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New Medicare Standards for DMEPOS Suppliers

Understanding Operational Requirements, Medicare Enrollment and Billing Privileges, and False Claims Act Considerations

THURSDAY, APRIL 7, 2011

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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New Medicare Standards for DMEPOS Suppliers:

Understanding Operational Requirements, Medicare Enrollment and Billing Privileges, and False Claims Act Considerations

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April 7, 2011

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DMEPOS Supplier Standards

- Background and Sources
- The New Supplier Standards
- The Revised Supplier Standards
- DMEPOS Supplier Compliance Resources

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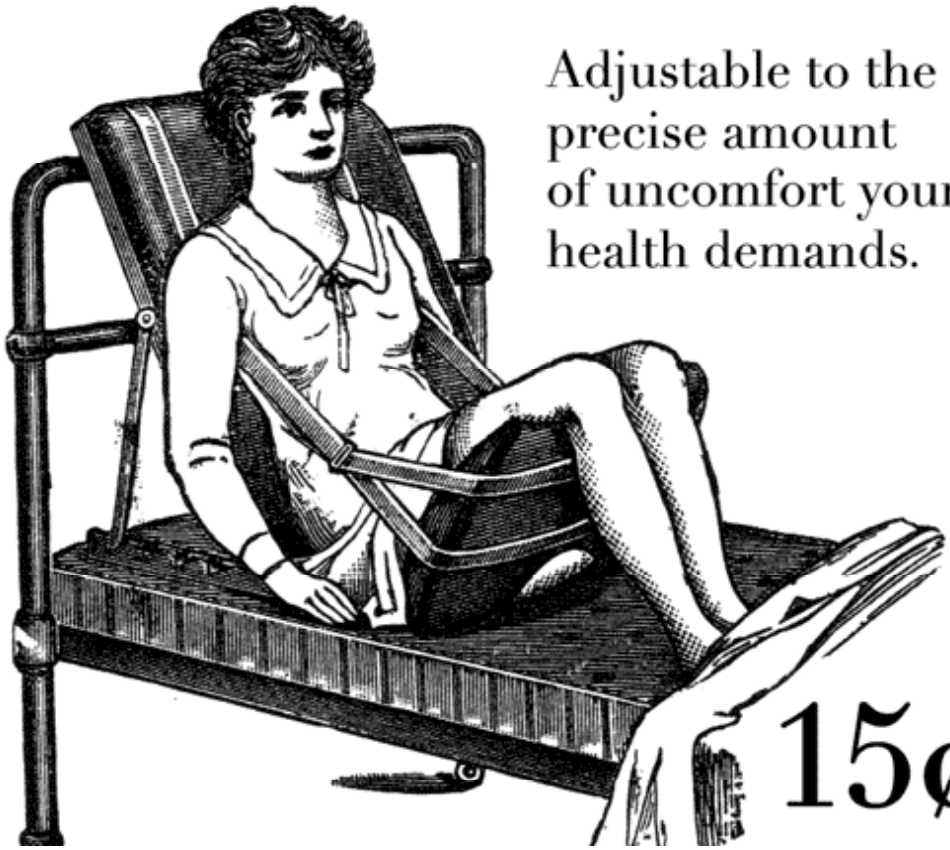
Mustrowski's Famous Bed-Bender



Adjustable to the precise amount of uncomfort your health demands.

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DMEPOS Supplier Standards: Background and Sources

- First published in 1992. Grew to 21 standards, then 26, now 30 standards.
- All Medicare DMEPOS suppliers must be in compliance with the supplier standards in order to obtain and retain their billing privileges. These standards, in their entirety, are listed at 42 CFR § 424.57(c).
  - Note: the supplier standards are contained under 42 CFR Part 424 (Conditions for Payment).

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DMEPOS Supplier Standards: Background and Sources

- On January 25, 2008, CMS published a proposed rule with new and revised supplier standards. 73 FR 4503.
- On August 27, 2010, CMS published a final rule titled, "Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Suppliers (DMEPOS) Supplier Enrollment Safeguards." 75 FR 52629.
- The new supplier standards became effective September 27, 2010.
- On April 4, 2011, CMS published a proposed rule relaxing and revising four supplier standards.

