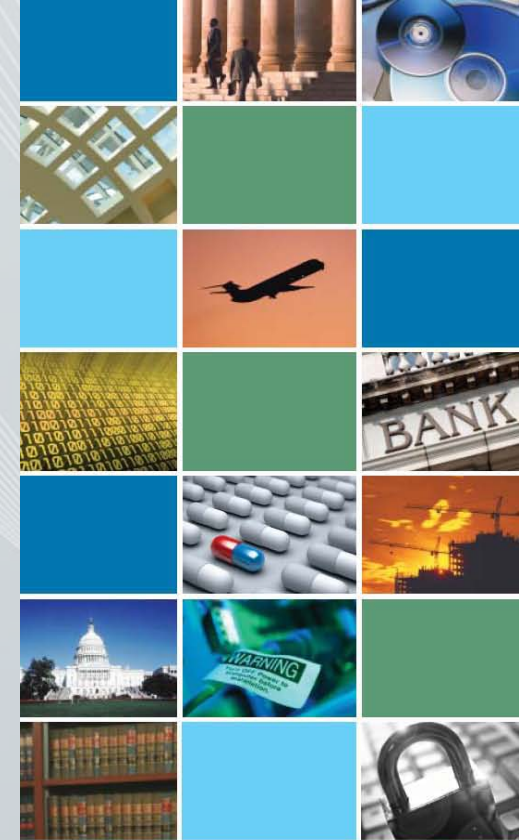


Agenda

1. Reimbursement Landscape
 - Coverage, Billing, Payment, Competitive Bidding Program
2. Summary of 2011 Enrollment Changes
3. Revised & New Supplier Standards
 - Revised - Licensing, Space Requirements, Business Telephone Operations, Solicitation of Beneficiaries
 - New - Obtaining Oxygen, Ordering & Referring Documentation, Shared Space, Hours of Operation
4. Accreditation & Surety Bond Requirements
5. Stark Law and Anti-kickback Considerations



Reimbursement Landscape



What is DMEPOS?

- **DMEPOS includes the following -**
 - **Durable medical equipment (DME)** – equipment furnished by a supplier or HHA that (1) can withstand repeated use, (2) is primarily and customarily used to serve a medical purpose, (3) generally is not useful to an individual in the absence of illness or injury and (4) is for use in the home. Examples – blood glucose monitors, hospital beds, nebulizers, oxygen delivery systems & wheelchairs.
 - **Prosthetics** – devices that replace all or part of an internal body organ, e.g., cardiac pacemakers, cochlear implants, electrical nerve stimulators, and parenteral and enteral (PEN) nutrition.



What is DMEPOS?

- **DMEPOS includes the following -**
 - **Orthotics and prosthetics** - leg, arm, back & neck braces (orthotics) and artificial legs, arms and eyes (prosthetics).
 - **Surgical dressings** - include dressings and splints, casts and other devices used for the reduction of fractures and dislocations.
 - **Other items include therapeutic shoes for diabetics, home dialysis supplies and equipment, self-care home dialysis support services and institutional dialysis services and supplies and self-administered erythropoietin.**



Coverage

- Medicare Benefit Policy Manual, ch. 15; Medicare Secondary Payer Manual; Medicare Program Integrity Manual
- National Coverage Decisions (NCDs)
 - Medicare National Coverage Decisions Manual or Medicare Coverage Database at www.cms.gov
 - Example - Coverage of TENS post-op (10.2) or as DME (280.13)
- Local Coverage Decisions (LCDs)
 - Medicare Coverage Database at www.cms.gov
 - Look at specific DME MAC jurisdiction
- Policy Articles
 - Example - Recently revised Urological Supplies Policy Article regarding A4353 kit

Medicare Coverage Database

The screenshot shows the Medicare Coverage Database website. At the top, there is a navigation bar with the U.S. Department of Health & Human Services logo and the URL www.hhs.gov. Below this is the CMS logo and the text "Centers for Medicare & Medicaid Services". A search bar is located on the right side of the header. The main navigation menu includes links for Home, Medicare, Medicaid, CHIP, About CMS, Regulations & Guidance, Research, Statistics, Data & Systems, Outreach & Education, and Tools. A secondary menu lists "People with Medicare & Medicaid", "Questions", "Careers", "Newsroom", "Contact CMS", "Acronyms", "Help", "Email", and "Print".

The main content area features a navigation bar with buttons for OVERVIEW, ADVANCED SEARCH, INDEXES, REPORTS, DOWNLOADS, and BASKET (0). There are also links for "Contextual Help is Off" and "Page Help".

Welcome to the Medicare Coverage Database

The Medicare Coverage Database (MCD) contains all National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs), local articles, and proposed NCD decisions. The database also includes several other types of National Coverage policy related documents, including National Coverage Analyses (NCAs), Coding Analyses for Labs (CALs), Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) proceedings, and Medicare coverage guidance documents.

