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A Primer on CMS' DMEPOS Accreditation Standards

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DME Competitive Bidding

- Section 302 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) mandated certain Medicare accreditation standards and nationwide competitive bidding for most DME.
- MMA requires suppliers to meet numerous quality standards as a condition to the award of a contract under the Medicare DMEPOS Competitive Bidding Program.

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Objectives of the Competitive Bidding Program

- To implement competitive bidding for DME and use the process to determine appropriate prices for categories of DME covered by Medicare Part B;
- To protect beneficiary access to quality DME;
- To reduce the amount Medicare pays for DME and bring the reimbursement amount more in line with that of a competitive market; and
- To reduce fraud.

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Where are we?

- April 10, 2007 CMS publishes final rules for the new Medicare DMEPOS Competitive Bidding Program and moves to implement the program in the ten largest MSAs
- Summer 2007 Bids submitted from suppliers; CMS awards approximately 325 contracts to qualified suppliers amid widespread criticism from the industry
- July 1, 2008 Program implemented
- July 15, 2008 Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) enacted; supplier contracts terminated; 18 month delay of competitive bidding program implemented; Round 1 re-bid ordered for 2009.

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Are we there yet?

- January 16, 2009 CMS publishes interim final rules amending changes to the original final rule as a result of MIPPA
- May 4, 2009 DME providers, as a condition of the issuance or renewal of a provider number, and therefore a requirement to bid must have a surety bond of \$50,000 in place
- Summer 2009 (est.) Bidder registration and submission of re-bids for round one
- September 30, 2009 Accreditation deadline
- 1st Quarter 2010 (est.) Winners announced; re-bid implemented

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Recap - Key Dates

- **May 4, 2009:** Surety bond required for suppliers seeking issuance of new or renewal provider numbers
- **October 1, 2009:** Accreditation Deadline*
- **October 2, 2009:** Surety bond in place for current DME suppliers

* Unless a grace period applies. For grace period to apply, a supplier must have submitted its application for accreditation to a CMS approved accreditation organization and be waiting for the process to be completed.

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Basic Information

- The MMA requires CMS to apply quality standards to suppliers of certain items and services:
 - Covered items defined in Section 1834 (a)(13)
 - Prosthetic devices, orthotics and prosthetics described in Section 1834(h)(4)
 - Items and services describe in Section 1842(s)(2)

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Basic Information

- Covered items include:
 - medical supplies (including catheters, catheter supplies, ostomy bags, and supplies related to ostomy care)
 - Home dialysis supplies and equipment
 - Therapeutic shoes
 - Parenteral and enteral nutrients, equipment, and supplies
 - Electromyogram devices
 - Salivation devices
 - Blood products
 - Transfusion medicine
 - Prosthetic Devices and orthotics

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Accreditation Criteria

- All DMEPOS suppliers must comply with published Quality Standards in order to retain a supplier billing number and to receive Medicare payment.
- Exemption for certain DME providers:
 - Physicians
 - PT, OT, Speech Language Pathologists
 - Physician Assistants
 - Nurse Practitioners, Clinical Nurse Specialists
 - Clinical Social Workers, Clinical Psychologists
 - Opticians, Audiologists

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Quality Standards

- Quality standards comprised of three separate categories:
 - Business Service Requirements
 - Supplier Product-Specific Service Requirements
 - Appendices for Certain Supplies and Equipment

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Business Service Requirements

- Administration
- Financial Management
- Human Resources Management
- Consumer Services
- Performance Management
- Product Safety
- Information Management

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Administration

- The supplier shall have one or more individuals who perform leadership functions with the authority, responsibility and accountability to direct the organization and its key activities and operations.
- The supplier must obtain and provide quality equipment, items, and services to beneficiaries.
- The supplier must have a physical location and display all licenses, certificates and permits required to operate the business.
- The supplier shall only provide DMEPOS that meet applicable FDA requirements and device effectiveness and safety standards.
- Compliance with all applicable laws, regulations, manuals, guidances and policies.