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DMEPOS Supplier Standards: Background and Sources

- Other important guidance regarding new supplier standards:
  - OIG 2010 Special Fraud Alert on DMEPOS Telemarketing
  - CMS 2010 FAQs on DMEPOS telemarketing
  - CMS 2011 FAQs on supplier standards (published through NSC)

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DMEPOS Supplier Standards: Background and Sources

- Failure to meet standards
  - Revocation. CMS will revoke a supplier's billing privileges if it is found not to meet the standards. 42 CFR § 424.57(d).
  - Overpayments associated with final adverse actions. CMS or a CMS contractor may reopen Medicare claims paid on or after the date of a final adverse action in order to establish an overpayment determination.

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DMEPOS Supplier Standards

- The Four New Supplier Standards
  - Oxygen
  - Ordering and referring documentation
  - Practice location sharing
  - Open 30 hours per week
- Revisions to Existing Standards
  - Licensing requirements and prohibition on outside contracting
  - Physical facility requirements
  - On-site inspections and sanctions
  - Telemarketing and solicitation of beneficiaries

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New DMEPOS Supplier Standards

- Standard #27
  - The supplier "[m]ust obtain oxygen from a State-licensed oxygen supplier (applicable only to those suppliers in States that require oxygen licensure)."
  - 42 CFR § 424.57(c)(27).

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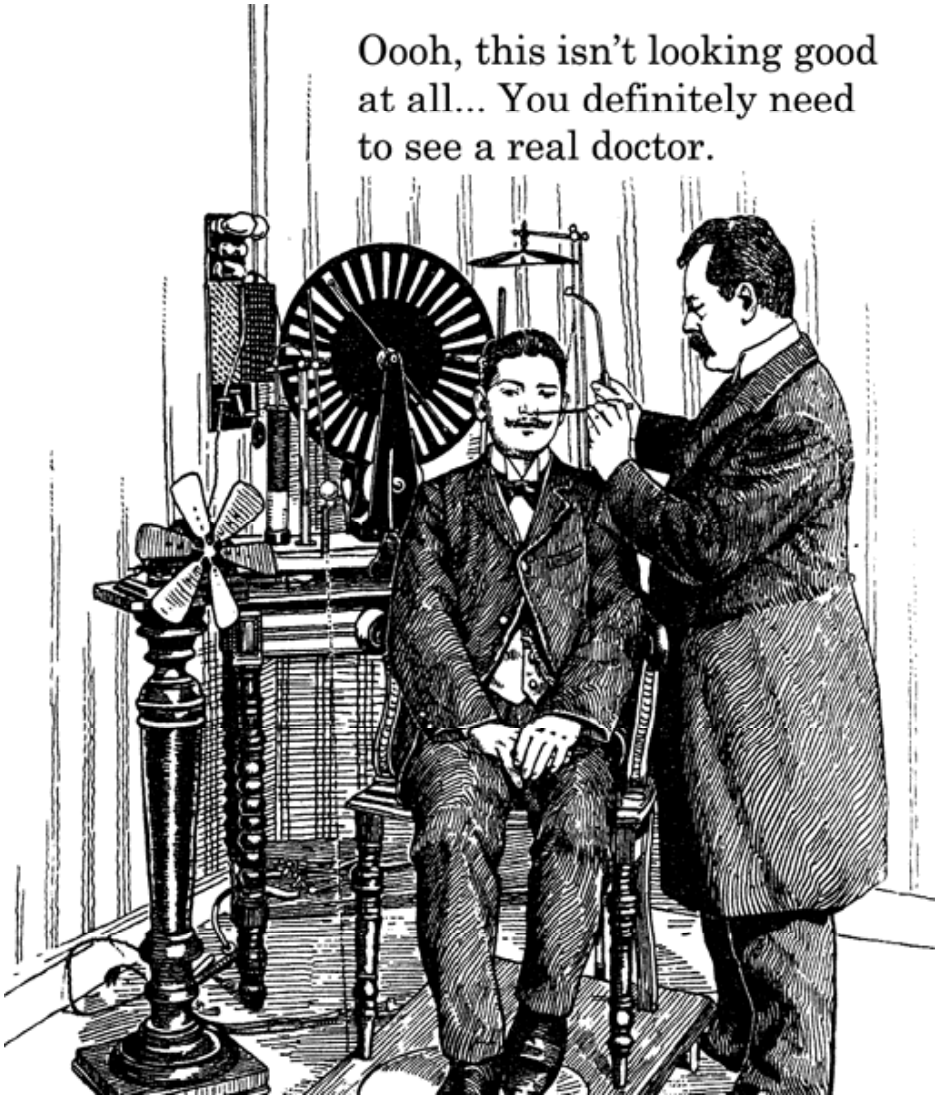

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New DMEPOS Supplier Standards

- Standard #27 - Insight
  - Must obtain oxygen from a state-licensed oxygen supplier if the DMEPOS supplier is located in a state that requires licensure for oxygen suppliers.
  - If the supplier is located in a state that requires licensure, but the supplier obtains its oxygen from an out-of-state oxygen supplier, that out-of-state oxygen supplier must be licensed.
  - Does not apply to DMEPOS suppliers located in states that do not require licensure of oxygen suppliers.

