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Editors: Leslie Demaree Goldsmith and Carel T. Hedlund

DMEPOS Suppliers Beware – Operational Changes May Be Required to Avoid Revocation

By: Donna Senft

CMS continues its efforts to reign in fraudulent suppliers, catching legitimate businesses in the net that it casts. On August 27, 2010, CMS released final regulations "Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards [PDF]," which expand and clarify the supplier standards. Although CMS certified that "this rule will not have a significant economic impact on a substantial number of small entities," many non-retail specialty suppliers may disagree. CMS determined it could provide this certification since the regulations "are primarily procedural and do not require DMEPOS suppliers to incur additional operating costs."

The publication of these final regulations comes just five months shy of the three-year time period CMS had to finalize the proposed rules without having to begin the process anew. The proposed rule [PDF], published on January 25, 2008, was the subject of a prior *Payment Matters* article, "Another Step Designed to Reign in Unscrupulous DMEPOS Suppliers." In finalizing the regulations, CMS considered 208 timely submitted comments to the proposed rule.

CMS acknowledged that the vast majority of Medicare-enrolled DMEPOS suppliers are small entities; however, CMS believed that most legitimate DMEPOS suppliers already comply with the standards adopted by this rule. With the exception of the phase-in period discussed below, the new regulations are effective September 27, 2010.

Proposed Changes Adopted By CMS

Before discussing the proposed changes, it is important to understand that the supplier standards apply to all DMEPOS suppliers, *including Part A providers (e.g., hospitals, nursing facilities, home health agencies)* that are also enrolled to furnish DMEPOS items and services. Some of the requirements of this final rule were

standards that the National Supplier Clearinghouse (NSC), the enrollment contractor for DMEPOS suppliers, had by policy already been requiring of DMEPOS suppliers.

- **Services must adhere to state license requirements and services requiring state licensure must be provided by W-2 employees:**
  - CMS reinforced that the onus is on the supplier, not the NSC, which may not have previously identified that a supplier lacked the required state license to provide an item or service.
  - CMS stated that for legal entities that have multiple supplier numbers under the same tax identification number or TIN, revocation of one of the supplier numbers due to not being properly licensed "will necessitate the revocation of related businesses associated with that TIN."
  - Exceptions were provided for: (1) suppliers participating in the competitive bidding program and (2) contracting for the licensed services in lieu of using W-2 employees if under the state licensing rules the state allows the services to be provided by contractors.
- **Services must be provided in an "appropriate site," which includes specific signage requirements:**
  - Applies to "closed door" businesses which includes suppliers who only provide services to nursing facility residents.
  - Must maintain an operational practice location that is a minimum of 200 square feet.
  - Must have a permanent, durable sign visible at the main entrance which identifies the supplier. For medical complexes that limit signage outside of the building, the requirement may be met by posting the sign in the building lobby. CMS recognized that outside signage may conflict with zoning ordinances, noting the supplier would need to obtain a zoning waiver or find an "appropriate site" elsewhere. There is a three-year phase-in period for existing suppliers (not those with enrollment applications in process or new applicants) that have long-term leases in place.

- Exception to the minimum square footage requirement was granted for a licensed orthotist or prosthetist in private practice providing custom-fabricated items only.

- **Cell phone, beepers, pagers and answering machines may not be used in lieu of a primary business telephone.**
- **The prohibition against the "direct solicitation" of patients was clarified to include computer, e-mail, instant messaging and in-person contacts, in addition to, the current prohibition against telephone contacts:**
  - CMS clarified that a DMEPOS supplier may not contact a beneficiary by any means based solely on a physician's order. In its commentary, CMS noted the physician would need to request the service on behalf of the beneficiary and indicated that the beneficiary would only need to be aware that a supplier would be making a contact. However, CMS also referenced having the beneficiary complete a consent form giving "permission to share the beneficiary's information with the DMEPOS supplier for the purpose of initiating service." The regulation requires "written permission."
  - Reference to "coercive response internet advertising" that was discussed in the proposed rule was deleted from the final regulation.
  - Television, radio and Internet advertising, and promoting items or services at health fairs and community events is permitted, since it is not the one-to-one contact that is involved in a direct solicitation.
- **Oxygen must be obtained from a state-licensed supplier in states that require such licensure.**
- **Written orders and referral documentation must be maintained for seven (7) years from the date of service.** This particular rule was modified from the proposed rule that set the time period for retention from the date the claim was paid based on comments received.
- **Prohibition against a supplier from sharing a practice location with another supplier:**