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Administration

- Implementation of business practices to prevent and control fraud, waste and abuse and ensure compliance with applicable laws and regulations.
 - Compliance program
 - Fraud, Waste and Abuse training

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Financial Management

- The supplier shall implement financial management practices that ensure accurate accounting and billing to beneficiaries and the Medicare program.
- The supplier shall manage and track revenues and expenses on an ongoing basis, including the following:
 - Reconciling charges to beneficiaries
 - Having an operating budget, as appropriate to the business's size and scope of services

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Human Resources Management

- The supplier shall implement policies and issue job descriptions that specify personnel qualifications, training, certifications/licensures experience, and continuing education requirements.
- Technical personnel shall be competent to perform designated tasks.
- Professional personnel shall be licensed, certified, or registered and function within their scope of practice as required by applicable state standards.

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Consumer Services

- When providing items or services, the supplier must:
 - Provide clear, written or pictorial, and oral instructions related to the use, maintenance, and potential hazards of the items/equipment
 - Provide information regarding expected time frames for receipt of delivered items
 - Verify that the items were received
 - Provide essential contact information for rental equipment and options for beneficiaries to rent or purchase equipment
 - Provide contact information for customer service, regular business hours, after-hours access, and emergency coverage
- Timely response to beneficiary complaints and notice of unavailability of items, services or equipment.

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Performance Management

- The supplier shall implement a performance management plan that measures outcomes of consumer services, billing practices, and adverse events, including, at a minimum:
 - Beneficiary satisfaction with and complaints about products and services
 - Timeliness of supplier's response to questions, problems, and concerns
 - Impact of the supplier's business practices on the adequacy of beneficiary access to equipment, items, services
 - Frequency of billing and coding errors
 - Adverse events suffered by beneficiaries due to inadequate services or malfunctioning equipment/items

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Product Safety

- The supplier must implement a program that promotes the safe use of equipment and minimizes safety risks, including:
 - Maintenance plan for equipment
 - Investigation of injuries or infections
 - Contingency plan for emergencies
 - Verification that products dispensed to beneficiaries are not adulterated or misbranded

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Information Management

- The supplier shall maintain accurate and secure records in accordance with the HIPAA privacy and security standards.
- The American Recovery and Reinvestment Act (ARRA) of 2009 Imposes the most significant set of privacy and security changes for the health care industry since the initial adoption of the HIPAA Privacy Rule.
 - provides substantial new authority for enforcement of HIPAA violations
 - adds significant penalties for HIPAA violations
 - adds new security breach notification requirements
 - effectively requires business associates to comply with all HIPAA requirements

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New Enforcement Mechanisms

- Substantially increases the amount of a penalty that may be imposed for violations of the rules, from the current high of \$25,000 to as much as \$1.5 million.
- State Attorneys General granted explicit authority to enforce the HIPAA rules.
- Explicitly permits enforcement actions against individuals employed by health care entities.

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Security Breach Notification

- Requires that most breaches be reported not only to affected consumers but also to the government (and in some cases, to media outlets).
- Broader than most state notification statutes:
 - applies to breaches involving *any* kind of personal information (not just specific kinds set forth in state statutes, like SSNs).
 - notification required irrespective of "risk of harm."
- But, new rules apply only to "unsecured" information; if provider utilizes encryption, it can avoid many requirements.

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Extension of HIPAA Requirements to Business Associates

- Business associates effectively required to maintain full compliance with HIPAA Privacy and Security Rules.
 - Under current regime, business associates (i.e., vendors) typically sign contracts with health care clients pursuant to which the business associate agrees by contract to assume compliance with selected HIPAA requirements.
 - ARRA now obligates business associates by law to comply with all HIPAA requirements, rather than the selected requirements included in business associate agreements.
 - *Best practices tip:* pharmacies should review/revise existing business associate agreements to incorporate new requirements, as well as develop standard contractual provisions for future contracts.