[How to Use this Site](#)
[MCD vs. Medicare.gov](#)
[Information about LCDs and LCD Challenges](#)

How to Use this Site

The MCD offers multiple ways to locate and view data:

- QUICK SEARCH** - Allows users to search both the NCD and LCD databases using a variety of criteria such as keyword, diagnosis/procedure, and date. You can use the Quick search to your right. Or click on **ADVANCED SEARCH** to use additional filters to find exactly what you are looking for.
- INDEXES** - Provides users with pre-defined lists of National and Local Coverage documents.
- REPORTS** - Provides users with reports of National and Local Coverage data.
- DOWNLOADS** - Allows users to download complete sets of LCDs and articles and the complete set of NCDs.

Contextual Help & Page Help - Contextual Help is a new feature that provides users with the ability to receive onscreen help for specific elements on the page. To use the feature, click the "Contextual Help" link and move the mouse to the onscreen location of the associated page element. The user can turn the feature off when help is no longer required. Users who are unable to use this feature, or who prefer to have a link to a single page of help for the entire page, may continue to use the "Page Help" link to get assistance.

Click on the corresponding link at the top of the page to get started.

[Back to Top](#)

[MCD vs. Medicare.gov](#)

QUICK SEARCH

An asterisk (*) indicates a required field.

YOU MAY SEARCH BY ID:

* Document ID:

SEARCH BY ID

OR BY DOCUMENT TYPE:

- National and Local Coverage Documents
- National Coverage Documents
- Local Coverage Documents

*Select Geographic Area/Region:

[View county listings for split states](#)
[View region descriptions](#)

*Select One or Both:

AND/OR

Need more search power? [Try Advanced Search](#)

RESET SELECTION CRITERIA

SEARCH BY TYPE

Coverage - Medicare Program Integrity Manual

Medicare Program Integrity Manual Chapter 5 – Items and Services Having Special DME Review Considerations

Table of Contents
(Rev. 281, 12-31-08)

Transmittals for Chapter 5

- 5.1 – Home Use of DME
- 5.2 – Rules Concerning Orders
 - 5.2.1 – Physician Orders
 - 5.2.2 – Verbal and Preliminary Written Orders
 - 5.2.3 – Detailed Written Orders
 - 5.2.3.1 – Written Orders Prior to Delivery
 - 5.2.4 – Requirement of New Orders
- 5.3 – Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs)
 - 5.3.1 – Completing a CMN or DIF
 - 5.3.2 – Cover Letters for CMNs
 - 5.3.3 - Reserved for Future Use
- 5.4 – DME MACs and DME PSC's Authority to Initiate an Overpayment or CMP When Invalid CMNs Are Identified

Coverage – Medicare Secondary Payer Manual

Medicare Secondary Payer (MSP) Manual

Chapter 3 - MSP Provider, Physician, and Other Supplier Billing Requirements

Table of Contents
(Rev. 57, 10-27-06)

[Transmittals for Chapter 3](#)

[Crosswalk to Old Manuals](#)

10 - General

- 10.1 - Limitation on Right to Charge a Beneficiary Where Services Are Covered by a GHP
 - 10.1.1 - Right of Providers to Charge Beneficiary Who Has Received Primary Payment from a GHP
 - 10.1.2 - Right of Physicians and Other Suppliers to Charge Beneficiary Who Has Received Primary Payment from a GHP
 - 10.1.3 - Payment When Proper Claim Not Filed
- 10.2 - Situations in Which MSP Billing Applies
- 10.3 – Provider, Physician, and Other Supplier Responsibility When a Request is Received From an Insurance Company or Attorney
- 10.4 – Provider, Physician, and Other Supplier Responsibility When Duplicate Payments Are Received
- 10.5 - Incorrect GHP Primary Payments
- 10.6 - Retroactive Application

Medicare Coverage Database - LCD Example - Urological Supplies

▼▲		▼▲			☐
L5080	UROLOGICAL Supplies	DME MAC	NHIC, Corp. (16003)	Effective: 10/01/1993 Revision Eff: 02/04/2011 End: N/A Updated: 01/28/2011	☐
L11566	UROLOGICAL Supplies	DME MAC	CIGNA Government Services (18003)	Effective: 10/01/1993 Revision Eff: 02/04/2011 End: N/A Updated: 01/28/2011	☐
L11581	UROLOGICAL Supplies	DME MAC	Noridian Administrative Services (19003)	Effective: 10/01/1993 Revision Eff: 02/04/2011 End: N/A Updated: 01/30/2011	☐
L27219	UROLOGICAL Supplies	DME MAC	National Government Services, Inc. (17003)	Effective: 10/01/1993 Revision Eff: 02/04/2011 End: N/A Updated: 12/12/2010	☐



Medicare Coverage Database – Policy Articles Example – Urological Supplies

Search Results for National and Local Coverage Documents

Page 1 of 1

View Items Per Page:

