunds. Self-reporting should be made in accordance with the protocols of the local fiscal intermediary, carrier, or contractor. CMS contemplates a standardized form to be used for repayments, but has not yet created one.

If an overpayment is claims-related, and would not be impacted by reconciliation of the cost report, the refund should not be delayed (according to CMS) until reconciliation of a cost report. For example, issues involving upcoding must be reported and returned within 60 days of identification, because the upcoded claims for payment are not submitted to Medicare as "costs" in the form of cost reports.

On a related note, CMS explained that the CMS Stark Self-Referral Disclosure Protocol (SRDP) tolls the obligation to refund the overpayment, but does not toll the obligation to report it. The OIG Self-Disclosure Protocol (SDP) also tolls the refund obligation, and a timely report to OIG under the SDP satisfies the reporting requirements under the 60-day refund rule.

### Drafting a policy and procedure on overpayments

Many organizations have already created policies and procedures on self-reporting of known overpayments. With the issuance of the proposed rule (and the eventual enactment of a final rule), those organizations will need to tweak their existing policies and procedures to conform to the new regulations. But for those organizations without any policy and procedure on overpayments, it is due time to start considering how to create such a policy (whether formally-promulgated or a well-designed guideline). Again, the proposed rule has not been finalized and it would be reasonable to commence work, but not publish a policy, until the regulations are final.

When drafting a policy on overpayments, it is important to acknowledge the legal requirements, but also properly balance competing duties, apply the law fairly, and mitigate risk. In connection with that, an organization should evaluate the following considerations:

- ▶ Develop a standard form to document an internal report of an alleged overpayment. Many of the elements on that form can

mirror the required elements of the official reporting form.

- ▶ Consider whether the overpayment investigation should be conducted under attorney-client and work product privileges. The organization should have a policy and procedure to assist in these determinations.
- ▶ Conduct and document employee interviews.
- ▶ Collect evidence and document the methodology used to determine if the alleged overpayment is a credible concern.
- ▶ Assess and analyze the causes of the overpayment as well as any defenses to the overpayment or limitations on the amount of overpayment calculated.
- ▶ Determine the amount of overpayment to report and return, and determine to whom the refund should be made. Document the methodology of how the refund amount was calculated.
- ▶ Determine what corrective action is necessary to address the root cause of the overpayment and prevent its future recurrence.

Consider those cases where the “reasonable inquiry” period is anticipated to continue for such a length of time that filing some preliminary “holding statement” with the Fiscal Intermediary/Carrier/MAC may be prudent.

When drafting an overpayments policy, the organization should also keep in mind the following considerations:

- ▶ Don’t create a policy that requires an unworkable bureaucracy or over-complicated process. It should be nimble, clear, and easy to complete in a timely manner.
- ▶ Do create a policy that allows for flexibility when information changes/develops during the investigation.
- ▶ Do create a policy that demonstrates the effectiveness of the organization’s compliance plan.
- ▶ Do include in the policy any necessary internal approvals which are required for processing of the refund, and build in time for securing these approvals.
- ▶ Don’t create a policy that conflicts with the organization’s internal accounting policies without first getting input from auditors and legal counsel.
- ▶ Do implement robust training and education around the policy, how to spot overpayments, the requirements for internal (or external) reporting, and the organization’s commitment against retaliation for whistleblowers and reporters.

### Conclusion

In light of the ambitious changes in the proposed rule, particularly the significant expansion of potential liability associated with a 10-year look back period, health care organizations need to understand the consequences of the 60-day refund rule and how to meet its requirements. A first step is to create and implement an appropriate policy and procedure for reporting and refunding identified overpayments. Organizations must currently meet the 60-day requirements already in place under Section 1320a-7k(d), even though the proposed rule is not finalized. Organizations that draw on the guidance in the proposed rule to create a viable policy for reporting and refunding overpayments should find themselves well-positioned when the final rule is issued. ©

# DMEPOS supplier marketing arrangements and HIPAA compliance

By *Nathaniel Lacktman, Esq., CCEP; and Leeann Habte, Esq., CIPP*

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*This article is the fourth in a series on DMEPOS compliance issues by Foley & Lardner LLP published in **Compliance Today**. Last month, the authors provided insight and strategic advice on DMEPOS supplier standards and the False Claims Act.*

*This month, the authors discuss the HIPAA implications for DMEPOS supplier marketing arrangements and provide a sample marketing authorization form as a supplier tool. Subsequent articles will discuss hospital-DMEPOS supplier arrangements under the Anti-kickback Statute; strategies for DMEPOS promotions and arrangements with manufacturers; and DMEPOS reimbursement compliance.*

Suppliers of durable medical equipment, prosthetics, and orthotics supplies (DMEPOS) play an essential role in the spectrum of patient care, particularly for a medically-fragile patient population seeking greater independence. The lifeblood of a DMEPOS supplier's business is its customer base—the patients. Motivated suppliers continue to seek out new ways to promote their items and services to customers, and rightly so. In addition, many established suppliers are exploring cross-promotional arrangements with other companies as a means to obtain additional revenue and expand their

footprint by tapping into other companies' customer bases.

Although such marketing strategies can offer significant benefits, they also present particular compliance risks in the health care context. DMEPOS suppliers interested in exploring collaborative or cross-promotional arrangements with other businesses must take time to understand the contours of the Health Insurance Portability and Accountability Act (HIPAA) and other applicable rules, because they affect the scope and terms of such cross-promotional arrangements. For purposes of this article and all the examples contained herein, the DMEPOS supplier is assumed to be a HIPAA covered entity (as would be the case in the vast majority of retailer DMEPOS suppliers).

## HIPAA marketing rules and restrictions

DMEPOS suppliers that plan to implement marketing or promotional arrangements should keep in mind that the HIPAA Privacy Rule restricts both the disclosure and use of protected health information (PHI) for marketing purposes.<sup>1</sup> With certain important exceptions, the Privacy Rule requires an individual's written authorization before his/her protected health information can be disclosed or used for any

*Continued on page 54*

communication that meets the definition of marketing.<sup>2</sup>

### **Definition of marketing**

Under HIPAA, a communication is considered to be marketing if the supplier makes “a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.”<sup>3</sup> Generally, if a communication meets the definition of marketing, the supplier may make that communication to a patient only if it first obtains the patient’s express written authorization. An example of a marketing communication requiring patient authorization is a letter sent from the supplier to its former patients, informing them about a special promotion from a local fitness center that is offering discounts to the general public on new workout memberships, when the communication is not for the purpose of providing treatment advice.<sup>4</sup> However, if a communication that otherwise meets the definition of marketing falls within one of the following three exceptions and does not involve direct or indirect payment for making such communication, an authorization will not be required.<sup>5</sup>

### **Exceptions to HIPAA definition of marketing**

The three exceptions below fall under the definitions of treatment and/or health care operations, and use or disclosure of PHI for these

purposes is permissible without written authorization.

#### **1. Supplier’s own health-related items or services**

Under the first exception, a communication is not considered marketing if it describes a health-related product or service provided by the supplier making the communication.<sup>6</sup> Among other things, this exception permits communications by a supplier about products or services “provided by” the supplier to its clients. For example, it would not be marketing for a supplier that has added a new anti-snoring device to its product supply catalog to send a flyer describing it to the supplier’s patients (whether or not each patient has actually previously sought treatment for snoring).

#### **2. Supplier’s treatment communications**

Under the second exception, a communication is not considered marketing if it is made for treatment of the individual and for the purpose of furthering the treatment of that individual.<sup>7</sup> For example, under this exception, it is not marketing when a supplier mails refill reminders to patients, or contracts with a mailing house to do so.<sup>8</sup>

#### **3. Coordination of care and recommendation of alternative treatments**

Under the third exception, a communication is not considered

marketing if it is made for “case management or care coordination for the individual, or to direct or recommend alternative treatments, therapies, health care providers, or settings of care to the individual.”<sup>9</sup> For example, under this exception, it is not marketing when an endocrinologist shares a patient’s medical record with several behavior management programs to determine which program best suits the ongoing needs of the individual patient.<sup>10</sup> This exception is less frequently utilized in the DMEPOS supplier context, because the supplier commonly fills the orders issued by the patient’s treating physician, and the supplier does not independently offer its own treatment recommendations.

### **Marketing and the sale of health information**

HIPAA also has a second definition of marketing, under which a communication is considered marketing if the supplier enters into an arrangement with another entity whereby the supplier:

...discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the communication to purchase or use that product or service.<sup>11</sup>



This type of marketing has no exceptions under the current HIPAA Privacy Rule. In other words, a supplier may not sell the PHI or names of its patients to a business associate or any third party without first obtaining express written authorization from each patient.<sup>12</sup> A valid authorization must state that such remuneration is involved.<sup>13</sup>

### **When are HIPAA authorizations for marketing not required?**

Even if a communication falls within the definition of marketing, there are certain situations where an authorization is not required. The HIPAA Privacy Rule provides an exception if the marketing communication is in the form of either a face-to-face communication made by the supplier to an individual, or a promotional gift of nominal value provided by the supplier.<sup>14</sup> This provision permits a supplier to discuss any services and products, including those of a third-party, during a face-to-face communication. The supplier could also give the patient sample products or other information in this setting (subject to other restrictions, such as the Anti-kickback Statute, Civil Monetary Penalties Law, and other laws not discussed in this article). From a HIPAA perspective, no written authorization is necessary when, for example, a supplier provides a free package of formula and other baby products

to new mothers as they leave the maternity ward.

Effective February 18, 2010, the Health Information Technology for Economic and Clinical Health (HITECH) Act revised the framework for the HIPAA exceptions to marketing communications. Under these changes, even if remuneration is involved, certain communications are considered health care operations and not marketing:

- if the communication is for treatment purposes; or
- if the communication only describes a drug or biologic that has been previously prescribed or administered, provided that the amount of the remuneration to the supplier is reasonable.<sup>15</sup>

For uses or disclosures other than these exceptions, a valid authorization from the patient is required.

### **Intersection of HIPAA marketing rules and DMEPOS Supplier Standards**

When marketing items and services, Medicare-participating DMEPOS suppliers must not only comply with HIPAA marketing restrictions, they must also comply with the Medicare DMEPOS Supplier Standards for marketing to beneficiaries. Although both sets of rules govern marketing communications, they

differ in how they restrict such communications.

### **Marketing your own DMEPOS items or services**

The HIPAA Privacy Rule makes clear that certain activities, such as communications made by a supplier for the purpose of describing the products and services it provides, do not constitute marketing. Under HIPAA's marketing rules, a DMEPOS supplier may freely market its own products and services to its own patients, and may use its patients' health information for such purpose without authorization. This is also allowed under the Medicare DMEPOS Supplier Standards.

### **Cross-promoting products or services of other companies**

Under the Privacy Rule, a DMEPOS supplier may not use its patients' PHI to promote the products and services of other businesses (i.e., products and services not offered by the DMEPOS supplier itself) unless it meets one of the exceptions. When a supplier sends another business's marketing materials to the supplier's patients and such communication is not for the treatment of an individual, the supplier would be using its patients' PHI. It matters not if the supplier does not actually disclose any PHI to the other business, because the

*Continued on page 57*

Privacy Rule restricts both the disclosure and the use of PHI.