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New DMEPOS Supplier Standards

- Standard #28
  - The supplier "[i]s required to maintain ordering and referring documentation consistent with the provisions found in §424.516(f)."
  - 42 CFR § 424.57(c)(28).

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Maintain Documentation

Come on, Douglas! Shred a little! Wipe that stupid look off your face. I'm gonna start shooting that snow-shoe chick if you don't step it up. Look at her! She's shredding like the IRS is outside!

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New DMEPOS Supplier Standards

- Standard #28 - Insight
  - Suppliers must continue to maintain ordering and referring documentation received from physicians or non-physician practitioners for seven years after the service or supply has been provided to assure that coverage criterion for an item has been met.
  - Proposed rule was date claim was paid; final rule is date of service.
  - If the information in the patient's medical records does not adequately support medical necessity, the supplier may be liable for recoupment. Appeal rights/process.

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New DMEPOS Supplier Standards

- Standard #29
  - The supplier "is prohibited from sharing a practice location with any other Medicare supplier or provider" EXCEPT where:
  - A physician, nonphysician practitioner, or physical or occupational therapist furnishes items directly to his or her own patients as part of his or her professional service; or
  - The DMEPOS supplier is co-located with and 100% owned by a hospital, HHA, SNF, or other Part A provider enrolled in Medicare, and the DMEPOS supplier operates as a separate unit.
  - 42 CFR § 424.57(c)(29).

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Location Sharing

Fifteen shillings?! I encourage you to double-check the price, chemist, or I shall go next door to purchase my suppositories from the skeletal Dark Lord of Pharmacy Street.

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New DMEPOS Supplier Standards

- Standard #29 - Insight
  - Suppliers may not share a physical practice location (*i.e.*, where the supplier operates his or her business and meets with customers) with other Medicare providers and suppliers.
  - CMS reasoned that legitimate suppliers would not share space with competitors and, in the event that it does occur, the practice often results in either poor service or fraud.
  - CMS carved out some exceptions.
  - Not considered to be sharing a practice location if suppliers have separate suites, addresses, entrances, telephone numbers and use separate equipment.

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New DMEPOS Supplier Standards

- Standard #30
  - The supplier must be “open to the public a minimum of 30 hours per week” EXCEPT where:
  - A physician, nonphysician practitioner, or physical or occupational therapist furnishes items directly to his or her own patients as part of his or her professional service; or
  - The DMEPOS supplier is working with custom made orthotics and prosthetics.
  - 42 CFR § 424.57(c)(30).

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New DMEPOS Supplier Standards

- Standard #30 - Insight
  - The supplier's location must be staffed during posted business hours and remain open and accessible to the public at least thirty hours per week (e.g., not in a gated community or area where access is restricted).
  - Note, this “open and accessible” requirement differs from a storefront. CMS does not require DMEPOS suppliers to maintain a storefront.
  - Proposed rule has exceptions to this requirement for suppliers of services listed under Section 1861(p) and (g) of the Social Security Act. Outpatient physical therapy.

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Revised DMEPOS Supplier Standards

- Standard #1 (Licensing requirements and prohibition on outside contracting)
  - A DMEPOS supplier must be licensed to provide licensed service(s), and the supplier cannot contract with a third party to provide the licensed service(s).
  - 42 CFR § 424.57(c)(1)(ii).

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New DMEPOS Supplier Standards

- Standard #1 - Insight
  - Onus is on the supplier to determine what licenses are required.
  - The prohibition on third party contracting prevents entities from enrolling in Medicare, only to subcontract out the operations to suppliers that are not (or may not) participate in the Medicare program. Applies to full and part-time professionals.
  - Under the proposed rule, a DMEPOS supplier may contract with an individual or entity to provide the licensed service(s) unless such a contractual arrangement is expressly prohibited by State law.