ARTICLE ID#	ARTICLE TITLE	CONTRACTOR TYPE	CONTRACTOR NAME	DATE INFO	SELECT ALL
A47784	Dear Physician UROLOGICAL s June 2008	DME MAC	CIGNA Government Services (18003)	Effective: 06/20/2008 Revision Eff: N/A End: N/A Updated: 06/20/2008	<input type="checkbox"/>
A50640	UROLOGICAL Supplies - A4353 Correct Coding Clarification Policy Revision	DME MAC	CIGNA Government Services (18003)	Effective: 01/27/2011 Revision Eff: 01/27/2011 End: N/A Updated: 01/28/2011	<input type="checkbox"/>
A50657	UROLOGICAL Supplies – A4353 Correct Coding Clarification Policy Revision	DME MAC	Noridian Administrative Services (19003)	Effective: 02/03/2011 Revision Eff: N/A End: N/A Updated: 01/30/2011	<input type="checkbox"/>
A50660	UROLOGICAL Supplies – A4353 Correct Coding Clarification Policy Revision	DME MAC	NHIC, Corp. (16003)	Effective: 02/03/2011 Revision Eff: N/A End: N/A Updated: 01/28/2011	<input type="checkbox"/>
A50662	UROLOGICAL Supplies – A4353 Correct Coding Clarification Policy Revision	DME MAC	National Government Services, Inc. (17003)	Effective: 02/03/2011 Revision Eff: N/A End: N/A Updated: 01/28/2011	<input type="checkbox"/>

Billing/Coding

- Medicare Claims Processing Manual, ch. 20 (DMEPOS)
- General Rules - DME MAC Supplier Manual by Jurisdiction, which provides information on -
 - Physician Orders
 - Certificates of Medical Necessity (CMNs) and DME MAC Information Forms (DIFs)
 - Medical Necessity Documentation
 - Proof of Delivery Requirements
 - Advanced Beneficiary Notice (ABNs)
- Specific Item Rules - LCDs/Policy Articles

Billing/Payment – Medicare Claims Processing Manual

Medicare Claims Processing Manual Chapter 20 - Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

Table of Contents
(Rev. 1961, 04-30-10)

[Transmittals for Chapter 20](#)

Crosswalk to Source Material

01 - Foreword

10 - Where to Bill DMEPOS and PEN Items and Services

10.1 - Definitions

10.1.1 - Durable Medical Equipment (DME)

10.1.2 - Prosthetic Devices - Coverage Definition

10.1.3 – Prosthetics and Orthotics (Leg, Arm, Back, and Neck Braces, Trusses, and Artificial Legs, Arms, and Eyes) - Coverage Definition

10.1.4 - Payment Definition Variances

10.1.4.1 - Prosthetic Devices

10.1.4.2 - Prosthetic and Orthotic Devices (P&O)

10.2 - Coverage Table for DME Claims

10.3 - Beneficiaries Previously Enrolled in Managed Care Who Return to Traditional Fee for Service (FFS)

Billing - DME MAC Supplier Manual



CIGNA Government Services

Search >>



CIGNA Government Services

DME MAC Jurisdiction C

Part B - Idaho & North Carolina

Claims Processing

Coverage & Pricing

Education

FAQs

Forms

News & Publications

Tools & Site Map

Customer Service



Jurisdiction C Supplier Manual

[Send this page to a colleague](#)

Archived versions of the DME MAC Jurisdiction C Supplier Manual can be found here.

The files offered below are in Adobe PDF format. [Download a free copy of Acrobat Reader.](#)



- [Winter 2011 Update](#)
- [Front Cover](#)
- [Table of Contents](#)
- [Chapter One - Introduction](#)
- [Chapter Two - Supplier Enrollment](#)
- [Chapter Three - Supplier Documentation](#)
- [Chapter Four - Certificates of Medical Necessity \(CMNs\)](#)
- [Chapter Five - DMEPOS Fee Schedule Categories](#)
- [Chapter Six - Claim Submission](#)
- [Chapter Seven - Crossover Claims](#)
- [Chapter Eight - Electronic Data Interchange \(EDI\)](#)
- [Chapter Nine - Coverage and Medical Policy](#)

Billing – Documentation – Example – CMNs/DIFs

CMNs

The following table indicates the current DME MAC CMN forms.

DME MAC FORM	CMS FORM	ITEMS ADDRESSED
484.03	484	Oxygen
04.04B	846	Pneumatic Compression Devices
04.04C	847	Osteogenesis Stimulators
06.03B	848	Transcutaneous Electrical Nerve Stimulators (TENS)
07.03A	849	Seat Lift Mechanisms
11.02	854	Section C Continuation Form

DIFs

The following table indicates the DIFs for external infusion pumps and enteral/parenteral nutrition.

DME MAC FORM	CMS FORM	ITEMS ADDRESSED
09.03	10125	External Infusion Pumps
10.03	10126	Enteral and Parenteral Nutrition

Printable copies of CMNs and DIFs are available on the CMS website at <http://www.cms.gov/CMSForms/CMSForms/list.asp>. To find the CMN/DIF you are looking for on the website, place a check next to the "Show only items containing the following word" field and enter the name of the CMN/DIF. For instance, if you are searching for the Oxygen CMN, enter the word "oxygen." Be sure that you have selected the "Show only" option and then press the "Show Items" button.