In this situation, none of the HIPAA marketing exceptions apply. The supplier is not marketing its own product or service. The supplier is not making a recommendation regarding treatment of an individual patient's medical condition. And, the supplier is not likely to be considered to be in a position to make specific medical treatment recommendations regarding alternative treatments to patients (as might a physician or hospital). Therefore, the supplier must obtain the authorization of its clients before sending those marketing materials. If the cross-promotion activities involve direct or indirect remuneration to the supplier from the third party, the patient authorization form must state that such remuneration is involved.<sup>16</sup>

### **Selling customer health information**

Likewise, if a supplier discloses PHI to the other entity, in exchange for direct or indirect remuneration so that the other entity may send marketing materials to the supplier's patients, the supplier must obtain a valid authorization from its patients. The authorization must expressly state that remuneration is involved.<sup>17</sup> For example, a supplier cannot, without authorization, sell a list of patients to a

pharmaceutical company so the pharmaceutical company can directly market its own products to the individuals on the list.

### **DMEPOS companies with multiple subsidiaries or sister suppliers**

Under HIPAA, legally separate but affiliated covered entities, such as subsidiaries or sister companies, may designate themselves as a single covered entity for purposes of HIPAA, as long as all the covered entities designated are under common ownership or control.<sup>18</sup> If designated as a single covered entity, the sharing of PHI among sister companies or subsidiaries within the same covered entity does not constitute a use or disclosure for which authorization is required.

Despite the fact that HIPAA allows multiple subsidiaries or sister companies to be deemed a single covered entity, CMS has stated that it considers each subsidiary to be a separate supplier.<sup>19</sup> Under DMEPOS Supplier Standard No. 11, CMS stated that the affiliated suppliers may not "reach out to" each other's Medicare beneficiaries for marketing (or at least, telemarketing) purposes. This means that a DMEPOS company with multiple subsidiary suppliers should take caution when implementing marketing endeavors to promote products and services to its own patients.

Such activities are not impossible, but require planning on how to execute them in compliance with both HIPAA and the Medicare supplier standards.

### **Obtaining authorization for marketing purposes**

One approach to permit broad marketing communications is for the supplier to obtain written authorization from its patients where the patients would consent, in advance, to receive marketing materials. The supplier could send its patients an authorization form. For those patients who sign and return the authorization, the supplier would then send those patients marketing materials, including marketing materials of other companies (assuming the scope of the authorization covered the intended marketing activities). Alternately, the supplier could include the marketing authorization in its patient welcome package. A third approach would be to place the authorization form online to obtain and track patient consent. Suppliers with multiple subsidiaries or sister companies should consider creating a master authorization, under which the patient would authorize marketing activities for the entire family of related suppliers, as well as the supplier's business partners.

Suppliers should note that HIPAA also imposes certain restrictions

*Continued on page 58*

on the scope, content, and duration of marketing authorizations.<sup>20</sup> The marketing authorization may not be combined with another type of authorization (so-called “compound authorizations”).<sup>21</sup>

In addition, certain state laws impose further restrictions on the disclosure and use of PHI for marketing purposes. When state law is more restrictive than HIPAA, the state law governs. If a supplier plans to distribute marketing materials to patients in various states, the authorization form must comply with the corresponding state law. See figure 1 on page 59 for a sample marketing authorization form.

Of course, different approaches present different logistical and operational challenges, such as time and expense, online capabilities, a system to track authorization forms, and patient preferences. Suppliers need to determine what approach is most cost-effective and feasible for their needs.

### Practical compliance advice

When drafting, reviewing and revising their written policies and procedures on marketing, suppliers should ensure the policies and procedures are current with the recent HIPAA developments and changes. The rules and regulations have undergone significant change as a result of amendments made by the HITECH Act.

New proposed regulations implementing the HITECH Act were published on July 14, 2010. The final regulations have not yet been issued, but are expected to be released soon. Suppliers will need to review these regulations and comply with them when they become effective.

When examining policies for HIPAA marketing compliance, suppliers should consider the following sample questions (by no means an exhaustive list):

- Does the supplier have a marketing authorization form? Does it meet current federal and state requirements? Is the form translated into other languages?
- What is the supplier’s process for a patient to opt out of receiving marketing communications?
- Does the supplier identify the specific marketing uses and disclosures for which an authorization is not required?
- How does the supplier document patient authorization to receive marketing materials?

In addition to the written procedures, suppliers should verify that their actual marketing practices correspond with the expectations set forth in their policies and procedures. The marketing staff should be periodically trained and educated on relevant marketing rules under federal and state law.

The supplier’s Notice of Privacy Practices should be current and accurate and its authorization form should be proper in scope and content.

### Conclusion

Marketing activities are integral to the continued growth of nearly any business, including DMEPOS suppliers. Given the regulatory environment and the intersection of HIPAA rules and the Medicare Supplier Standards, suppliers should implement—and adhere to—a framework of safeguards designed to allow robust marketing efforts while maintaining high levels of compliance. ■

1. 45 C.F.R. Part 160 and Part 164, Subparts A and E.
2. See 45 C.F.R. § 164.508(a)(3).
3. 45 C.F.R. § 164.501.
4. See Marketing FAQ at p. 1, Office of Civil Rights, HIPAA Privacy (April 3, 2003).
5. 42 U.S.C. § 17936(a)(2).
6. 45 C.F.R. § 164.501.
7. 45 C.F.R. §§ 164.501; 164.506(c)(1).
8. See Marketing FAQ, *supra*, at p. 3.
9. 45 C.F.R. § 164.501.
10. See Marketing FAQ, *supra*, at p. 3.
11. 45 C.F.R. § 164.501.
12. See Marketing FAQ, *supra*, at p. 2.
13. 45 C.F.R. § 164.508(a)(3)(ii).
14. 45 C.F.R. § 164.508(3)(i).
15. 42 U.S.C. § 17936(a)(2).
16. See 45 C.F.R. § 164.508(3)(ii).
17. 45 C.F.R. 164.105(b).
18. 45 C.F.R. 164.508(a)(3)(ii).
19. See 42 C.F.R. § 424.57(c)(11); “CMS FAQ Concerning the Revised Standards for DMEPOS Suppliers,” CMS-6036-F (Feb. 16, 2011).
20. See 45 C.F.R. § 164.508(c).
21. See 45 C.F.R. § 164.508(b)(3).

Figure 1: Authorization For Use And Disclosure Of Health Information\*

Name		Date of Birth	
Street Address	City	State	Zip
Phone		Email	

I hereby authorize ABC DMEPOS Supplier, Inc. to use and/or disclose my health information specifically [identify nature of information that would be used or disclosed for DMEPOS marketing purposes] for the specific purposes of informing me about new products and services, and for ABC's marketing, promotions and advertising activities. ABC's use and/or disclosure will result in the disclosure of such health information among and between [identify entities that will receive the information]. ABC may receive direct or indirect remuneration (payment) from these third parties as a result of health information obtained and shared with those business partners pursuant to this Authorization. Health information disclosed pursuant to this Authorization may be subject to redisclosure and no longer protected by federal health care privacy laws.

- You have the right to inspect or copy the health information authorized to be used and/or disclosed by this Authorization.
- You have a right to receive a copy of this signed Authorization and ABC will provide you with a copy, should you choose to sign it.
- This Authorization is voluntary and you do not have to sign it. Your refusal to sign this Authorization will not affect your ability to obtain treatment, payment, health plan enrollment, or eligibility for benefits.
- You may revoke this Authorization at any time. To revoke this Authorization, notify ABC in writing at: [insert address]. Additional information may be found in ABC's Notice of Privacy Practices at [insert website].
- This Authorization is valid for five (5) years from the date signed below.

I have had an opportunity to review and understand the content of this Authorization. By signing this Authorization, I am confirming that it accurately reflects my wishes.

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

**\* This form is for sample educational purposes only. Suppliers should not rely solely on this form and are advised to seek input from legal counsel to comply with all applicable federal and state laws, rules and regulations.**

# Cold calls, hot lines: DMEPOS telemarketing and beneficiary contact

By Nathaniel Lacktman, Esq., CCEP; and Heidi Sorensen, Esq.

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*This article is the first in a series on DMEPOS marketing compliance by Foley & Lardner published in **Compliance Today**. Next month, the authors will develop this topic by providing a practical summary of the various telemarketing rules, strategic advice for DMEPOS telemarketing, and guidelines for applying the rules to real-world situations. Subsequent articles will discuss DMEPOS marketing arrangements under the Anti-kickback Statute, HIPAA, practical solutions for obtaining beneficiary consent to marketing, and strategies for allowable cross-promotion and co-promotion of DMEPOS items.*

Suppliers of durable medical equipment, prosthetics, and orthotic supplies (DMEPOS), whether home care

companies, mail-order suppliers, or manufacturers, provide an important service to a medically-frail group of people. The Medicare population, in particular, constitutes an important customer base and a significant source of revenue for DMEPOS suppliers. Understandably, suppliers continue to seek new ways to reach out to Medicare beneficiaries and grow their customer base. However, agencies such as the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) have announced new restrictions on how DMEPOS suppliers can conduct telemarketing activities and solicit beneficiaries.

## The Telemarketing Statute

The Telemarketing Statute<sup>1</sup> prohibits suppliers from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of covered DMEPOS items unless one of three exceptions apply. The statute does not apply if:

- the beneficiary has given the supplier written permission to contact him/her by telephone;
- the supplier has already furnished a covered item to the beneficiary and the supplier is contacting the beneficiary regarding the furnishing of that item; or
- the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months, in which case the supplier may discuss or promote other covered items with the beneficiary.

A point of caution: a supplier cannot avoid application of the statute by contracting with a third-party vendor or telemarketing company. The statute also applies to vendors or agents working on the supplier's behalf. If the vendor violates the telemarketing statute, both the vendor and the supplier can be held responsible.

The penalties for violating the statute can be severe. If a supplier knowingly submits a claim for an item in violation of the statute, CMS must deny payment. Violations of the statute, particularly a pattern of violations, can expose suppliers to potential civil, criminal, and administrative penalties, including exclusion from participation in federal health care programs.

## OIG Guidance and Updated Special Fraud Alert

OIG has long cautioned suppliers against improper telemarketing practices and noted, in its DMEPOS Compliance Program Guidance,<sup>2</sup> that suppliers are prohibited from making unsolicited telephone contact to Medicare beneficiaries. OIG also issued a 2003 Special Fraud Alert<sup>3</sup> reiterating the prohibition on unsolicited telemarketing. Both publications reference the Telemarketing Statute but do not expand on the scope of the statutory language.

In 2010, OIG issued an Updated Special Fraud Alert on DMEPOS telemarketing, drawing attention to the telemarketing activities of independent marketing firms that make unsolicited telephone calls on behalf of suppliers to Medicare beneficiaries to market the suppliers' products.<sup>4</sup> In the updated alert, OIG explained that the practice violates the Telemarketing Statute because "suppliers cannot do indirectly that which they are prohibited from doing directly." OIG has indicated that the need for the Special Fraud Alert grew directly out of ongoing enforcement activities

it was undertaking in conjunction with the Department of Justice (DOJ).

The updated alert took the position that, when a physician sends a supplier the written or verbal order for a beneficiary, and the supplier calls the beneficiary regarding that order, such telephone contact is a violation of the Telemarketing Statute. OIG reasoned that “a physician’s preliminary written or verbal order is not a substitute for the requisite written consent of a Medicare beneficiary.”