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Revised DMEPOS Supplier Standards

- Standards #7, 9 (Physical facility requirements)
  - Physical location (200sq ft)
  - Visible, permanent signage
  - Accessible to public, CMS, NSC, etc.
  - Adequate record storage
  - No cell phones or pagers as a primary business telephone number, nor may answering services be used exclusively as the primary telephone number during posted business hours
  - Exceptions
  - 42 CFR §§ 424.57(c)(7), (9)

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Accessible to Public

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New DMEPOS Supplier Standards

- Standards #7, 9 - Insight
  - Size: 200 sq ft. minimum includes all space within the location (storage, administrative, etc.) but not any off-site areas.
    - Exception for state-licensed orthotic and prosthetic personnel providing custom fabricated orthotics or prosthetics in private practice, or if a state does not offer such licensure (proposed rule).
  - Location must contain adequate space for storing business records, including the supplier's delivery, maintenance, and beneficiary communication records.
    - Records may be stored off site, and multi-state suppliers may maintain central record storage locations, so long as the supplier can readily access them as needed.
    - 2011 FAQs state it is not permissible to use an off-site third party (e.g., vendor or third party biller) to store supplier's records even if they could be retrieved quickly.

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Revised DMEPOS Supplier Standards

- Standard #8 (On-Site Inspections and Sanctions)
  - The supplier must permit "CMS, the NSC, or agents of CMS of the NSC to conduct on-site inspections to ascertain supplier compliance with the [supplier standards]."
  - 42 CFR § 424.57(c)(8).

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New DMEPOS Supplier Standards

- Standard #8 - Insight
  - The revised standard allows CMS and the NSC to conduct routine, unscheduled site visits during the supplier's posted hours of operation.
  - If CMS or the NSC is unable to perform a site visit during normal operating hours, the NSC will revoke the supplier’s Medicare billing privileges.
  - A supplier would be afforded appeal rights if its billing privileges are revoked.
  - Severe remedies, but CMS lacks authority to suspend billing privileges under these circumstances.

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Revised DMEPOS Supplier Standards

- Standard #11 (Telemarketing and Solicitation of Beneficiaries)
  - Supplier may not "make a direct solicitation … of a Medicare beneficiary" unless:
    - The beneficiary has given written permission to contact him or her;
    - 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.
  - 42 CFR § 424.57(c)(11); Section 1843(a)(17)(A) of the Social Security Act; 42 U.S.C. § 1395m(a)(17)(A).

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Beneficiary Solicitation

Cure-alls! Come and buy your homeopathic cure-alls! Heals every disease, relieves aches and pains! Contains nothing but water! Cure-alls!

Damn, I should start saying that about my lemonade.

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Revised DMEPOS Supplier Standards

- Standard #11 - Insight
  - Direct solicitation means “direct contact, which includes, but is not limited to, telephone, computer, e-mail, instant messaging or in-person contact, by a DMEPOS supplier or its agents to a Medicare beneficiary without his or her consent for the purpose of marketing the DMEPOS supplier's health care products or services or both.” 42 CFR § 424.57(a).
  - Internet advertising is exempt (for now).

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Revised DMEPOS Supplier Standards

- Standard #11 - Insight
  - The proposed rule deletes “direct solicitation” and instead tracks the exceptions under the Telemarketing Statute.
  - Under the Proposed Rule, DMEPOS suppliers are prohibited from contacting a beneficiary ***by telephone when supplying a Medicare-covered item*** unless: 1) the supplier has received written permission from the beneficiary to contact them ***by telephone concerning the furnishing of a covered item***; 2) the supplier has furnished a covered item to the beneficiary and is contacting the beneficiary to coordinate the delivery of the item; or 3) if the contact concerns a covered item other than one already furnished to the beneficiary, the supplier has furnished at least one covered item to the beneficiary within the previous 15 months.

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Revised DMEPOS Supplier Standards

- Standard #11 – Insight
  - OIG 2010 Special Fraud Alert
  - CMS 2010 FAQs
  - CMS 2011 FAQs
  - CMS January 2011 Open Door Forum
  - Proposed Rule

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Revised DMEPOS Supplier Standards

- Standard #11 – Insight
  - A supplier cannot avoid application of the statute by contracting with a third party vendor or telemarketing company. If the vendor violates the telemarketing statute, the vendor and the supplier can be held responsible.
  - If a supplier knowingly submits a claim for an item in violation of the statute, CMS must deny payment.
  - Violations, particularly a pattern of violations, can expose suppliers to civil, criminal, and administrative penalties, including exclusion.