Billing/Coding - LCD Example - Urological Supplies

Local Coverage Article for UROLOGICAL Supplies - Policy Article - Effective February 2011 (A25230)

Contractor Information

Contractor Name NHIC, Corp. Back to Top	Contractor Number 16003	Contractor Type DME MAC
--	-----------------------------------	-----------------------------------

Article Information

General Information

Article ID Number A25230	AMA CPT / ADA CDT Copyright Statement CPT codes, descriptions and other data only are copyright 2010 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. Current Dental Terminology (CDT) (including procedure codes, nomenclature, descriptors and other data contained therein) is copyright by the American Dental Association. © 2002, 2004 American Dental Association. All rights reserved. Applicable FARS/DFARS apply.
Article Type Article	
Key Article Yes	

Article Title UROLOGICAL Supplies - Policy Article - Effective February 2011	Primary Geographic Jurisdiction Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont
--	--

DME Region Article Covers
Jurisdiction A

Original Article Effective Date
04/01/2005

Article Revision Effective Date
02/04/2011

CODING GUIDELINES

The general term "external urinary collection devices" used in this policy includes male external catheters and female pouches or meatal cups. This term does not include diapers or other types of absorptive pads.

A meatal cup female external urinary collection device (A4327) is a plastic cup, which is held in place around the female urethra by suction or pressure and is connected to a urinary drainage container such as a bag or bottle.

A pouch type female external collection device (A4328) is a plastic pouch which is attached to the periurethral area with adhesive and which can be connected to a urinary drainage container such as a bag or bottle.

A urinary catheter-anchoring device described by code A4333 has an adhesive surface, which attaches to the patient's skin and a mechanism for releasing and re-anchoring the catheter multiple times without changing the anchoring device.

A urinary catheter-anchoring device described by code A4334 is a strap, which goes around a patient's leg and has a mechanism for releasing and re-anchoring the catheter multiple times without changing the anchoring device.

A urinary intermittent catheter with insertion supplies (A4353) is a kit which includes a catheter and all supplies necessary for sterile insertion (see below). Code A4353 may be used if either 1 or 2 is supplied:

1. A sterile intermittent urinary catheter plus a separately packaged sterile kit of insertion/collection supplies; or,
2. A single sterile package containing both a catheter and all insertion/collection supplies.

The insertion kit (A4353) contains a catheter (may be packaged separately from the other components), lubricant, gloves, antiseptic solution, applicators, a drape, and a collection tray/bag in a sterile package intended for single use. The collection tray/bag is a separate item included as part of the kit; therefore, materials that serve as non-sterile packaging to contain all of the items in the kit do not meet this requirement. Except as noted in 1 above, code A4353 must not be billed if individual insertion kit components are provided as separate items. When providing a sterile kit, the individual components must not be separately billed.

Therapeutic agent for urinary irrigation (A4321) is defined as a solution containing agents in addition to saline or sterile water (for example acetic acid or hydrogen peroxide) which is used for the treatment or prevention of urinary catheter obstruction.

Code A5105 should be used when billing for a urinary suspensory with leg bag.

Payment

- During a Part A stay, DMEPOS is not separately billable.
- Under Part B, DMEPOS is typically paid under a fee schedule.
 - The Pricing, Data Analysis & Coding (PDAC) contactor (formerly known as the SADMERC) conducts coding verification and pricing of DMEPOS items.
 - With the exception of customized items, a fee schedule amount is calculated for each item/category of DMEPOS that is identified by a code in the Healthcare Common Procedure Coding System (HCPCS).

Competitive Bidding Program

- DMEPOS Competitive Bidding Program was statutorily mandated and was intended to begin in 2007.
- Round One delayed in 2008 for 18 months, then MIPPA required CMS to terminate Round One contracts.
- MIPPA added a financial document review process and a requirement for contract suppliers to report contractor relationships.
- Round One Rebid involved 9 of 10 metropolitan statistical areas (MSAs) and 9 of 10 product categories of Round One.



Competitive Bidding Program

- **Round One Rebid Results -**
 - CMS received 6,215 bids from 1,011 suppliers during 60-day bidding period.
 - CMS awarded 1,217 contracts with 356 suppliers.
 - Small suppliers (with annual receipts less than \$3.5 million) make up 51% of contract suppliers.
 - CBIC estimates overall weighted average savings as 32%

- **Round Two -**
 - Scheduled to begin in Spring 2011
 - Covers 91 MSAs

How to Participate in Competitive Bidding

- **Suppliers must meet the requirements in 42 CFR § 414.414.**
 - **Supplier Standards at 42 CFR § 424.57**
 - **Accreditation**
 - **Financial Standards**
 - **Licensure – for all locations identified in the bid(s) – a competitive bidding area (CBA) can cross multiple states**
- **Small suppliers (i.e., suppliers that generate \$3.5 M or less in annual receipts, including MCR and non-MCR revenue) have the option to form networks.**
- **SNFs & nursing facilities – can bid as "specialty suppliers"**