A number of industry representatives criticized the OIG’s position, because it is common practice for physicians to send orders directly to the supplier. Requiring physicians to obtain a beneficiary’s written consent for each new patient could be a challenging task, particularly because the already busy physicians have no incentive to add this step to their paperwork process. It would be similarly challenging to require the supplier to obtain the written consent. For example, it would be impractical, costly, and inefficient for a supplier, after receiving the physician order, to then mail a written authorization card to the new patient and wait for a signed response before contacting the patient by telephone to arrange for delivery of the ordered item.

From a legal perspective, it is unclear whether the OIG’s expanded interpretation is adequately rooted in the language of the Telemarketing Statute and, at the time the updated alert was issued, no regulations were in place. From an operational perspective, the OIG’s interpretation would likely result in significant delays before patients could receive their prescribed items, thereby limiting beneficiary access to essential Medicare-covered items.

### **CMS response to Updated Special Fraud Alert**

A month after the OIG released its updated alert, CMS responded by issuing Frequently

Asked Questions (FAQs) regarding telemarketing.<sup>5</sup> The CMS FAQs differed from the OIG alert, and many believed CMS took a more reasonable interpretation consistent with how the DMEPOS industry operates. The fact that CMS responded with differing guidance so quickly after the OIG’s release of the Updated Special Fraud Alert suggests that OIG and CMS did not coordinate prior to the OIG release. The CMS FAQs included the following guidance:

- If a supplier returns a beneficiary’s phone call, the supplier’s contact is not unsolicited.
- If a physician contacts a supplier on behalf of a beneficiary and with the beneficiary’s knowledge, and a supplier then calls the beneficiary to confirm or gather information needed to provide that particular covered item (including delivery and billing information), then that contact is *not* unsolicited. The beneficiary need only be aware that a supplier will be calling him/her regarding the covered item, recognizing that the appropriate supplier might not be identified at the time of the physician’s consultation. This guidance provided flexibility, because the physician need not inform the patient that a specific supplier will call the patient. It also did not require a physician to obtain the beneficiary’s written consent.
- If a supplier calls a beneficiary based solely on the physician order, but the beneficiary did not know a supplier would call him/her, that call would be unsolicited contact. The physician must let the beneficiary know the physician will send the order to a DMEPOS supplier and a supplier will call the beneficiary.
- A supplier is not required to collect and maintain documentation from the physician reflecting that the physician informed the beneficiary that a supplier will call. CMS stated “It would be a business decision on

the part of the supplier whether to collect and obtain such documentation for their records.”

- If a supplier makes solicited contact with a beneficiary for a particular covered item, the supplier cannot speak with the beneficiary about other covered items during that same contact. This generally applies to new customers because, after the supplier has provided a covered item to the beneficiary, the supplier may then subsequently contact the beneficiary to offer other covered items in accordance with the exceptions in the Telemarketing Statute.

The CMS FAQs elucidated a reasonable position consistent with existing business practices and the Telemarketing Statute, and provided useful and practical guidance to DMEPOS suppliers. OIG indicated both informally, and through a cover letter distributing the FAQs to suppliers that it would defer to these interpretations by CMS. However, the CMS FAQs differed from the OIG’s published position and, moreover, CMS continued to change its position in the regulations and a second set of FAQs, as discussed in detail below.

### **New regulations and Preamble commentary**

In August, 2010, CMS released final regulations updating the DMEPOS supplier enrollment standards.<sup>6</sup> The regulations introduced new telemarketing rules, imposed stricter program standards for suppliers, and implemented many of the standards in CMS’ 2008 proposed regulations.<sup>7</sup> The regulations took effect on September 27, 2010 and all suppliers must meet these standards.

The Preamble to the regulations contains twelve comments regarding telemarketing and beneficiary contact. CMS’s comments in the Preamble are consistent with its FAQs;

*Continued on page 44*

namely, while a Medicare beneficiary must know that a supplier will be contacting him/her, nowhere did CMS state that the referring physician must obtain the beneficiary's written permission. For example, CMS stated:

[A] supplier may contact a beneficiary if a physician contacts a DMEPOS supplier on behalf of a beneficiary with the beneficiary's knowledge, and then a supplier contacts the beneficiary to confirm or gather information needed to provide that particular covered item (including delivery and billing information). In that instance, the contact would not be considered a direct solicitation and therefore, would not implicate [the Telemarketing Statute].

However, CMS also stated it considers the Telemarketing Statute to apply not only to solicitation by telephone, but also by "e-mail, instant messaging, or in-person contact." That position represented a significant expansion on the statutory language. Although e-mail and instant messaging may arguably be sufficiently similar to telephone calls to be a reasonable extension of the statute, CMS offered no basis to support its position that the prohibition on *telephone contact* would also ban in-person contact. OIG has previously expressed concerns with in-person direct marketing, but that OIG position cannot serve as the basis for expanding the statute.

In addition, the regulation required that a referring physician obtain *written permission* before the supplier may contact the beneficiary. It required that "[t]he individual has given written permission to the supplier or the ordering physician or non-physician practitioner to contact them concerning the furnishing of a Medicare-covered item that is to be rented or purchased." (emphasis added)

Yet, the Telemarketing Statute has always held that if a beneficiary gives written permission to a supplier, the supplier may contact that beneficiary. It seemed to many that the language "or the ordering physician or non-physician practitioner" was misplaced and did not belong in the regulation because it meant a physician must obtain written permission (not simply inform the beneficiary) before the supplier could contact the beneficiary.

CMS could have expressed a more consistent position by deleting the language "or the ordering physician or non-physician practitioner." Suppliers could then refer to the Preamble to understand that the beneficiary must know that a supplier will contact him/her. This approach would have remedied the inconsistency between the regulations and the FAQs and Preamble, and provided clear instruction to suppliers who receive orders from referring physicians. This approach would also have been also consistent with current industry practices and standards. Instead, the regulation triggered the same concerns as the OIG's Updated Special Fraud Alert, and suppliers were concerned that a requirement for written permission would be burdensome, costly, and cause potential delays for Medicare beneficiaries.

#### CMS 2011 FAQs

CMS received a number of critical responses to the regulations and, in January 2011, issued updated FAQs addressing the industry queries.<sup>8</sup> For suppliers, these 2011 FAQs were even more problematic than the regulations. CMS seemed to take some inexplicable and highly unfavorable positions regarding telemarketing and beneficiary contacts, including:

- The 2011 FAQs expanded telephone contact to include mailings made through the US Post Office. The 2011 FAQs prohibit "targeted mailings to specific

beneficiaries," although "general mass advertising" is allowed. CMS offered no explanation of what those terms mean or how the Telemarketing Statute could apply to direct mail.

- A supplier may not contact a beneficiary based solely on a physician order unless the physician obtains the beneficiary's written permission. This position is consistent with the language of the regulation, but differs from the guidance in CMS' previous FAQs.
- If a supplier makes solicited contact with a beneficiary for a particular covered item, the supplier cannot speak with the beneficiary about other covered items during that same contact. This position is largely consistent with CMS' previous FAQs.
- For companies with multiple subsidiaries, if one subsidiary is permitted to contact a beneficiary (e.g., by written permission or by previously providing covered items), a related company under the same parent corporation may not make contact without separately meeting one of the exceptions in the Telemarketing Statute. Even if all the subsidiaries are enrolled DMEPOS suppliers, CMS seems to view each as a separate entity and require each to meet an exception to the Telemarketing Statute in order to contact beneficiaries.

Rather than providing clarity, the 2011 FAQs served to increase confusion about CMS' restrictions on telemarketing and beneficiary solicitation.

#### Revised regulations

On April 4, 2011, CMS released a proposed rule revising supplier standards, particularly supplier standard 11.<sup>9</sup> CMS acknowledged that its expanded interpretation had been criticized as overly broad and prohibited marketing activities in a manner that would be unfeasible for DMEPOS suppliers to

implement. CMS indicated that it will further investigate how to address its concerns of abusive DMEPOS marketing practices. In the interim, CMS will instruct its contractors to apply the restrictions on telephone solicitation that were in effect prior to the August 2010 regulations (rather than all types of beneficiary solicitation and contact).

The current proposed rule deletes the reference to direct solicitation and instead focuses on telemarketing, tracking the exceptions under the Telemarketing Statute. It also deletes the language that requires a referring physician to obtain the beneficiary's written permission. CMS did not include any comments regarding its 2010 or 2011 FAQs, nor how suppliers should interpret the proposed regulations in light of those FAQs, nor which FAQs still remain in effect.

### Conclusion

The changing landscape and conflicting guidance has led to much confusion among DMEPOS suppliers regarding telemarketing

and beneficiary solicitation. Penalties for failing to comply with the telemarketing rules are severe. Because these rule changes have a significant impact on suppliers' business operations and marketing efforts, it is imperative for suppliers that serve Medicare beneficiaries to be aware of the restrictions. Despite the confusion, the various guidance can be boiled down into a manageable set of practical rules suppliers can use in their marketing activities, particularly as new communication technologies and marketing approaches change these activities. Next month's article will set forth those practical rules, apply them to a series of real-world DMEPOS marketing situations, and highlight key opportunities and approaches suppliers can take while still complying with the telemarketing and beneficiary solicitation rules. ■

1. Section 1843(a)(17)(A) of the Social Security Act; 42 U.S.C. § 1395m(a)(17)(A).
2. 64 FR 36368, 36380 (July 6, 1999).
3. 68 FR 10254 (Mar. 4, 2003).
4. 75 FR 2105 (Jan. 14, 2010).
5. Available at [www.cms.gov/MedicareProviderSupEnroll/Downloads/DME%20Supplier%20Telemarketing%20FAQ.pdf](http://www.cms.gov/MedicareProviderSupEnroll/Downloads/DME%20Supplier%20Telemarketing%20FAQ.pdf).
6. 75 Fed. Reg. 52629 (Aug. 27, 2010).
7. 73 Fed. Reg. 4503 (January 25, 2008) (proposed rules); 42 C.F.R. § 424.57(c) (supplier standards).
8. Available at [www.palmettogba.com/Palmetto/Providers.Nsf/files/FAQS6036FINAL.pdf/\\$File/FAQS6036FINAL.pdf](http://www.palmettogba.com/Palmetto/Providers.Nsf/files/FAQS6036FINAL.pdf/$File/FAQS6036FINAL.pdf).
9. 76 Fed. Reg. 18472 (April 4, 2011).

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# Compliant DMEPOS telemarketing: Strategic approaches and practical tips

By Nathaniel Lacketman, Esq., CCEP; and Heidi Sorensen

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*This article is the second in a series on DMEPOS marketing compliance by Foley & Lardner LLP published in **Compliance Today**. This month, the authors provide a practical summary of the Medicare DMEPOS telemarketing rules, offer strategic advice and opportunities regarding DMEPOS telemarketing,*

*and apply the rules to real-world situations. Subsequent articles will discuss marketing arrangements under the Anti-kickback Statute and HIPAA; practical solutions for obtaining beneficiary consent to marketing; and strategies for allowable cross-promotion and co-promotion of DMEPOS items.*

**P**art 1 of this series (published in the May 2011 issue of **Compliance Today**) explained the statutory and regulatory requirements relating to durable medical equipment, prosthetics and orthotics supplies (DMEPOS) telemarketing and beneficiary solicitation under the Medicare regulations and guidance. This article covers how that guidance is transformed into a manageable set of rules and applied to a number of real-world DMEPOS marketing situations. Suppliers will learn: (1) what is allowed and prohibited under the telemarketing and beneficiary contact rules; (2) advice to ensure compliance with these rules; (3) strategic marketing opportunities for suppliers; and (4) practical

solutions and real-world examples of permissible telemarketing and beneficiary contact activities.