- Exceptions were granted to: (1) physicians and non-physician practitioners including physical and occupational therapists, if only supplying DMEPOS items to current patients and (2) Part A providers that have a DMEPOS enrollment under the same ownership.
- CMS refused to consider exceptions for suppliers under common ownership or companies wishing to have a separately enrolled pharmacy and DMEPOS business at the same location.

- **Requirement to be open to the public a minimum of 30 hours per week:**
  - In response to the proposed rule, CMS modified the enrollment application (i.e., the CMS 855S form) to include fields for suppliers to report days and hours of operation. As with any other change in enrollment data, a supplier would need to report a change in hours of operation within 30 days following the change. CMS had proposed to require a 15-day advance notice of a proposed change in hours, which was not adopted in the final rule.
  - The hours of operation must be posted on the outside sign, discussed above, or at the entrance to the supplier.
  - Exceptions were provided for: (1) physicians and non-physician practitioners including physical and occupational therapists, if only supplying DMEPOS items to current patients, and (2) for orthotists and prosthetists supplying custom-fabricated items only.
- **Ability to seek a Medicare overpayment action from the date of an adverse legal action:**
  - CMS agreed with a commenter requesting "adverse legal action" to be defined, to clearly understand what actions may lead to an overpayment.
  - CMS included a definition for "final adverse action."
- **Clarification that the authority to conduct unannounced, on-site inspections and determination of revocation for failing to have an "operational" site:**
  - CMS, the NSC or agents of either entity have the authority to conduct site visits.

- An unannounced follow-up visit will be conducted prior to denying or revoking billing privileges.
- CMS announced that it will be expanding its current funding to support an increased number of planned site visits.
- Although not indicated in this final rule, CMS had previously published manual guidance requiring a two-year bar to re-enrollment when the revocation was due to the failure to maintain an operational site. See Medicare Program Integrity Manual, Pub. 100-08, Ch. 10 § 22.2.

Changes Considered But Not Adopted

Included in the proposed rule were several changes that were not adopted in the final rule for several reasons, none of which included CMS' agreement that the proposed change was not needed.

- Comprehensive liability in the amount of $300,000 per incident and listing the NSC as a certificate holder on the policy. The current supplier standards already require this amount of coverage; and, by policy, the NSC requires that it be listed as a certificate holder on the policy.
- Requiring suppliers that contract out the delivery of items to maintain specific documentation related to the delivery, such as proof of delivery, instruction in the use of the item, and how to contact the supplier.
- Inability to be an enrolled supplier with any delinquent IRS or state tax obligation.

Ober|Kaler's Comments

DMEPOS suppliers need to carefully review the new standards and make the necessary operational changes to comply, since failure to comply is likely to result in a revocation of billing privileges. If hours of operation had not previously been reported, due to the submission of an older version of the CMS 855S form, it would be advisable to complete the applicable sections of the current CMS 855S form to report: (1) days and hours of operation and (2) any particular facts regarding the practice location to avoid a failed site verification visit.

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Donna Senft is author of the blog MedicareforGeeks.com, which provides information relating to the requirements and new initiatives with respect to PECOS (Provider Enrollment, Chain, and Ownership System), the national electronic database for recording and retaining data on Medicare-enrolled providers and suppliers.