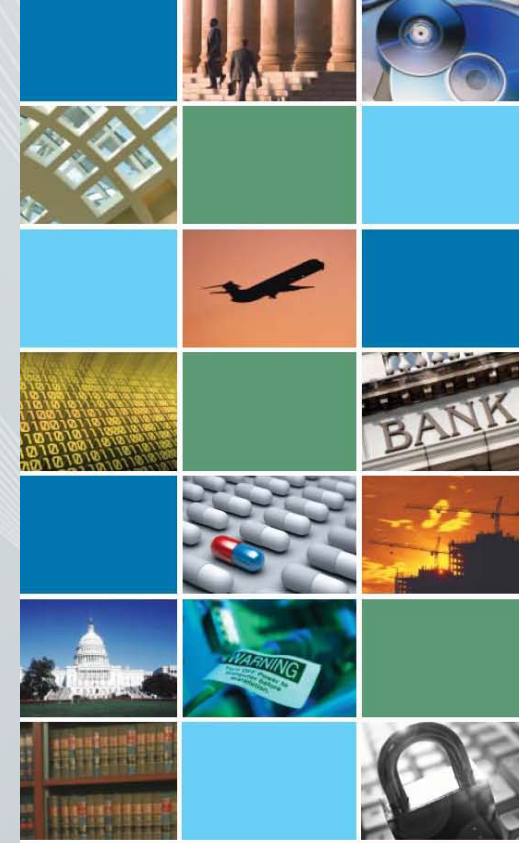


How to Participate in Competitive Bidding

- **Noncontract suppliers that furnish competitively bid items in a CBA are not eligible for MCR payment for such items unless one or more of the following exceptions apply -**
 - **Suppliers of grandfathered DME (e.g., Oxygen)**
 - **Repairs/replacement**
 - **Physicians and other practitioners who are enrolled Medicare DMEPOS suppliers (canes, crutches, walkers, folding manual wheelchairs, blood glucose monitors and DME infusion pumps)**
 - **PTs and OTs in private practice who are enrolled DMEPOS suppliers (off-the-shelf orthotics)**
 - **Medicare secondary payer**



2011 Enrollment Changes



2011 Enrollment Changes

- Effective March 25, 2011,
 - Newly enrolling DMEPOS suppliers are classified in the "*high*" risk category of fraud, waste or abuse under CMS' new enrollment standards;
 - Currently enrolled DMEPOS suppliers are classified in the "*moderate*" risk level.
- Application fee (new enrollment, revalidation, new practice location) – 2010 set at \$500 per application (for 2011 will be increased by CPI-U)

2011 Enrollment Changes

- Risk categories determine what screening procedures –
 - "Limited" risk – verification of provider/supplier-specific requirements in the FHCPs, verification of licensure, and database checks.
 - "Moderate" risk – all "limited" risk procedures PLUS unannounced pre- and post-enrollment site visits
 - "High" risk – all "moderate" risk procedures PLUS fingerprint-based criminal history record check of Federal and State law enforcement databases

- Medicaid and CHIP programs will adopt same standards OR can add screening procedures or increase the risk level for categories of providers/suppliers.

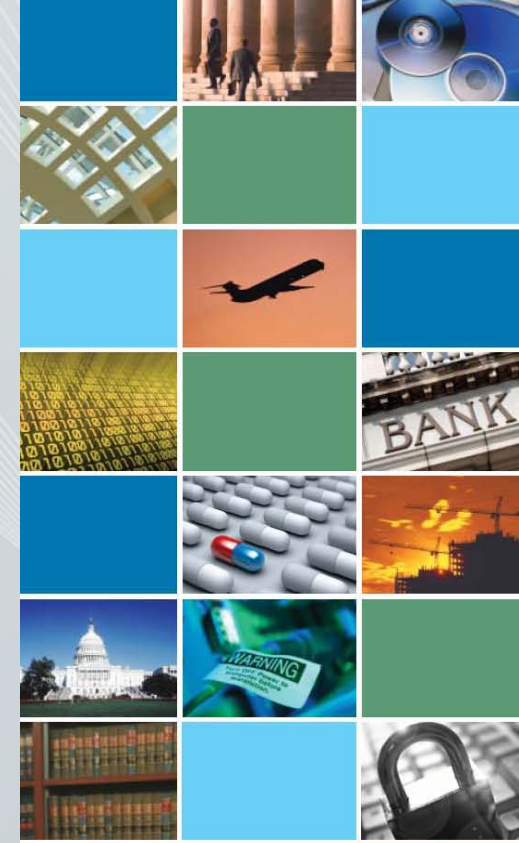


2011 Enrollment Rule's Additional Changes

- Temporary moratorium on enrollment for Medicare, Medicaid & CHIP programs
- Payment suspensions pending **an investigation** of a "credible allegation of fraud" unless "good cause" for the Medicare and Medicaid programs
- Cross-termination of provider/supplier participation if terminated under the Medicare, Medicaid or CHIP programs



Supplier Standards



Supplier Standards - REVISED

- **Supplier Standard #1** – supplier must operate a business in compliance with Federal and State laws.
 - If a State requires licensure to furnish certain items or services, a DMEPOS supplier –
 1. must be licensed;
 2. must employ the licensed professional on a full-time or part-time basis; and
 3. must not contract with an individual/entity to provide the licensed services, unless allowed by the State where the licensed services are being performed.