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Supplier Product-Specific Service Requirements

- CMS Quality Standards, Section II
 - Intake and Assessment
 - Delivery and Set-up
 - Training/Instruction to Beneficiary
 - Follow-up

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Intake and Assessment

- The supplier shall consult with the prescribing physician as needed to confirm the order and to recommend any necessary changes, refinements, or additional evaluations to the prescribed equipment.
- Review the beneficiary's record as appropriate and incorporate any pertinent information related to the beneficiary's conditions.
- Accurate recordkeeping of prescriptions, CMNs and pertinent documentation from the beneficiary's prescribing physician.

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Delivery and Set-up

- Provide the equipment in the time scheduled.
- Perform any adjustments.
- Provide or arrange for a loaner-except for orthotics and prosthetics.
- Equipment delivered has to be consistent with what was ordered.

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Training/Instruction

- The supplier must provide appropriate information related to the set-up, features, routine use, troubleshooting, cleaning, infection control practices, and maintenance of equipment.
- Provide written instructions for initial equipment.
- Document in the beneficiary record that the patient/caregiver received and understood the instructions.

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Follow-up

- The supplier must provide follow-up services to the beneficiary and/or caregiver, consistent with the type of equipment, item and service provided.
 - Place communications in the beneficiary's record
 - Adequately documented

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Quality Standards - Appendices

- Appendix A: Respiratory Equipment, Supplies, and Services
- Appendix B: Manual Wheelchairs and PMD, including Complex Rehab and Assistive Technology
- Appendix C: Custom Fabricated, Custom Fitted, Custom-Made Orthotics, Prosthetic Devices, Somatic, Ocular and Facial Prosthetics, and Therapeutic Shoes and Inserts

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Basic Information - Accreditation

- CMS has approved the following organizations for accreditation:
 - The Joint Commission (www.jointcommission.org)
 - National Association of Boards of Pharmacy (www.nabp.net)
 - Board of Orthotist/Prosthetist Certification (www.bocusa.org)
 - The Compliance Team, Inc. (www.exemplaryprovider.com)
 - American Board for Certification in Orthotics & Prosthetics, Inc. (www.abcop.org)
 - The National Board of Accreditation for Orthotic Suppliers (www.nbaos.org)
 - Commission on Accreditation of Rehabilitation Facilities (www.carf.org)
 - Community Health Accreditation Program (www.chapinc.org)
 - HealthCare Quality Association on Accreditation (www.hqaa.org)
 - Accreditation Commission for Health Care, Inc. (www.achs.org)

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Surety Bond Requirements

- As of May 4, 2009, applies to suppliers seeking to enroll or change the ownership of a DMEPOS supplier.
- Applies to each assigned NPI for which the DMEPOS supplier is seeking to obtain Medicare billing privileges.
- Existing DMEPOS suppliers have until October 2, 2009 to submit a surety bond for each assigned NPI.
- Suppliers enrolling a new practice location also must submit a new surety bond or an amendment or rider to the existing bond, showing the new practice location is covered by an additional base surety bond of \$50,000.
- Some exemptions from bond requirements:
 - Certain physician and non-physician practitioners
 - OT, PT, speech language pathologists
 - Registered nurses, clinical nurse specialists
 - clinical social workers, clinical psychologists

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FAQ

- **Question:** Must I obtain accreditation to acquire or retain my Medicare Part B supplier billing number?
 - Yes.
- **Question:** My pharmacy is not planning to seek accreditation because we will not be participating in this round of competitive bidding and we are not planning to continue as a Medicare provider. Is there any downside to this approach?
 - *This is unclear. It is possible that state Medicaid agencies, as well as commercial payors, could require accreditation as a condition to continued participation in their programs.*

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Additional Resources

- **CMS DME Supplier Enrollment:**
http://www.cms.hhs.gov/MedicareProviderSupEnroll/03_DeemedAccreditationOrganizations.asp#TopOfPage

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Questions

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