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DMEPOS Supplier Standards

- Other useful compliance resources for DMEPOS suppliers:
  - OIG Compliance Program Guidance
  - OIG Advisory Opinions
  - CMS Manuals and Transmittal Letters
  - CMS Open Door Forums
  - NSC and DME MAC Publications and Manuals

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DMEPOS Supplier Standards

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- Read our AHLA article on the new DMEPOS supplier standards.
- Read our DMEPOS supplier compliance series, published in HCCA's *Compliance Today.*

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New Medicare Standards for DMEPOS Suppliers

Strafford Webinar

April 7, 2011

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Topics to Cover

- New Medicare enrollment rules with DMEPOS suppliers in "high risk" category -- effective 3/25/2011.
- DMEPOS supplier Medicare revalidation considerations and advice.
- Responding to contractor inquires.

Provider and Supplier Risk Categories

42 C.F.R. § 424.518

- CMS established three categories of providers and suppliers based on perceived risk of fraud:
  - Limited Risk,
  - Moderate Risk, or
  - High Risk
- More rigorous enrollment screening procedures as the perceived risk increases.

Provider and Supplier Risk Categories

TABLE 1—CATEGORY OF RISK AND REQUIRED SCREENING FOR MEDICARE PHYSICIANS, NON-PHYSICIAN PRACTITIONERS, PROVIDERS, AND SUPPLIERS

Type of screening required	Limited	Moderate	High
Verification of any provider/supplier-specific requirements established by Medicare	X	X	X
Conduct license verifications, (may include licensure checks across States)	X	X	X
Database Checks (to verify Social Security Number (SSN), the National Provider Identifier (NPI), the National Practitioner Data Bank (NPDB) licensure, an OIG exclusion, taxpayer identification number, tax delinquency, death of individual practitioner, owner, authorized official, delegated official, or supervising physician)	X	X	X
Unscheduled or Unannounced Site Visits		X	X
Criminal Background Check			X
Fingerprinting			X

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Provider and Supplier Risk Categories

Table 6. Final Medicare Providers and Suppliers Categories Designated to the "Limited" Level for Screening Purposes

Provider/Supplier Category
Physician or non-physician practitioners and medical groups or clinics, with the exception of physical therapists and physical therapist groups
Ambulatory surgical centers, competitive acquisition program/Part B vendors, end-stage renal disease facilities, Federally qualified health centers, histocompatibility laboratories, hospitals, including critical access hospitals, Indian Health Service facilities, mammography screening centers, mass immunization roster billers, organ procurement organizations, pharmacies newly enrolling or revalidating via the CMS-855B, radiation therapy centers, religious non-medical health care institutions, rural health clinics, , and skilled nursing facilities.

Provider and Supplier Risk Categories

Table 7. Final Medicare Providers and Suppliers Categories Designated to the "Moderate" Level for Screening Purposes

Provider/Supplier Category
Ambulance suppliers, community mental health centers; comprehensive outpatient rehabilitation facilities; hospice organizations; independent diagnostic testing facilities; independent clinical laboratories; physical therapy including physical therapy groups and portable x-ray suppliers.
Currently enrolled (revalidating) home health agencies.

Table 8. Final Medicare Providers and Suppliers Categories Designated to the "High" Level for Screening Purposes

Provider/Supplier Category
Prospective (newly enrolling) home health agencies and prospective (newly enrolling) suppliers of DMEPOS..

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Licensure and Database Checks

- Licensure -- State licensing data:
  - Verify still in effect, correct location, any sanctions imposed.
  - When: initial enrollment, on monthly basis, revalidation.
- Database --initial enrollment, some monthly, revalidation:
  - Check all names on the CMS-855S form against the OIG List of Excluded Parties and the GSA Debarment List.
  - All Social Security numbers listed on the CMS-855S are electronically matched against the SSA's database. CMS contractors receive a monthly file that lists individuals who have been reported as deceased to the SSA.
  - The provider's legal name and tax identification number verified via the submission of the IRS documentation (e.g., CP-575).
  - The CMS 855S data is compared against the NPI data in the NPPES database.
  - NPDB – no procedures in place yet to verify NPDB information.

Site Verification Visits

- June 2006 enrollment regulation changes authorized CMS to conduct on-site reviews to determine if "operational." Site verification visits differs from NSC inspection to determine compliance with supplier standards.
- Final 2011 enrollment regulations:
  - CMS noted it already had authority to "conduct ad hoc pre- and post enrollment site visits to any prospective … or any enrolled Medicare provider or supplier."
  - Although primary purpose is to determine if "operational" the "contractor may also verify established supplier standards or performance standards" to ensure "compliance with program requirements."