Supplier Standards - REVISED

➤ Supplier Standard #7 - Physical facility

- Supplier must maintain a physical facility on an "appropriate site."
- An "appropriate site" must meet the following –
 - Maintain a practice location that is at least 200 square feet (beginning 9/27/2010)
 - Is in a location accessible to the public, Medicare beneficiaries, CMS, NSC and its agents
 - Is accessible and staffed during posted hours of operation
 - Maintains a permanent visible sign in plain view and posts hours of operation
 - Is in a location that contains space for storing business records
 - Is in a location that contains space for retaining the necessary ordering and referring documentation



Supplier Standards - REVISED

➤ Supplier Standard #8 - On-site Inspections

- Supplier must permit NSC or CMS agents to conduct on-site inspections
- Unannounced visits can be conducted during operating hours
- If CMS/NSC shows up during operating hours and the site is closed, they have the authority to revoke the billing privileges.

➤ Supplier Standard #9 - Business Telephone

- Supplier must maintain a primary business telephone that is operating at the "appropriate site"
- Calls may not be exclusively forwarded to a cell phone, beeper or pager
- Suppliers may not exclusively use answering machines, answering services or fax machines during posted operating hours.



Supplier Standards - REVISED

- Supplier Standard #11 – Solicitation of Beneficiaries
 - DMEPOS suppliers cannot make direct solicitation of Medicare beneficiaries by telephone, computer, email, instant messaging or in-person contacts without the beneficiary's consent for the purpose of marketing.



Supplier Standards - REVISED

➤ Supplier Standard #11 - Solicitation of Beneficiaries

- Exceptions to the solicitation of beneficiaries prohibition include the following -

(i) The 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.

(ii) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(iii) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such a contact.

Supplier Standards - REVISED

➤ Supplier Standard #11 - Solicitation of Beneficiaries

- A physician order does not constitute written permission from the beneficiary to contact the beneficiary.
- **HOWEVER**, if the physician contacts the supplier on behalf of the beneficiary with the beneficiary's knowledge, then a supplier may contact the beneficiary to confirm or gather information needed to provide that particular covered item.



Supplier Standards - NEW

- **Supplier Standard #27 - A supplier must obtain oxygen from a State-licensed oxygen supplier.**
- **Supplier Standard # 28 - A supplier must maintain ordering and referring documentation for 7 years after the claim has been paid.**
- **Supplier Standard # 30 - A supplier must be open to the public a minimum of 30 hours per week, except for those suppliers where -**
 - **A physician or NPP furnishes items to his/her own patients as part of his/her professional services or**
 - **A supplier is working with custom-made orthotics and prosthetics.**

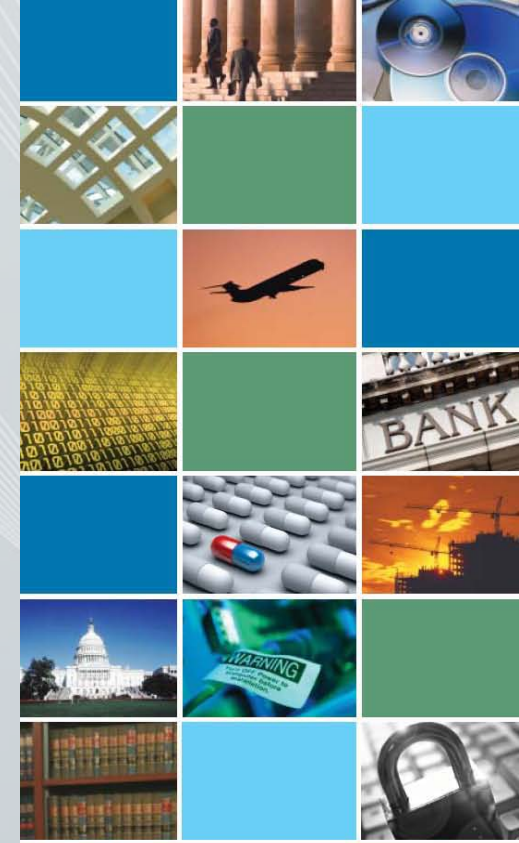


Supplier Standards - NEW

- **Supplier Standard #29 – A supplier is prohibited from sharing a practice location (as that physical location is described on the CMS-855S) with any other Medicare supplier/provider except in the following circumstances:**
 - **Physician/NPP furnishing items to his/her patients as part of his/her professional service;**
 - **PT/OT furnishing items to his/her own patients as part of his/her own professional service;**
 - **DMEPOS supplier is co-located with and owned by an enrolled Medicare provider where DMEPOS supplier operates as a separate unit and meets the Supplier Standards.**