## Enforcement of telemarketing rules

Complaints about telemarketing practices filter into a number of different regulators and law enforcement agencies. We are aware of criminal investigations by the Department of Justice (DOJ) of some suppliers and their marketing vendors related to allegations of cold-calling Medicare beneficiaries. The Office of the Inspector General (OIG) settled a Civil Monetary Penalties case in 2009 with Matrix Diabetics, Inc., a Florida distributor of blood glucose testing supplies. The former owners and officers of the DMEPOS company agreed to pay \$260,000 for allegedly paying telemarketing firms to make unsolicited telephone calls to beneficiaries to market DMEPOS items on behalf of the company. The company in turn submitted claims for these items for Medicare reimbursement.<sup>1</sup>

Medicare's Zone Program Integrity Contractors (ZPICs) have also made outreach through letters to suppliers alerting them to complaints of violations of the Telemarketing Statute. The volume of these enforcement activities and the number of different agencies involved highlight that the risk to suppliers who violate the Anti-kickback Statute is real, not hypothetical.

## Rules for DMEPOS telemarketing and beneficiary solicitation

DMEPOS suppliers may not make unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of covered items, unless:

- the beneficiary first calls the supplier or initiates contact, and the supplier is responding to that contact;
- the beneficiary gave the supplier written permission to contact the beneficiary;
- the supplier has already furnished a covered item to the beneficiary and the supplier is contacting the beneficiary regarding the furnishing of that same item; or
- the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months, in which case the supplier may discuss or promote other covered items with the beneficiary.<sup>2</sup>

Although these summarized rules may seem simple enough, they can become complicated and nuanced when applied to real-world DMEPOS marketing situations. The table on page 56 applies the telemarketing rules to a number of DMEPOS situations.

Suppliers should keep in mind, however, there are a number of other federal and state laws that impose restrictions on telemarketing in general (e.g.,

the Federal Trade Commission's Telemarketing Sales Rule and state restrictions on telemarketing) and to Medicare beneficiaries in particular (e.g., HIPAA, the Anti-kickback Statute, and the Civil Monetary Penalties Law, including the provisions on beneficiary inducements). Those laws intersect with DMEPOS marketing and must also be considered, but the scope of this article is limited to the Medicare rules on telemarketing and beneficiary solicitation.

## Contracting with third-party vendors and telemarketers

Third-party vendors and telemarketing companies are commonly used vehicles for marketing and customer outreach. DMEPOS suppliers may engage these vendors, but should understand that if the vendor violates the Telemarketing Statute, the supplier can be held responsible and face severe sanctions for the vendor's conduct. For this reason, suppliers who choose to contract with these vendors should include oversight provisions in their vendor contracts, under which the vendor agrees to adhere to the telemarketing rules applied to Medicare beneficiaries and patients in general. This is important because many vendors, particularly those who deal with a broad spectrum of customers beyond solely Medicare beneficiaries, are unaccustomed to these restrictions. In addition to the contractual language, suppliers should be diligent in ensuring the

vendor is complying with those restrictions.

## Written policies and procedures

Suppliers should have written policies and procedures in place to delineate the steps the supplier will take to promote compliance with the Medicare supplier standards and the Telemarketing Statute. The written policy should clearly state that the supplier's employees, as well as individuals and entities working on the supplier's behalf, are prohibited from making unsolicited contact with Medicare beneficiaries unless one of the statutory exceptions apply. The written procedure should include a step-by-step process for contacting current and prospective customers. It should be written in a manner employees can easily understand and follow, and should be tailored to the supplier's specific business practices. As with all compliance policies and procedures, it should be reviewed periodically and updated as needed to comply with changes in the law and the supplier's operational requirements.

## Documentation advice and approaches

The original Centers for Medicare and Medicaid Services (CMS) Frequently Asked Questions (FAQs) took the position that a supplier need not collect and maintain documentation from the physician reflecting that the

*Continued on page 58*

**Table 1: DMEPOS Medicare Telemarketing and Beneficiary Solicitation**

Telemarketing Situation	Allowed Under Telemarketing Rules?
A physician sends the supplier a work order for a new patient. The patient is informed that a supplier will contact him, but does not sign a written permission form. The supplier then calls the patient.	No, because the current regulations require the beneficiary's written permission. Under the proposed rule, this would be allowed.
A physician sends the supplier a work order for a new patient and checks a box attesting that the patient has given written permission to contact. The supplier then calls the patient.	Yes, but only if the beneficiary actually gave written permission. Because the supplier does not know whether or not the beneficiary actually gave written permission, this situation presents a high level of risk and is not recommended. Under the proposed rule, this would be allowed, but the proposed rule does not require the patient to give written permission.
A physician sends the supplier a work order for a new patient, along with the patient's signed written permission to contact. The supplier then calls the patient.	Yes, because the beneficiary gave written permission. Under the proposed rule, this would be allowed, but the proposed rule does not require the patient to give written permission.
A physician sends the supplier a work order for a new patient, along with the patient's signed written permission to contact. The order is for home oxygen equipment. The supplier calls the customer and promotes/discusses other items (e.g., ventilator or respiratory assist devices).	No, because the scope of consent was limited only to those items in the physician order. If this is the first contact ever made by the supplier to the beneficiary, the supplier may not attempt to solicit the purchase of additional covered items. After the supplier provides the covered items to the beneficiary, the supplier may then promote additional products.
A potential customer sees the supplier's television commercial and places a call to a third-party vendor handling responses to the commercial. The vendor then transfers the patient to the supplier (i.e., a warm transfer).	Yes, because the beneficiary initiated contact.
A potential customer finds the supplier's Internet site and completes an online form asking the supplier to contact him. The supplier then calls the customer.	Yes, because the beneficiary initiated contact. The supplier should verify that the language of the online consent is adequate. Also a two-step process (e.g., two clicks to submit) is advised to guarantee the customer's willful consent and to serve as an online signature.
A potential customer finds the supplier's Internet site and completes an online form asking the supplier to contact him. Although there are a number of possible areas of interest, the customer only checks the "wound care" box as his interest. The supplier calls the customer and promotes/discusses other non-wound care items (e.g., crutches and ambulatory equipment).	No, because the beneficiary gave consent only to wound care supplies. If this is the first contact ever made by the supplier to the beneficiary, the supplier may not attempt to solicit the purchase of additional covered items because the supplier only had permission to contact the beneficiary regarding the particular covered items ordered. After the supplier provides the covered item to the beneficiary, the supplier may then promote additional products.
A potential customer sees the supplier's television commercial and places a call to the supplier, leaving a voicemail message. The supplier then calls the customer the next day.	Yes, because the beneficiary initiated contact.
A hospital care coordinator sends the supplier an enrollment form for the patient to coordinate the patient's discharge orders. The patient previously gave the hospital written permission or the patient signs the form to give permission for a supplier to contact him. The supplier then calls the patient.	Yes, because the beneficiary gave written permission. Under the proposed rule, this would be allowed, but the proposed rule does not require the patient to give written permission.

*Table 1 continued*

Telemarketing Situation	Allowed Under Telemarketing Rules?
<p>A hospital care coordinator sends the supplier an enrollment form for the patient to coordinate the patient's discharge orders. The patient is informed that his care is being coordinated through the supplier, but has not given any written permission. The supplier then calls the patient.</p>	<p>No, because the current regulations require the beneficiary's written permission. The Preamble to the regulations explains that, if hospital staff obtain a patient's written consent, the hospital may order supplies on the patient's behalf. The patient's written permission need not be on the enrollment form itself, but could be on another document. Under the proposed rule, this would be allowed because the proposed rule does not require the patient to give written permission.</p>
<p>A DMEPOS manufacturer receives an order from a physician, with the proper patient written permission. After calling the patient, the manufacturer determines it does not provide the items directly to patients, so the manufacturer sends the order to the supplier. The supplier then calls the patient.</p>	<p>Yes, this is potentially allowed because the beneficiary gave written permission. However, it depends on the scope of that permission. If the permission form allows phone contact by "a supplier," it is probably acceptable. If the permission form allows a call only by the particular manufacturer, the supplier should not call the patient.</p>
<p>A DMEPOS manufacturer receives a call from a patient asking about how to get the manufacturer's DMEPOS supplies. The manufacturer then transfers the patient to the supplier (i.e., a warm transfer).</p>	<p>Yes, because the beneficiary initiated contact.</p>
<p>The supplier hosts a health fair or community event. A potential customer visits the event and gives his information on a written card, giving permission for the supplier to contact him. After the event, the supplier calls the customer.</p>	<p>Yes, because the beneficiary gave written permission. In addition, health fairs and community events are permissible methods of beneficiary contact.</p>
<p>The supplier hires a third-party vendor to use door-to-door salespeople to reach out to beneficiaries.</p>	<p>No, because under the current regulations, CMS expanded the telemarketing and beneficiary contact restrictions to include in-person contact. The proposed rule deletes this restriction.</p>
<p>The supplier mails a card to a large number of potential customers who are Medicare beneficiaries. After receiving the card, a potential customer places a call to the supplier.</p>	<p>Yes, this is probably allowed because the beneficiary initiated contact and the supplier's contact was sent by mail to a large number of customers. CMS' 2011 FAQs state that "targeted mailings to specific beneficiaries are prohibited," but that "general mass advertising through the post office" is allowed." However, neither the regulation nor the statute expressly encompass direct mail and CMS has not explained the basis for its authority to expand the Telemarketing Statute into direct mailings. There are arguments that the telemarketing rules should not apply to direct mailings. The proposed rule deletes this restriction.</p>
<p>The supplier mails cards to a group of potential customers who are Medicare beneficiaries. A potential customer fills in his phone number and mails back the card, indicating his interest in being contacted about the supplier's services. The supplier then calls the customer.</p>	<p>Yes, this is probably allowed because the beneficiary initiated contact and the supplier's contact was sent by mail. A customer signature field on the card, if not per se required, is a best practice and the recommended approach. The supplier should ensure the customer signed the card before telephoning the customer.</p>

physician contacted the supplier with the beneficiary's knowledge. CMS stated "it would be a business decision on the part of the supplier whether to collect and obtain such documentation for their records." Even if it is not per se required that a supplier collect and maintain a copy of that documentation, the compliance risks are too high for a supplier not to take steps to ensure the beneficiaries gave their written permission (under the current regulation) or were made aware that a supplier would be contacting them (under the proposed rule).<sup>3</sup>

However, deciding to collect the documents is a far easier task than actually doing so, and suppliers understandably face a challenge in operationalizing this documentation requirement. One approach might be to build it into the supplier's physician work order. The revised work order would include a check box where the physician affirms he or she has obtained the patient's written permission for the supplier to contact the patient. This alone is likely not adequate under the current regulations, but it can serve as a reminder to the physician that he or she must obtain the beneficiary's written permission (or inform the beneficiary, under the proposed rule). The check box represents an affirmative effort by the supplier to help ensure compliance with the Telemarketing Statute and

supplier standard number 11. This is a beneficial tool designed to protect the supplier in the event a patient complains that the supplier violated the Telemarketing Statute. On the other hand, if the physician submits a work order without checking the box, it might suggest the patient did not give permission, and could require additional back-and-forth with the physician to obtain such.