Site Verification Visits

- Operational means the provider or supplier [PIM CMS Pub. 100-08, Ch. 15 § 1.1]:
  - Has a qualified physical practice location,
  - Is open to the public for the purpose of providing health care related services,
  - Is prepared to submit valid Medicare claims; and
  - Is properly staffed, equipped, and stocked (as applicable, based on the type of facility or organization, supplier specialty, or the services or items being rendered) to furnish these items or services.

Site Verification Visits

Additional Rules for DMEPOS Suppliers -- Effective 9/27/10 generally require:

- Operational practice location – minimum of 200 square feet.
- Permanent, durable sign which is visible at the main entrance and identifies the DMEPOS supplier.
- CMS 855S form changed to require reporting days & hours of operation.

Site Verification Visits

CMS Guidance for Site Verification Visits for providers and non-DMEPOS suppliers (PIM CMS Pub. 100-08, Ch. 15 § 20):

- Should be done Monday - Friday (excluding holidays) during:
  - The provider or supplier's posted business hours, or
  - If no hours posted, then between 9 a.m. and 5 p.m.
- First attempt:
  - If obvious signs that facility or practice location is no longer operational, then no second attempt is required.
  - If facility or practice locations is closed but no obvious indications it is non-operational, then make a second attempted site visit on a different day during the posted hours of operation.
- CMS instructs the NSC to continue to conduct onsite inspections consistent with NSC's Statement of Work.

Site Verification Visits

- Inspectors conducting site visits required to:
  - Document the date and time of the attempted visit.
  - Take photographs of the business as appropriate. Date and time stamp the photographs.
  - Fully document observations made – facility vacant, eviction notice, space occupied by another provider or supplier.
  - Write a report of findings.
  - Sign a declaration stating the facts and verifying the completion of the site visit.

Site Verification Visits

- Steps to take to avoid a revocation action based on an unsuccessful site visit:
  - Confirm that current and complete data regarding practice location is on file.
  - Timely report any change in business name, address, hours of operation.
  - Ensure that existing signage is accurate, including posted hours of operation.
  - Update enrollment data to include information that would be necessary to find the practice location.

Site Verification Visits

- Concerns with Site Verification Visit policy:
  - Site Visits: no procedural safeguards to protect legitimately operating business:
    - Inspector fails to gain access during hours of operation -- could require inspector to call supplier to notify of attempted visit.
    - NSC failure to have entered current address in PECOS database in response to supplier revalidation or change of information filing -- could require temporary deactivation with opportunity to prove compliance with requirements.

Criminal Background Checks and Fingerprint Screening

- Individuals with a 5% or more direct or indirect ownership interest.
  - Must submit fingerprints for national background check.
  - When: in conjunction with submission of enrollment application and within 30 days of request by NSC to do so.

NOTE: Only provision in final rules that did not become effective 3/25/2011.

Other Changes in Enrollment Rules

- Enrollment and Revalidation Application Fees for all "institutional" providers (42 C.F.R. § 424.514):
  - Includes DMEPOS suppliers.
  - Amount is $505 for 2011 with annual update.
  - May request "hardship" exception.
- Temporary Enrollment Moratoria (42 C.F.R. § 424.570(a)):
  - If determined to be "necessary to combat fraud, waste, or abuse."
  - Initial 6 month moratorium which can be renewed.
- Suspension of Payments (42 C.F.R. §§ 405.370 and 405.371):
  - During an investigation of a "credible allegation of fraud" i.e., from a reliable source with an "indicia of reliability."
  - Sets an 18-month time limit for the payment suspension except in certain specific situations.
- Requirements for Medicaid revalidations and terminations.

Other Changes in Enrollment Rules

Medicaid Enrollment Screening 42 C.F.R. §§ 455.410 and 455.450

- State must enroll all ordering or referring physicians or other professionals rendering Medicaid services.
- Must identify limited, moderate, and high risk categories of providers with similar screening requirements for each category.
- Identifies specific situations in which the State must adjust the risk category.
- Timing of screening is the same: initial, new practice location, and re-enrollment or revalidation.

Medicare Revalidation

- DMEPOS suppliers are required to revalidate enrollment information:
  - Change in terminology for from every 3-year re-enrollment to every 3-year revalidation.
  - Within 60 days of the NSC's request to do so.
  - May voluntarily revalidate enrollment.
- Failure to do so could result in revocation of billing privileges.
- Revalidation does not negate the need to timely report changes in enrollment data -- 30 days to report <u>any</u> changes in <u>any</u> information on the CMS 855S form.