Accreditation/Surety Bond



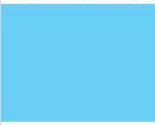
Accreditation

- **As of 10/1/2009, DMEPOS suppliers must be accredited by a Medicare "deemed" accreditation organization ("AO") in order to obtain/maintain billing privileges if they furnish covered items and services.**
- **Covered items and services include –**
 - **DME**
 - **Medical supplies**
 - **Home dialysis supplies and equipment**
 - **Therapeutic shoes**
 - **PEN nutrients, equipment and supplies**
 - **Blood products**
 - **Transfusion medicine**
 - **Prosthetic devices**
 - **Prosthetics & Orthotics**



Accreditation

- **NOTE: There is a difference between the Supplier Standards and the Quality Standards.**
 - **Suppliers must be in compliance with the Supplier Standards to obtain/maintain Medicare billing privileges.**
 - **Suppliers must be in compliance with the Quality Standards to attain accreditation by a CMS-approved AO.**



Accreditation

- Certain supplier types are exempt from accreditation – physicians, dentists, orthotists, prosthetists, opticians, optometrists, audiologists, OTs, PTs and podiatrists.
- CMS has deemed 10 AOs – including the Joint Commission, ACHC, ABC, BOC, CARF, CHAP, HCAA, NABP, TCT and NBAOs.
- Quality Standards are divided into the following areas –
 - Business Services – including Administration, Financial Management, Human Resource Management, Consumer Services, Performance Management, Product Safety and Information Management
 - General Product-Specific Service Standards – includes Preparation, Delivery and Setup, Training/Instruction to Beneficiary and Caregiver and Follow-up
 - Appendix A – deals with respiratory equipment, supplies and services
 - Appendix B – deals with manual wheelchairs and power mobility devices including complex rehab and assistive technology.
 - Appendix C – deals with custom fabricated, custom fitted, custom-made orthotics, prosthetic devices, soatic, ocular, and facial prosthetics and therapeutic shoes and inserts.



Surety Bond

- As of May 4, 2009, new enrollees, suppliers undergoing a CHOW or existing suppliers establishing a new practice location are required to obtain and submit a surety bond to the NSC with their CMS-855S application. **As of October 2, 2009, each Medicare-enrolled DMEPOS supplier must have a surety bond.**
- Obtain through sureties identified on U.S. Department of Treasury's "Listing of Certified (Surety Bond) Companies" at www.fms.treas.gov
- Bond - must be a continuous bond in an amount not less than \$50,000 per location that has a separate NPI
- Higher bond amount will be required if "final adverse action"



Surety Bond

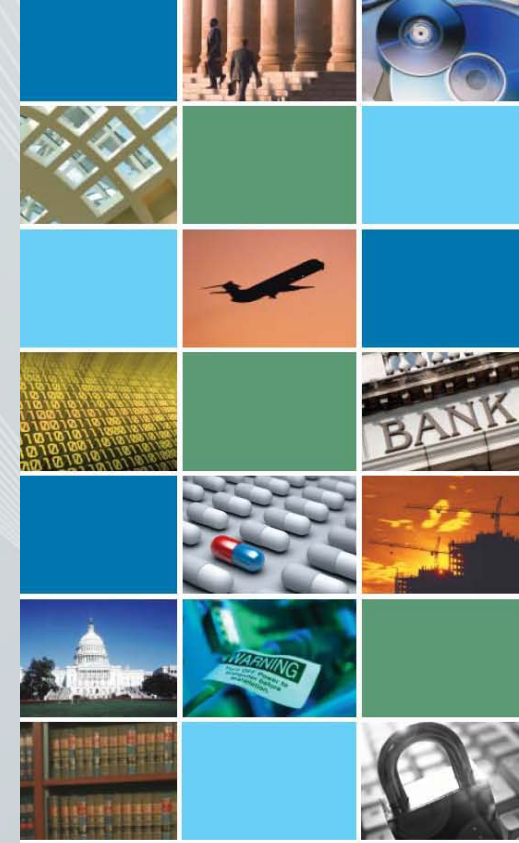
- **Certain DMEPOS suppliers are exempt from surety bond requirements –**
 - **Government-operated DMEPOS suppliers (if the DME supplier has provided CMS with a comparable surety bond under State law);**
 - **State-licensed orthotic and prosthetic personnel in private practice making custom-made orthotics and prosthetics if (1) the business is solely-owned and operated by the orthotic and prosthetic personnel, and (2) the business is only billing for orthotic, prosthetics and supplies;**



Surety Bond

- **Certain DMEPOS suppliers are exempt from surety bond requirements –**
 - **Physicians and nonphysician practitioners (as defined in section 1842(b)(18) of the Act) when items are furnished only to the physician or nonphysician practitioner's own patients as part of his or her physician service;**
 - **Physical and occupational therapists in private practice if (1) the business is solely-owned and operated by the physical or occupational therapist; (2) the items are furnished only to the physical or occupational therapist's own patients as part of his or her professional service, and (3) the business is only billing for orthotics, prosthetics and supplies.**

Stark Law & AKBS Considerations



Stark Law

- "Designated health services" or "DHS" under the Stark Law includes -
- Durable medical equipment (DME);
 - parenteral and enteral nutrients, equipment and supplies;
 - prosthetics, orthotics and prosthetic devices and supplies; and
 - outpatient prescription drugs.