Another approach would be to update the existing physician work order to include a signature portion where the patient authorizes the supplier to contact him/her. The patient would sign that portion in the physician's office. This approach allows the supplier to obtain the beneficiary's explicit written permission in accordance with the current regulations. But, having a patient sign a physician work order is very unusual, and the same risks apply if the physician forgets to have the patient sign the work order. Moreover, under the proposed rule, the patient is not required to give his or her written permission.

A third approach would be to create an authorization form/response card and mail it to the beneficiary immediately upon receipt of the written order for a new patient. Once the beneficiary signs and returns the authorization card, the supplier can telephone the patient. The response

card could also ask the patient to call the supplier and discuss the order. This approach could be a potential fail-safe in the event a supplier receives a work order without the beneficiary's written permission (or physician attestation that the beneficiary knows a supplier will call him or her). But, from an operational perspective, mailing a card and waiting for the response would likely cause unacceptable delays in sending the patient his/her medically-necessary items.

A fourth approach would be to create a complete authorization form and provide it to the supplier's referring physicians. The physician would have the patient review and sign the form during the office visit. The physician would then send the signed authorization form along with the work order. Once the supplier receives the signed authorization form, the supplier could contact the patient.

This approach imposes the greatest operational burden on suppliers and physicians, because it requires a separate document in addition to the existing paperwork physicians must send to suppliers. However, it is probably the most comprehensive practice because it most clearly satisfies the current regulations (though this should not be necessary under the proposed rule).

## DMEPOS advertisements in Internet, television, and new media

Although the current regulations and guidance purport to restrict communications through certain new technologies such as e-mail, instant messaging, and text messages, the Internet remains—at least to a certain degree—fair game. In 2008, CMS drafted a proposed prohibition on “coercive Internet advertising,” but did not include it in the 2010 final regulations. The revised DMEPOS supplier standards do not prohibit television, radio, or Internet advertisements, or advertisements at health fairs, community events, or the supplier’s own website.<sup>4</sup> Implementing and enforcing a restriction on Internet advertising might be (for the time being) too difficult and costly for CMS or the OIG to manage. In addition, media such as television and the Internet can be considered advertisements to the public or to Medicare beneficiaries generally.

The fact that the Telemarketing Statute does not apply to Internet advertisements may potentially open some opportunities for savvy suppliers who are interested in using social media tools to promote their products. For example, a supplier might consider using Google’s sponsored searches so their website appears at the top when someone enters a search for “Medicare prosthetic arm.” Sponsored searches are not new,

and are permitted under the new regulation. But, for something more cutting-edge, suppliers might consider other Internet advertising methods, such as Facebook.

The Facebook advertisement tool allows someone to publish their advertisement to a certain segment of Facebook users, narrowed by the users’ demographics and stated interests. For example, a diabetes supplier might want to place a Facebook advertisement, requesting that the advertisement only be displayed to Facebook users who are over 65 years old and who have an interest in diabetes or who “like” the American Diabetes Association. New Internet advertising approaches such as these can potentially pose a higher level of compliance risk, because the advertisements are targeted toward a specific group of people, rather than Medicare beneficiaries generally. The more specific and targeted the advertisement, the more likely CMS or OIG will find it objectionable. And yet, the Facebook advertising tool is still a “passive” advertisement in that it is placed on a webpage and not directly sent to a beneficiary by telephone, e-mail, instant messaging, or in-person contact (the four CMS-defined methods of direct solicitation). Unless and until CMS issues further guidelines on Internet advertising, the landscape of opportunities and risk remains largely uncharted.

## Conclusion

The telemarketing and beneficiary contact rules have a significant impact on a DMEPOS supplier’s operations because the restrictions go to the lifeline of a supplier’s business: the customers. The April 4, 2011 proposed rule helps to make these restrictions more workable and better reflect industry practices. Yet, it remains essential for DMEPOS suppliers to understand the applicable restrictions and build operational and procedural safeguards to promote compliance, while also having a keen knowledge of the marketing opportunities that can be pursued. ■

1 See [www.oig.hhs.gov/fraud/enforcement/cmp/false\\_claims.asp](http://www.oig.hhs.gov/fraud/enforcement/cmp/false_claims.asp).

2 As explained in the previous article, John Spiegel, Director of CMS’ Program Integrity Group, stated on January 19, 2011 that CMS “does not intend to instruct Medicare contractors to implement the expanded provision” of the telemarketing regulations. The telemarketing rules may change depending on CMS’ subsequent actions.

3 The differences between the current regulation and the proposed rule were discussed in last month’s issue, particularly the proposed change in the written permission requirement. See also 76 Fed. Reg. 18472 (Apr. 4, 2011).

4 75 Fed. Reg. 52629, 52638-9 (Aug. 27, 2010).

# DMEPOS and the False Claims Act: Compliance and litigation strategies

By Nathaniel Lactman, CCEP and Michael McCollum

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*This article is the third in a series on DMEPOS compliance issues by Foley & Lardner LLP published in **Compliance Today**. In the June issue of **Compliance Today**, the authors provided practical tips and compliance advice regarding DMEPOS telemarketing and beneficiary contact. This month, the authors discuss the Medicare*

*DMEPOS supplier standards, liability under the False Claims Act, and strategic approaches to limiting damages in whistleblower lawsuits.*

Suppliers of durable medical equipment, prosthetics, and orthotic supplies (DMEPOS) face increasing scrutiny and oversight from federal agencies such as the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG). In order to obtain and maintain Medicare billing privileges, DMEPOS suppliers need to meet the Medicare supplier standards. Late in 2010, CMS expanded the supplier standards and imposed significant new burdens on DMEPOS suppliers. The industry opposed many of these changes, but it remains likely that the government will continue to argue in the appropriate cases that failure to comply with the supplier standards not only exposes DMEPOS suppliers to administrative sanctions, but also creates False Claims Act liability. DMEPOS suppliers should understand the supplier standards and the enforcement implications, both to ensure

compliance going forward, and, if necessary, to effectively defend past conduct in the event of an enforcement action, government investigation, or False Claims Act litigation.

Medicare has strict guidelines and standards that DMEPOS suppliers must meet to establish and maintain Medicare billing privileges. Among these rules is the set of federal regulations known as the Medicare DMEPOS supplier standards.<sup>1</sup> The supplier standards apply to all Medicare-participating DMEPOS suppliers and set forth the minimum operational requirements suppliers are asked to follow. First introduced in 1992, the supplier standards have expanded, and currently there are 30 standards.

## New supplier standards and proposed revisions

In August 2010, CMS released a final rule that added four new DMEPOS supplier standards and made the existing standards more onerous. In response to significant backlash from the DMEPOS industry, CMS issued a proposed rule in April 2011, relaxing some of the standards introduced in the August 2010 final rule. When this article went to press, the April 2011 proposed rules had not been finalized.

## DMEPOS supplier standards and Medicare enrollment

The National Supplier Clearinghouse (NSC) processes DMEPOS

supplier applications for Medicare, oversees the enrollment process, and with CMS is responsible for oversight of compliance with the supplier standards. Effective March 2011, new DMEPOS suppliers are now classified by the government as a “high risk” category for fraud, waste, and abuse and are subject to more stringent enrollment screening and oversight controls.

Generally, the Medicare DMEPOS supplier enrollment process is as follows. First, the applicant submits the CMS 855S enrollment application and supporting documentation to the NSC. In the application, the DMEPOS supplier certifies that it meets and will continue to meet the supplier standards. The NSC reviews the application and conducts a site visit to verify compliance with all DMEPOS supplier standards. After completing its review, the NSC notifies the applicant in writing of the enrollment decision. After enrollment, a DMEPOS supplier must maintain compliance with the supplier standards.

**Implications of failure to comply** DMEPOS suppliers can face severe penalties for failing to comply, at least in material respects, with the supplier standards. From the government’s perspective, all deviations from the black letter standards are material and require sanctions, including administrative penalties,

billing revocation, Medicare recoupment, potential criminal liability, and potential liability under the False Claims Act. But, there are limits. Understanding the contours and limits of these potential penalties—and the issues and arguments that typically arise—is essential for a DMEPOS supplier to effectively position itself to avoid scrutiny by maintaining an effective compliance program and, if necessary, to respond to a regulatory or False Claims Act action.

#### **Administrative penalties**

If a DMEPOS supplier is found to not meet the supplier standards, CMS may revoke the supplier’s billing privileges. The revocation is effective within 15 or 30 days of the notice of revocation, depending on the standard violated.

The new DMEPOS regulations also allow CMS to attempt recoupment of payments as of the date of certain final adverse actions:

- Revocation of Medicare billing privileges
- Suspension or revocation of a state license
- Conviction of a felony
- Exclusion from participation in a state or federal health care program
- Revocation for failure to meet DMEPOS quality standards

Under this rule, CMS is authorized to assess and collect Medicare

overpayments back to the date of the final adverse action. This means that all funds received by a DMEPOS supplier subject to one of the adverse actions can potentially be deemed an overpayment. This rule strengthens CMS’ view that when a DMEPOS supplier is not allowed to participate in Medicare, funds the supplier receives are deemed to be overpayments.

However, the new regulations do not contain a provision authorizing recoupment retroactive to the date of the DMEPOS supplier’s non-compliance—only to the date of the final adverse action. The lack of a retroactive recoupment provision benefits DMEPOS suppliers significantly, because it limits the potential overpayment liability for non-compliance with certain supplier standards. Moreover, a DMEPOS supplier who is assessed an overpayment under this provision has administrative appeal rights. Given the current regulatory environment and the new 60-day overpayment rule, DMEPOS suppliers should develop a thoughtful approach for determining how overpayments are identified and potentially reported and refunded.<sup>2</sup>

#### **Potential liability under the False Claims Act**

Of potentially even greater concern than the possible administrative sanctions is the potential for False

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Claims Act liability. Given the current enforcement environment, government scrutiny and *qui tam* whistleblowers are a reality for DMEPOS suppliers. The supplier standards have been considered a hybrid between the Medicare conditions of participation and the conditions for payment. Whereas a violation of Medicare conditions for payment is generally considered grounds for a False Claims Act violation, some courts have ruled that a violation of Medicare conditions of participation does not necessarily give rise to a False Claims Act violation. In some recent cases in the DMEPOS industry, the government has taken a more aggressive position that the supplier standards are conditions for payment. The good news for DMEPOS suppliers is that at least one recent court ruling held that a violation of the supplier standards does not necessarily trigger a false claim.<sup>3</sup>

### **Supplier standards as conditions of participation or conditions for payment**

The vast majority of courts that have examined the issue have held that False Claims Act liability does not arise simply by virtue of a violation of an underlying Medicare rule or regulation.<sup>4</sup> Rather, one of two conditions must exist:

- The supplier expressly certified compliance with the standards when submitting a claim; or

- Compliance with the standards is written into the regulation as a condition for payment, rather than simply a condition of participation, in the Medicare program.