Tips for the Completing CMS 855S Form

- Names are important: legal and trade name -- be sure the signage is consistent with name listed for Practice Location in Section 4.
- If something is unusual, provide comments.
- Reporting Ownership Interests:
  - All 5% or more owners – individuals or entities unless partnership then all owners.
  - Financial ownership - Secured interest in 5% or more of the total property and assets of the enrolled supplier.
- Reporting Controlling Interests:
  - All officers and governing body members (directors, trustees).
  - Any Authorized and Delegated Officials.
  - At least one Managing Employee.

Tips for Post-Submission Follow-up

- Periodically follow-up with the assigned credentialing specialist:
  - Need to ensure that development letter has been received. Letter could inadvertently be sent to the wrong address, not delivered as sent, or misplaced following delivery.
  - To track the process to be sure forms are being timely processed.
- Timely respond to all requests.
- Prepare for site verification visit.
- Keep copies of fax confirmations, overnight delivery confirmations, and telephone calls.

Enforcement Efforts Increasing

- Effective June 2006: Change in regulations to allow the imposition of sanctions for failing to provide timely updates:
  - Deactivation of billing privileges.
  - Revocation of billing privileges.
- Effective August 2008: Implemented a *one- to three-year bar to Medicare re-enrollment* following a revocation.
- Effective January 2009: Change to authorize CMS to initiate certain *overpayment actions* for services provided from the date of the reportable event.
- Effective September 2010: Change to authorize CMS to initiate *overpayment actions* for DMEPOS supplier from date of final adverse action.

Sanctions for Failing to Comply

- Deactivation -- temporary suspension of billing privileges without termination of the supplier agreement. May need to submit new CMS 855S form to obtain reactivation.
- Revocation -- automatic termination of supplier agreement:
  - Generally, effective 30 days following notice.
  - Exception if based on final adverse action, then effective date of the action.
  - Becomes reportable event to Medicare (for other enrollments under the same legal entity or situations in which revoked entity holds an ownership or controlling interest), Medicaid, other third party payers, and licensing agencies.
- Overpayment action following revocation for DMEPOS supplier due to "final adverse action" from date of action.
- Automatic 1-3 year bar to re-enrollment following revocation.

Re-enrollment Bar

- Bar itself is not discretionary with the exception of revocation for failing to submit application fee or hardship waiver request.
- Length of bar is discretionary for most revocations and is to be based on the severity of the basis for revocation.
- Exceptions:
  - Failure to report final adverse action: 1-year if already enrolled, 3-years if new enrollee.
  - Failure to timely respond to revalidation request: 1-year bar.
  - Failed site visit: 2-year bar.
  - Submitting claims after license suspension or felony conviction: 3-year bar.

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DMEPOS Supplier Standards Enforcement Trends:

A Tale of Two Governments

Presented by

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April 7, 2011

Supplier Standards – Some Important Enforcement-Related Milestones

1992 Supplier Standards promulgated; National Supplier Clearinghouse established

1996 CMS institutes site inspection pilot

1997 OIG audit finds that suppliers only fully meeting one of 11 standards

1999 CMS/NSC expands site inspection pilot

2001 OIG audit finds 56% of suppliers non-compliant with at least one Supplier Standard

2002 CMS/NSC begins program of random, unannounced site inspections and inspections prior to reenrollment

2004 GAO report notes CMS/NSC statements that Supplier Standards are “broad,” “not explicit,” “difficult to interpret”

(e) *Failure to meet standards—*

(1) *Revocation.* CMS revokes a supplier's billing privileges if it is found not to meet the standards . . . Except as otherwise provided in this section, the revocation is effective 30 days after the entity is sent notice of the revocation as specified in § 405.874 of this subchapter.

(2) *Overpayments associated with final adverse actions.* CMS or a CMS contractor may reopen (in accordance with § 405.980 of this chapter) all Medicare claims paid ***on or after the date of a final adverse action*** (as defined in paragraph (a) of this section) in order to establish an overpayment determination.

Final adverse action means one or more of the following actions:

(i) A Medicare-imposed revocation of any Medicare billing privileges

(ii) Suspension or revocation of a license to provide health care by any State licensing authority

(iii) Revocation for failure to meet DMEPOS quality standards

(iv) A conviction of a Federal or State felony offense (as defined in § 424.535(a)(3)(i) within the last 10 years preceding enrollment

(v) An exclusion or debarment from participation in a Federal or State health care program.