Stark Law

- The Stark Law provides that "a physician who has a direct or indirect financial relationship with [a DHS] entity, or who has an immediate family member who has a direct or indirect financial relationship with the entity, may not make a referral for the furnishing of DHS for which payment otherwise may be made under Medicare."
- Further, an entity that furnishes DHS pursuant to a prohibited referral may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral.



Stark Law

- In order to avoid the Stark Law's referral prohibitions, if the physician has a "direct or indirect financial relationship with [a DHS] entity" the financial relationship must meet an applicable exception.
- "Financial relationship" means
 - (i) a direct or indirect ownership or investment interest (as defined by 42 C.F.R. § 411.354(b)) in any entity that furnishes DHS or
 - (ii) a direct or indirect compensation arrangement (as defined by 42 C.F.R. § 411.354(c)) with an entity that furnishes DHS.



Stark Law

- The Stark Law applies not only to relationships between third-party DMEPOS suppliers and physicians, but also to a physician's referrals within his/her physician practice entity.
- Under the Federal physician self-referral law (commonly known as the "Stark Law"), physicians and physician group practice entities may furnish DHS pursuant to the "in-office ancillary services" exception.



Stark Law

- DME may only be furnished by physicians' offices under the in-office ancillary services exception if it falls under specific categories of DME - namely, (1) DME infusion pumps or (2) canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors that meet certain conditions.
- Note: For purposes of the in-office ancillary services exception, an item is "furnished" in the location where the service is actually performed upon a patient or where an item is dispensed to a patient in a manner that is sufficient to meet the applicable Medicare payment and coverage rules.

Stark Law – IOAS Exception

- In addition, in order to meet the IOAS exception, the services must meet the following conditions:

1. Who –

GENERALLY, they must be furnished personally by one of the following individuals: (i) the referring physician; (ii) a physician who is a member of the same group practice as the referring physician; (iii) an individual who is supervised by the referring physician or, if the referring physician is in a group practice, by another physician in the group practice, provided that the supervision complies with all other applicable Medicare payment and coverage rules for the services.

DME is restricted in that it may only be furnished personally by the physician who ordered the DME, by another physician in the group practice or by an employee of the physician or the group practice.

Stark Law – IOAS Exception

2. Where –

- **DME must exclusively be furnished in the "same building".**
- Other DMEPOS items must be furnished in one of the following locations:
 - (i) the same building (as defined at § 411.351), but not necessarily in the same space or part of the building, in which all of the conditions of 42 C.F.R. § 411.355(b)(2)(i)(A), (B) or (C) are satisfied;
 - (ii) a centralized building (as defined at § 411.351) that is used by the group practice for the provision of some or all of the group practice's clinical laboratory services; or
 - (iii) a centralized building (as defined in § 411.351) that is used by the group practice for the provision of some or all of the group practice's DHS (other than clinical laboratory services).



Stark Law – IOAS Exception

- 3. How Billed - They are billed by one of the following: (i) the physician performing or supervising the service; (ii) the group practice of which the performing or supervising physician is a member under a billing number assigned to the group practice; (iii) the group practice if the supervising physician is a "physician in the group practice" (as defined at § 411.351) under a billing number assigned to the group practice; (iv) an entity that is wholly owned by or by that physician's group practice under the entity's own billing number or under a billing number assigned to the physician or group practice; or...



Stark Law – IOAS Exception

- **3. How Billed (continued) - They are billed by one of the following: ... (v) an independent third party billing company acting as an agent of the physician, group practice, or entity specified in subsections (i) through (iv) under a billing number assigned to the physician, group practice, or entity, provided that the billing arrangement meets the requirements of 42 C.F.R. § 424.80(b)(5).**
- **Note: With regard to the billing requirements, a group practice may have, and bill under, more than one Medicare billing number, subject to any applicable Medicare program restrictions.**
- **With regard to DME, a physician or group practice that furnishes DME must meet all DME supplier standards set forth at 42 C.F.R. §424.57(c).**

AKBS Considerations – Supply Closets

- The OIG has had longstanding concern regarding space rental arrangements in physician office space.
- "Consignment closets" (also called "supply closets") have been specifically mentioned in OIG guidance.
- Concern is that such arrangements are a disguised kickback from a supplier to a physician/group practice for referrals of DMEPOS items.
- Arrangements should be structured to meet the AKBS rental safe harbor and the Stark Law's rental of office space exception, as well as the Supplier Standards.



QUESTIONS?

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