The issue of Medicare conditions of participation versus conditions for payment is more complicated for DMEPOS suppliers than for other providers, such as hospitals. This is largely due to the nature of the supplier standards. The government has pointed to some characteristics of the supplier standards to support its argument that the supplier standards are conditions for payment. For example, the supplier standards are contained under the regulatory section titled “Conditions for Medicare Payment.” The payment regulations require that certain conditions be met “as a basis for Medicare payment,” including, among other things, conditions regarding the source of services.<sup>5</sup> The “source of services” category includes the requirement that services must have been furnished by a provider, nonparticipating hospital, or supplier that was qualified to have payment made for the services at the time it furnished them. Under the government’s argument, these payment regulations can and should be interpreted to mean that compliance with the supplier standards is a condition for payment.<sup>6</sup>

However, DMEPOS suppliers can identify other aspects of the supplier standards to refute the government’s argument, and instead demonstrate that the supplier standards are simply conditions of eligibility that afford the DMEPOS supplier the privilege to prospectively bill the Medicare program. The regulatory subsection titled “Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges” sets forth several conditions that a DMEPOS supplier must meet “in order to be eligible to receive payment for a Medicare-covered item.” One of those conditions is listed as “CMS has not revoked or excluded the DMEPOS supplier’s privileges during the period which the item was furnished.”<sup>7</sup> The 30 supplier standards are listed thereafter as standards “the supplier must meet and must certify in its application for billing privileges.” As noted above, there is no provision for retroactive recoupment, only recoupment following actual revocation. These aspects make the supplier standards akin to conditions of participation.

No appellate court has opined on this issue. However, in examining the interplay between these regulatory provisions, at least one court clearly held that the supplier standards are conditions of participation and not payment,

concluding that “proper redress for violations of the standards established therein is not the denial of payment, but the revocation of the supplier’s billing privileges.”<sup>8</sup> Case law continues to evolve and DMEPOS suppliers—and their legal counsel—should stay attuned to new developments on this issue.

### **Falsity, knowledge, and limits on damages**

If a DMEPOS supplier is facing a False Claims Act investigation or lawsuit that alleges liability based on noncompliance with the supplier standards, the supplier should articulate several reasons why key elements of False Claims Act liability cannot be met. This is because alleged violations of the supplier standards may bear little-to-no relation to the core elements of False Claims Act liability, namely the knowing submission of a false or fraudulent claim or statement that is material to the government’s payment of a claim. A DMEPOS supplier will want to be familiar, in particular, with the legal elements of falsity and knowledge, and how damages are to be measured under the False Claims Act.

Regarding falsity, obviously, if no supplier standard has been violated, no false claim or statement can be predicated on noncompliance with the supplier standards. Yet, the government can, and sometimes does, interpret a standard

in a manner unsupported by the regulatory language itself. Further, compliance with the supplier standards can sometimes be unclear, particularly where the regulations are vague or complicated. A recent court ruling lends support to the argument that lack of clarity alone may undermine the ability of the government or a private litigant to satisfy the “falsity” element of the False Claims Act.<sup>9</sup>

By that same token, courts have held that even if a claim is technically false, a sufficiently high level of uncertainty and vagueness in the regulations will undermine the knowledge element of False Claims Act liability. Under the same court’s opinion noted above, it was noted that a defendant cannot have knowingly submitted a false claim if the regulations are thoroughly unclear (i.e., where there are legitimate grounds for disagreement over the scope of the regulatory provisions) or if CMS actually knows and approves of the facts surrounding the supplier’s conduct before the challenged claims for payment are submitted, upon which conduct the supplier relies.

Beyond the issue of liability, DMEPOS suppliers should further seek to limit the amount of damages by arguing that damages are to be calculated not as the full amount of the Medicare payment, but instead according to a benefit-of-the-bargain analysis. Under that

approach, damages are measured by the difference between the value of what Medicare paid for the item and the value of what the beneficiary actually received. This concept is increasingly being applied by courts in False Claims Act cases.<sup>10</sup>

This methodology does not apply to actions under the Civil Monetary Penalties Law because that statute fixes damages as the full value of the claims improperly made. There is also some authority holding that a Medicare regulatory violation demands full repayment of the Medicare payments, because Medicare would not have paid any funds without the false claims, and Medicare does not actually receive any direct benefit from the supply of covered items.<sup>11</sup> But, that ignores the fact that beneficiaries are the true recipients of the covered items, as well as the Medicare funds to pay for those items. Therefore, DMEPOS suppliers may find success with courts recognizing that the government receives a benefit from the provision of covered items to beneficiaries, and the courts may apply the benefit-of-the-bargain rule in the Medicare context to limit the damages in DMEPOS supplier False Claims Act lawsuits.<sup>12</sup>

### **Practical compliance advice for future conduct**

DMEPOS suppliers should carefully review the existing supplier

*Continued on page 47*

standards to ensure they understand all the rules and requirements for Medicare participation. In addition to the regulations, DMEPOS suppliers should review the preambles to the 2010 final rule and the 2011 proposed rule. That will help DMEPOS suppliers understand CMS' purpose in issuing the rules, as well as give additional detail on how CMS interprets the regulatory language. CMS and NSC have also published FAQs on the new supplier standards and DMEPOS suppliers should read them to help answer any additional questions on how to interpret the regulations.<sup>13</sup> (Note: These FAQs have been revised, so be certain to obtain a copy of the most current version.) DMEPOS suppliers will also find a wealth of information in Chapter 15 of the *Medicare Program Integrity Manual*, as well as the supplier manuals issued by each of the four regional DME Medicare Administrative Contractors.

Using these materials, as well as the regulations themselves, DMEPOS suppliers can create and tailor risk assessment tools specific to their company's compliance needs on a going forward basis. Certainly, DMEPOS suppliers should address key risk areas, such as accreditation compliance, billing and documentation, medical necessity of items ordered, state licensure and Medicaid requirements, referral relationships and contracting,

and marketing to beneficiaries. DMEPOS suppliers should also ensure their compliance program policies and procedures are current with the recent changes to the supplier standards, keeping in mind the relaxed rules contained in the recent proposed rule. DMEPOS suppliers should then verify that their actual practices regarding the supplier standards match up with the expectations set forth in their written policies and procedures. Staff should be periodically trained and educated on relevant requirements under the supplier standards and related state law rules (e.g., licensure and contracting).

### **Responding to an investigation of past conduct**

Once the foundation has been built for an effective compliance program, DMEPOS suppliers should also be aware of the various legal arguments and strategies to defend against a CMS administrative action or a False Claims Act lawsuit regarding past conduct. Suppliers should not assume the government's informal interpretation of a standard is the only interpretation or even the correct interpretation, nor should suppliers assume that any and every violation of the supplier standards is of equal materiality or significance. Suppliers should recognize that CMS may only try to recoup funds paid after a formal adverse action, not before. Suppliers should be able

to articulate why a particular violation of a supplier standard may not give rise to a false claim (e.g., the standard may not be a condition for payment) and why the government or a litigant cannot prove the other elements of False Claims Act liability. Suppliers should be able to articulate how the regulations or previous government conduct might have been overly vague or confusing and how that uncertainty might have contributed to the suppliers' past conduct in reliance thereon. Finally, suppliers should understand how to argue for a proper measure of damages based on the benefit-of-the-bargain approach.

### **Conclusion**

DMEPOS suppliers can look to the supplier standards as the cornerstone of their operational compliance concerns. The supplier standards can serve as the framework for risk assessments and proactive compliance reviews as part of an overall effective compliance program. In the unfortunate event of an administrative enforcement action or a whistleblower lawsuit under the False Claims Act, DMEPOS suppliers should be certain their legal counsel understands and takes full advantage of the various defenses they can raise in such litigation. ■

1 42 C.F.R. § 424.57(c).  
2 J. Gresko, M. McCollum, H. Sorensen, L. Noller: "A Reasoned Approach to Identify-

*Continued on page 66*

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- ing Federal Health Care Program Overpayments.” *Compliance Today Magazine*, vol. 13, no. 2, February 2011, pp 8-11,19.
- 3 *United States ex rel. Cooper v. Gentiva Health Serv’s, Inc.*, 2003 WL 22495607 \* 9 (W.D. Pa., Nov. 4, 2003). See also *United States ex. rel. Jamison v. McKesson Corp.*, 2011 WL 1158945 \* 1 (N.D. Miss., March 28, 2011)
  - 4 See e.g., *United States of America ex rel. Williams v. Renal Care Group*, 2010 WL 1062634 \*10 (M.D. Tenn., March 22, 2010) (listing similar holdings from courts in the 2nd, 5th, 6th, and 7th Circuits); *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 997-1001 (9th Cir. 2010); *United States ex rel. Conner v. Salina Regl Health Ctr.*, 543 F.3d 1211, 1217 (10th Cir. 2008); *United States ex rel. Freedman v. Suarez-Hoyos*, 2011 WL 972585 \* 8 (M.D. Fla., March 18, 2011); *United States ex rel. Landers v. Baptist Memorial Health Care Corp.*, 25 F. Supp. 2d 972 (W.D.Tenn., 2007).
  - 5 42 C.F.R. § 424.5.
  - 6 See e.g., *United States ex. rel. Jamison v. McKesson Corp.*, 2011 WL 1158945 \* 1 (N.D. Miss., March 28, 2011); *United States ex. rel. Jamison v. McKesson Corp.*, 2009 WL 3176168 (M. D. Miss., Sept. 29, 2009) (supplier standards are a condition for payment based on the three-year enrollment certification).
  - 7 42 C.F.R. § 424.57(b)(3).
  - 8 *United States ex rel. Cooper v. Gentiva Health Serv’s, Inc.*, 2003 WL 22495607 \* 9 (W.D. Pa., Nov. 4, 2003).
  - 9 *United States ex rel. Jamison*, supra, at \*11, 13.
  - 10 See, e.g., *United States ex rel. Science Applications Int’l Corp.*, 626 F.3d 1257 (Dec. 3, 2010).
  - 11 See, e.g., *United States v. Rogan*, 459 F.Supp.2d 692, 726 (N.D.Ill. 2006), affirmed at 517 F.3d 449 (7th Cir. 2008).
  - 12 See, e.g., *United States of America ex rel. Williams v. Renal Care Group*, 2010 WL 1062634 \*10 (M.D. Tenn. (March 22, 2010) (calculating government’s recovery to be the difference between more expensive rate for home-provision of dialysis equipment and less expensive rate for equipment provided at facilities).
  - 13 N. Lackman, H. Sorensen: “Cold calls, hot lines: DMEPOS telemarketing and beneficiary contact. *HCCA Compliance Today Magazine*, vol. 13, no. 5, May 2011, pp 42-45.

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## **ACKNOWLEDGEMENT**

This educational resource represents a unique collaboration between the American Health Lawyers Association and the Office of the Inspector General of the United States Department of Health and Human Services. This publication would have not been possible without the dedicated effort of numerous individuals at both organizations. It is intended to be a useful resource for those serving on the Boards of Directors of our nation's health care institutions.

## I. INTRODUCTION

As corporate responsibility issues fill the headlines, corporate directors are coming under greater scrutiny. The Sarbanes-Oxley Act, state legislation, agency pronouncements, court cases and scholarly writings offer a myriad of rules, regulations, prohibitions, and interpretations in this area. While all Boards of Directors must address these issues, directors of health care organizations also have important responsibilities that need to be met relating to corporate compliance requirements unique to the health care industry. The expansion of health care regulatory enforcement and compliance activities and the heightened attention being given to the responsibilities of corporate directors are critically important to all health care organizations. In this context, enhanced oversight of corporate compliance programs is widely viewed as consistent with and essential to ongoing federal and state corporate responsibility initiatives.

Our complex health care system needs dedicated and knowledgeable directors at the helm of both for-profit and non-profit corporations. This educational resource, co-sponsored by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services and the American Health Lawyers Association, the leading health law educational organization, seeks to assist directors of health care organizations in carrying out their important oversight responsibilities in the current challenging health care environment. Improving the knowledge base and effectiveness of those serving on health care organization boards will help to achieve the important goal of continuously improving the U.S. health care system.