Administrative Enforcement

- *Thus, the regulation now permits recoupment* ***as of the date of these specified adverse actions.***
- Confirms that any recoupment authority related to non-compliance with Supplier Standards is ***prospective only***.
- No provision authorizing reopening/recoupment retroactive to the date of non-compliance.

Administrative Enforcement

- ALJ/DAB decisions in appeals of revocation actions, confirm that administrative remedies for non-compliance with Supplier Standards do not include retrospective recoupment.
- Medisource Corp. v. Palmetto GBA and NSC illustrates this point:
  - NSC revoked Medisource's supplier number for non-compliance with the standard requiring suppliers to have an appropriate physical site
  - ALJ agreed revocation was appropriate but determined that supplier had later moved to an appropriate site; the ALJ reinstated Medisource's supplier number from the date of compliance
  - DAB upheld ALJ
  - Despite finding that Medisource was out of compliance with the physical site Supplier Standard, administrative remedies did not include recoupment of payments made during period of non-compliance

False Claims Act Elements

- To succeed in an FCA action, the government or a whistleblower must prove

  (1) that the defendant presented or caused to be presented to the US government a claim for payment or approval, or a document to facilitate the payment of a false claim;

  (2) that the claim or document was false or fraudulent;

  (3) that the defendant knew that the claim was false or fraudulent or acted with reckless disregard of the truth or falsity of the claim; and

  (4) that the false statement at issue was material to the government's decision to pay the claim.

False Certification of Compliance

- Even if claims are literally true (*i.e.*, have no false statements on the face of the claim), most courts have held that the claims may be rendered "legally false" by virtue of an implied or express certification of compliance with certain laws and regulations.
- However, courts have generally limited the application of the false certification theories to laws and regulations that are "conditions of payment."
- In other words, when a provider submits a Medicare claim, it does not certify that it has complied with all conceivable laws and regulations – but only those that are directly linked to the government's decision to pay.

- **Conditions of Participation/Conditions of Payment Dichotomy**
- **U.S. ex rel Conner v. Salina Regional Health Center** (10th Cir 2008)
  - Whistleblower action alleging hospital violated the FCA by failing to comply with CoPs relating to quality of care, adequate staffing, etc.
  - District Court dismissed, finding that Medicare payment to the hospital was not conditioned on the hospital's compliance with the conditions of participation
  - Tenth Circuit affirmed:

    "Based on the fact that the government has established a detailed administrative mechanism for managing Medicare participation, we are compelled to conclude that although the government considers substantial compliance a condition of ongoing Medicare *participation*, it does not require perfect compliance as an absolute condition of receiving Medicare *payments* for services rendered."

- **One District Court has relied on the same reasoning to find that Supplier Standards are not Conditions of Payment**
- **US ex rel. Cooper v. Gentiva Health Services** (W.D. Pa. 2003)
  - Whistleblower action alleging, *inter alia*, an infusion pump supplier violated the FCA by failing to comply with the equipment maintenance and repair requirements set forth in the Supplier Standards.
  - District Court dismissed finding that
    - the supplier's Form 855 certification that it would meet all supplier standards was a condition of enrollment not a condition of payment; and
    - the Supplier Standards are not conditions of payment

      "Section 424.57 makes abundantly clear that the proper redress for violations of the standards established therein is not denial of payment, but revocation of the supplier's billing privileges…"

DOJ's contrary view

- In two pending FCA cases, DOJ contends Medicare payment ***is*** conditioned on compliance with the Supplier Standards.

U.S. ex rel. Jamison v. McKesson Corp. (N.D. Miss.)

- DOJ alleges that McKesson set up a "sham" DME supply company to "capture Medicare Part B reimbursement for a nursing home operator.
- Complaint includes an allegation that because the supplier failed to fully comply with DME Supplier Standards, it was not functionally equipped to deliver DME supplies.

U.S. ex rel. Williams v. Renal Care Group (M.D. Tenn.)

- DOJ alleges that a dialysis corporation's subsidiary DME supplier was not a "legitimate" supplier because it was used to capture higher reimbursement available to DME suppliers but not dialysis facilities.
- Complaint includes allegations regarding supplier's purported non-compliance with specific Supplier Standards; asserts they are condition of payment.

Defending Against FCA Actions Based on Non-Compliance with Supplier Standards

- No falsity
  -- no misrepresentations on claims
  -- no misrepresentations on enrollment forms
- Supplier Standards not a conditions of payment
  -- administrative remedies do not include recoupment
  -- OIG reports do not recommend recoupment
- Government knowledge/approval
  -- site inspections/reenrollment
- Vagueness/Ambiguity