### **Fiduciary Responsibilities**

The fiduciary duties of directors reflect the expectation of corporate stakeholders regarding oversight of corporate affairs. The basic fiduciary duty of care principle, which requires a director to act in good faith with the care an ordinarily prudent person would exercise under similar circumstances, is being tested in the current corporate climate. Personal liability for directors, including removal, civil damages, and tax liability, as well as damage to reputation, appears not so far from reality as once widely believed. Accordingly, a basic understanding of the director's fiduciary obligations and how the duty of care may be exercised in overseeing the company's compliance systems has become essential.

Embedded within the duty of care is the concept of reasonable inquiry. In other words, directors should make inquiries to management to obtain information necessary

to satisfy their duty of care. Although in the *Caremark* case, also discussed later in this educational resource, the court found that the Caremark board did not breach its fiduciary duty, the court's opinion also stated the following: "[A] director's obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the Board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards." Clearly, the organization may be at risk and directors, under extreme circumstances, also may be at risk if they fail to reasonably oversee the organization's compliance program or act as mere passive recipients of information.

On the other hand, courts traditionally have been loath to second-guess Boards of Directors that have followed a careful and thoughtful process in their deliberations, even where ultimate outcomes for the corporation have been negative. Similarly, courts have consistently upheld the distinction between the duties of Boards of Directors and the duties of management. The responsibility of directors is to provide oversight, not manage day-to-day affairs. It is the process the Board follows in establishing that it had access to sufficient information and that it has asked appropriate questions that is most critical to meeting its duty of care.

### **Purpose of this Document**

This educational resource is designed to help health care organization directors ask knowledgeable and appropriate questions related to health care corporate compliance. These questions are not intended to set forth any specific standard of care. Rather, this resource will help corporate directors to establish, and affirmatively demonstrate, that they have followed a reasonable compliance oversight process.

Of course, the circumstances of each organization differ and application of the duty of care and consequent reasonable inquiry will need to be tailored to each specific set of facts and circumstances. However, compliance with the fraud and abuse laws and other federal and state regulatory laws applicable to health care organizations is essential for the lawful behavior and corporate success of such organizations. While these laws can be complex, effective compliance is an asset for both the organization and the health care delivery system. It is hoped that this educational resource is useful to health care organization directors in exercising their oversight responsibilities and supports their ongoing efforts to promote effective corporate compliance.

## II. DUTY OF CARE

Of the principal fiduciary obligations/duties owed by directors to their corporations, the one duty specifically implicated by corporate compliance programs is the *duty of care*.<sup>1</sup>

As the name implies, the *duty of care* refers to the obligation of corporate directors to exercise the proper amount of care in their decision-making process. State statutes that create the duty of care and court cases that interpret it usually are identical for both for-profit and non-profit corporations.

In most states, duty of care involves determining whether the directors acted (1) in “good faith,” (2) with that level of care that an ordinarily prudent person would exercise in like circumstances, and (3) in a manner that they reasonably believe is in the best interest of the corporation. In analyzing whether directors have complied with this duty, it is necessary to address each of these elements separately.

The “good faith” analysis usually focuses upon whether the matter or transaction at hand involves any improper financial benefit to an individual, and/or whether any intent exists to take advantage of the corporation (a corollary to the duty of loyalty). The “reasonable inquiry” test asks whether the directors conducted the appropriate level of due diligence to allow them to make an informed decision. In other words, directors must be aware of what is going on about them in the corporate business and must in appropriate circumstances make such reasonable inquiry, as would an ordinarily prudent person under similar circumstances. And, finally, directors are obligated to act in a manner that they reasonably believe to be in the best interests of the corporation. This normally relates to the directors’ state of mind with respect to the issues at hand.

In considering directors’ fiduciary obligations, it is important to recognize that the appropriate standard of care is not “perfection.” Directors are *not* required to know everything about a topic they are asked to consider. They may, where justified, rely on the advice of management and of outside advisors.

Furthermore, many courts apply the “business judgment rule” to determine whether a director’s duty of care has been met with respect to corporate decisions. The rule

provides, in essence, that a director will not be held liable for a decision made in good faith, where the director is disinterested, reasonably informed under the circumstances, and rationally believes the decision to be in the best interest of the corporation.

Director obligations with respect to the duty of care arise in two distinct contexts:

- The *decision-making function*: The application of duty of care principles to a specific decision or a particular board action; and
- The *oversight function*: The application of duty of care principles with respect to the general activity of the board in overseeing the day-to-day business operations of the corporation; *i.e.*, the exercise of reasonable care to assure that corporate executives carry out their management responsibilities and comply with the law.

Directors’ obligations with respect to corporate compliance programs arise within the context of that oversight function. The leading case in this area, viewed as applicable to all health care organizations, provides that a director has two principal obligations with respect to the oversight function. A director has a duty to attempt in good faith to assure that (1) a corporate information and reporting system exists, and (2) this reporting system is adequate to assure the board that appropriate information as to compliance with applicable laws will come to its attention in a timely manner as a matter of ordinary operations.<sup>2</sup> In *Caremark*, the court addressed the circumstances in which corporate directors may be held liable for breach of the duty of care by failing to adequately supervise corporate employees whose misconduct caused the corporation to violate the law.

In its opinion, the *Caremark* court observed that the level of detail that is appropriate for such an information system is a matter of business judgment. The court also acknowledged that no rationally designed information and reporting system will remove the possibility that the corporation will violate applicable laws or otherwise fail to identify corporate acts potentially inconsistent with relevant law.

Under these circumstances, a director’s failure to reasonably oversee the implementation of a compliance program may put the organization at risk and, under extraordinary circumstances, expose individual directors to personal liability for losses caused by the corporate non-

<sup>1</sup> The other two core fiduciary duty principals are the duty of loyalty and the duty of obedience to purpose.

<sup>2</sup> *In re Caremark International Inc. Derivative Litigation*, 698 A.2d 959 (Del. Ch. 1996). A shareholder sued the Board of Directors of Caremark for breach of the fiduciary duty of care. The lawsuit followed a multi-million dollar civil settlement and criminal plea relating to the payment of kickbacks to physicians and improper billing to federal health care programs.



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compliance.<sup>3</sup> Of course, crucial to the oversight function is the fundamental principle that a director is entitled to rely, in good faith, on officers and employees as well as corporate professional experts/advisors in whom the director believes such confidence is merited. A director, however, may be viewed as not acting in good faith if he/she is aware of facts suggesting that such reliance is unwarranted.

In addition, the duty of care test involving reasonable inquiry has not been interpreted to require the director to exercise “proactive vigilance” or to “ferret out” corporate wrongdoing absent a particular warning or a “red flag.” Rather, the duty to make reasonable inquiry increases when “suspicions are aroused or *should be aroused*,” that is, when the director is presented with extraordinary facts or circumstances of a material nature (*e.g.*, indications of financial improprieties, self-dealing, or fraud) or a major governmental investigation. Absent the presence of suspicious conduct or events, directors are entitled to rely on the senior leadership team in the performance of its duties. Directors are not otherwise obligated to anticipate future problems of the corporation.

Thus, in exercising his/her duty of care, the director is obligated to exercise general supervision and control with respect to corporate officers. However, once presented (through the compliance program or otherwise) with information that causes (or should cause) concerns to be aroused, the director is then obligated to make further inquiry until such time as his/her concerns are satisfactorily addressed and favorably resolved. Thus, while the corporate director is not expected to serve as a compliance officer, he/she is expected to oversee senior management’s operation of the compliance program.

### III. THE UNIQUE CHALLENGES OF HEALTH CARE ORGANIZATION DIRECTORS

The health care industry operates in a heavily regulated environment with a variety of identifiable risk areas. An effective compliance program helps mitigate those risks. In addition to the challenges associated with patient care, health care providers are subject to voluminous and sometimes complex sets of rules governing the coverage and reimbursement of medical services. Because federal and state-sponsored health care programs play such a significant role in paying for health care, material non-compliance with these rules can present substantial risks to the

health care provider. In addition to recoupment of improper payments, the Medicare, Medicaid and other government health care programs can impose a range of sanctions against health care businesses that engage in fraudulent practices.

Particularly given the current “corporate responsibility” environment, health care organization directors should be concerned with the manner in which they carry out their duty to oversee corporate compliance programs.

Depending upon the nature of the corporation, there are a variety of parties that might in extreme circumstances seek to hold corporate directors personally liable for allegedly breaching the duty of oversight with respect to corporate compliance. With respect to for-profit corporations, the most likely individuals to bring a case against the directors are corporate shareholders in a derivative suit, or to a limited degree, a regulatory agency such as the Securities and Exchange Commission. With respect to non-profit corporations, the most likely person to initiate such action is the state attorney general, who may seek equitable relief against the director (*e.g.*, removal) or damages. It is also possible (depending upon state law) that a dissenting director, or the corporate member, could assert a derivative-type action against the directors allegedly responsible for the “inattention,” seeking removal or damages.

Over the last decade, the risks associated with non-compliance have grown dramatically. The government has dedicated substantial resources, including the addition of criminal investigators and prosecutors, to respond to health care fraud and abuse. In addition to government investigators and auditors, private whistleblowers play an important role in identifying allegedly fraudulent billing schemes and other abusive practices. Health care providers can be found liable for submitting claims for reimbursement in reckless disregard or deliberate ignorance of the truth, as well as for intentional fraud. Because the False Claims Act authorizes the imposition of damages of up to three times the amount of the fraud and civil monetary penalties of \$11,000 per false claim, record level fines and penalties have been imposed against individuals and health care organizations that have violated the law.

In addition to criminal and civil monetary penalties, health care providers that are found to have defrauded the federal health care programs may be excluded from participation in these programs. The effect of an exclusion can be profound because those excluded will not

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<sup>3</sup> Law is not static, and different states will have different legal developments and standards. Standards may also vary depending on whether an entity is for profit or non-profit. Boards of public health care entities may have additional statutory obligations and should be aware of state and federal statutory requirements applicable to them.

receive payment under Medicare, Medicaid or other federal health care programs for items or services provided to program beneficiaries. The authorities of the OIG provide for mandatory exclusion for a minimum of five years for a conviction with respect to the delivery of a health care item or service. The presence of aggravating circumstances in a case can lead to a lengthier period of exclusion. Of perhaps equal concern to board members, the OIG also has the discretion to exclude providers for certain conduct even absent a criminal conviction. Such conduct includes participation in a fraud scheme, the payment or receipt of kickbacks, and failing to provide services of a quality that meets professionally recognized standards. In lieu of imposing exclusion in these instances, the OIG may require an organization to implement a comprehensive compliance program, requiring independent audits, OIG oversight and annual reporting requirements, commonly referred to as a Corporate Integrity Agreement.

#### IV. THE DEVELOPMENT OF COMPLIANCE PROGRAMS

In light of the substantial adverse consequences that may befall an organization that has been found to have committed health care fraud, the health care industry has embraced efforts to improve compliance with federal and state health care program requirements. As a result, many health care providers have developed active compliance programs tailored to their particular circumstances. A recent survey by the Health Care Compliance Association, for example, has found that in just three years, health care organizations with active compliance programs have grown from 55 percent in 1999 to 87 percent in 2002. In support of these efforts, the OIG has developed a series of provider-specific compliance guidances. These voluntary guidelines identify risk areas and offer concrete suggestions to improve and enhance an organization's internal controls so that its billing practices and other business arrangements are in compliance with Medicare's rules and regulations.

As compliance programs have matured and new challenges have been identified, health care organization boards of directors have sought ways to help their organization's compliance program accomplish its objectives. Although health care organization directors may come from diverse backgrounds and business experiences, an individual director can make a valuable contribution toward the compliance objective by asking practical questions of management and contributing his/her experiences from other industries. While the opinion in *Caremark* established a Board's duty to oversee a compliance program, it did not enumerate a specific methodology for

doing so. It is therefore important that directors participate in the development of this process. This educational resource is designed to assist health care organization directors in exercising that responsibility.

#### V. SUGGESTED QUESTIONS FOR DIRECTORS

Periodic consideration of the following questions and commentary may be helpful to a health care organization's Board of Directors. The structural questions explore the Board's understanding of the scope of the organization's compliance program. The remaining questions, addressing operational issues, are directed to the operations of the compliance program and may facilitate the Board's understanding of the vitality of its compliance program.

#### STRUCTURAL QUESTIONS

1. **How is the compliance program structured and who are the key employees responsible for its implementation and operation? How is the Board structured to oversee compliance issues?**

The success of a compliance program relies upon assigning high-level personnel to oversee its implementation and operations. The Board may wish as well to establish a committee or other subset of the Board to monitor compliance program operations and regularly report to the Board.

2. **How does the organization's compliance reporting system work? How frequently does the Board receive reports about compliance issues?**

Although the frequency of reports on the status of the compliance program will depend on many circumstances, health care organization Boards should receive reports on a regular basis. Issues that are frequently addressed include (1) what the organization has done in the past with respect to the program and (2) what steps are planned for the future and why those steps are being taken.

3. **What are the goals of the organization's compliance program? What are the inherent limitations in the compliance program? How does the organization address these limitations?**

The adoption of a corporate compliance program by an organization creates standards and processes that it should be able to rely upon and against which it may be held accountable. A solid understanding of the rationale and objectives of the compliance program, as well as its goals and inherent limitations, is essential if the Board is to evaluate the reasonableness of its design and the effectiveness of its operation. If the Board has unrealistic expectations of its compliance program, it may place undue reliance

on its ability to detect vulnerabilities. Furthermore, compliance programs will not prevent all wrongful conduct and the Board should be satisfied that there are mechanisms to ensure timely reporting of suspected violations and to evaluate and implement remedial measures.

4. **Does the compliance program address the significant risks of the organization? How were those risks determined and how are new compliance risks identified and incorporated into the program?**

Health care organizations operate in a highly regulated industry and must address various standards, government program conditions of participation and reimbursement, and other standards applicable to corporate citizens irrespective of industry. A comprehensive ongoing process of compliance risk assessment is important to the Board's awareness of new challenges to the organization and its evaluation of management's priorities and program resource allocation.

5. **What will be the level of resources necessary to implement the compliance program as envisioned by the Board? How has management determined the adequacy of the resources dedicated to implementing and sustaining the compliance program?**

From the outset, it is important to have a realistic understanding of the resources necessary to implement and sustain the compliance program as adopted by the Board. The initial investment in establishing a compliance infrastructure and training the organization's employees can be significant. With the adoption of a compliance program, the organization is making a long term commitment of resources because effective compliance systems are not static programs but instead embrace continuous improvement. Quantifying the organization's investment in compliance efforts gives the Board the ability to consider the feasibility of implementation plans against compliance program goals. Such investment may include annual budgetary commitments as well as direct and indirect human resources dedicated to compliance. To help ensure that the organization is realizing a return on its compliance investment, the Board also should consider how management intends to measure the effectiveness of its compliance program. One measure of effectiveness may be the Board's heightened sensitivity to compliance risk areas.

## OPERATIONAL QUESTIONS

The following questions are suggested to assist the Board in its periodic evaluation of the effectiveness of the organization's compliance program and the sufficiency of its reporting systems.

### A. Code of Conduct

**How has the Code of Conduct or its equivalent been incorporated into corporate policies across the organization? How do we know that the Code is understood and accepted across the organization? Has management taken affirmative steps to publicize the importance of the Code to all of its employees?**

Regardless of its title, a Code of Conduct is fundamental to a successful compliance program because it articulates the organization's commitment to ethical behavior. The Code should function in the same way as a constitution, *i.e.*, as a document that details the fundamental principles, values, and framework for action within the organization. The Code of Conduct helps define the organization's culture; all relevant operating policies are derivative of its principles. As such, codes are of real benefit only if meaningfully communicated and accepted throughout the organization.

### B. Policies and Procedures

**Has the organization implemented policies and procedures that address compliance risk areas and established internal controls to counter those vulnerabilities?**

If the Code of Conduct reflects the organization's ethical philosophy, then its policies and procedures represent the organization's response to the day-to-day risks that it confronts while operating in the current health care system. These policies and procedures help reduce the prospect of erroneous claims, as well as fraudulent activity by identifying and responding to risk areas. Because compliance risk areas evolve with the changing reimbursement rules and enforcement climate, the organization's policies and procedures also need periodic review and, where appropriate, revision.<sup>4</sup> Regular consultation with counsel, including reports to the Board, can assist the Board in its oversight responsibilities in this changing environment.

4 There are a variety of materials available to assist health care organizations in this regard. For example, both sponsoring organizations of this educational resource offer various materials and guidance, accessible through their web sites.

**C. Compliance Infrastructure**

- 1. Does the Compliance Officer have sufficient authority to implement the compliance program? Has management provided the Compliance Officer with the autonomy and sufficient resources necessary to perform assessments and respond appropriately to misconduct?**

Designating and delegating appropriate authority to a compliance officer is essential to the success of the organization's compliance program. For example, the Compliance Officer must have the authority to review all documents and other information that are relevant to compliance activities. Boards should ensure that lines of reporting within management and to the Board, and from the Compliance Officer and consultants, are sufficient to ensure timely and candid reports for those responsible for the compliance program. In addition, the Compliance Officer must have sufficient personnel and financial resources to implement fully all aspects of the compliance program.

- 2. Have compliance-related responsibilities been assigned across the appropriate levels of the organization? Are employees held accountable for meeting these compliance-related objectives during performance reviews?**

The successful implementation of a compliance program requires the distribution throughout the organization of compliance-related responsibilities. The Board should satisfy itself that management has developed a system that establishes accountability for proper implementation of the compliance program. The experience of many organizations is that program implementation lags where there is poor distribution of responsibility, authority and accountability beyond the Compliance Officer.

**D. Measures to Prevent Violations**

- 1. What is the scope of compliance-related education and training across the organization? Has the effectiveness of such training been assessed? What policies/measures have been developed to enforce training requirements and to provide remedial training as warranted?**

A critical element of an effective compliance program is a system of effective organization-wide training on compliance standards and procedures. In addition, there should be specific training on identified risk areas, such as claims development and submission, and marketing practices.

Because it can represent a significant commitment of resources, the Board should understand the scope and effectiveness of the educational program to assess the return on that investment.

- 2. How is the Board kept apprised of significant regulatory and industry developments affecting the organization's risk? How is the compliance program structured to address such risks?**

The Board's oversight of its compliance program occurs in the context of significant regulatory and industry developments that impact the organization not only as a health care organization but more broadly as a corporate entity. Without such information, it cannot reasonably assess the steps being taken by management to mitigate such risks and reasonably rely on management's judgment.

- 3. How are "at risk" operations assessed from a compliance perspective? Is conformance with the organization's compliance program periodically evaluated? Does the organization periodically evaluate the effectiveness of the compliance program?**

Compliance risk is further mitigated through internal review processes. Monitoring and auditing provide early identification of program or operational weaknesses and may substantially reduce exposure to government or whistleblower claims. Although many assessment techniques are available, one effective tool is the performance of regular, periodic compliance audits by internal or external auditors. In addition to evaluating the organization's conformance with reimbursement or other regulatory rules, or the legality of its business arrangements, an effective compliance program periodically reviews whether the compliance program's elements have been satisfied.

- 4. What processes are in place to ensure that appropriate remedial measures are taken in response to identified weaknesses?**

Responding appropriately to deficiencies or suspected non-compliance is essential. Failure to comply with the organization's compliance program, or violation of applicable laws and other types of misconduct, can threaten the organization's status as a reliable and trustworthy provider of health care. Moreover, failure to respond to a known deficiency may be considered an aggravating circumstance in evaluating the organization's potential liability for the underlying problem.

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## E. Measures to Respond to Violations

1. **What is the process by which the organization evaluates and responds to suspected compliance violations? How are reporting systems, such as the compliance hotline, monitored to verify appropriate resolution of reported matters?**

Compliance issues may range from simple overpayments to be returned to the payor to possible criminal violations. The Board's duty of care requires that it explore whether procedures are in place to respond to credible allegations of misconduct and whether management promptly initiates corrective measures. Many organizations take disciplinary actions when a responsible employee's conduct violates the organization's Code of Conduct and policies. Disciplinary measures should be enforced consistently.

2. **Does the organization have policies that address the appropriate protection of "whistleblowers" and those accused of misconduct?**

For a compliance program to work, employees must be able to ask questions and report problems. In its fulfillment of its duty of care, the Board should determine that the organization has a process in place to encourage such constructive communication.

3. **What is the process by which the organization evaluates and responds to suspected compliance violations? What policies address the protection of employees and the preservation of relevant documents and information?**

Legal risk may exist based not only on the conduct under scrutiny, but also on the actions taken by the organization in response to the investigation. In addition to a potential obstruction of a government investigation, the organization may face charges by employees that it has unlawfully retaliated or otherwise violated employee rights. It is important, therefore, that organizations respond appropriately to a suspected compliance violation and, more critically, to a government investigation without damaging the corporation or the individuals involved. The Board should confirm that processes and policies for such responses have been developed in consultation with legal counsel and are well communicated and understood across the organization.

4. **What guidelines have been established for reporting compliance violations to the Board?**

As discussed, the Board should fully understand management's process for evaluating and responding to identified violations of the organization's policies, as well as applicable federal and state laws. In addition, the Board should receive sufficient information to evaluate the appropriateness of the organization's response.

5. **What policies govern the reporting to government authorities of probable violations of law?**

Different organizations will have various policies for investigating probable violations of law. Federal law encourages organizations to self-disclose wrongdoing to the federal government. Health care organizations and their counsel have taken varied approaches to making such disclosures. Boards may want to inquire as to whether the organization has developed a policy on when to consider such disclosures.

## VI. Conclusion

The corporate director, whether voluntary or compensated, is a bedrock of the health care delivery system. The oversight activities provided by the director help form the corporate vision, and at the same time promote an environment of corporate responsibility that protects the mission of the corporation and the health care consumers it serves.

Even in this "corporate responsibility" environment, the health care corporate director who is mindful of his/her fundamental duties and obligations, and sensitive to the premises of corporate responsibility, should be confident in the knowledge that he/she can pursue governance service without needless concern about personal liability for breach of fiduciary duty and without creating an adversarial relationship with management.

The perspectives shared in this educational resource are intended to assist the health care director in performing the important and necessary service of oversight of the corporate compliance program. In so doing, it is hoped that fiduciary service will appear less daunting, and provide a greater opportunity to "make a difference" in the delivery of health care.