

# HEALTH LAW

## Update

NEWS FOR THE CLIENTS AND FRIENDS OF BASS, BERRY & SIMS PLC

### Raising the Bar: CMS Proposes New Enrollment Requirements for DMEPOS Suppliers

February 27, 2008

On January 25, 2008, the Centers for Medicare & Medicaid Services ("CMS") published in the Federal Register a proposed rule setting forth new requirements that suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies ("DMEPOS") must meet in order to establish and maintain enrollment with Medicare.<sup>1</sup> The proposed rule revises certain existing standards and also proposes several new standards, all of which are designed to address CMS' concern about the "easy entry into the Medicare program by unqualified or even fraudulent providers or suppliers" of DMEPOS.<sup>2</sup>

#### **Revisions to Supplier Standards**

Set forth below are some of the more significant modifications and clarifications to existing enrollment standards in the proposed rule:

##### *Licenses*

The proposed rule clarifies that each DMEPOS supplier must directly maintain all federal and state licenses that are required to provide licensed services and cannot instead contract with an individual or entity to provide the licensed services.<sup>3</sup> In particular, if a state requires a certain service be provided by a licensed individual, the DMEPOS supplier should hire the individual as a W-2 employee, and not as an independent contractor, in order to meet the requirement.<sup>4</sup>

<sup>1</sup> 73 Fed. Reg. 4503 et seq. (Jan. 25, 2008).

<sup>2</sup> Id. at 4505.

<sup>3</sup> Id. at 4505-06.

<sup>4</sup> Id. at 4506.

### *Appropriate Site*

The proposed rule also clarifies the requirements for an "appropriate site." Under the proposed rule, the supplier location must have posted business hours, be accessible during posted business hours, have staff on-site during posted business hours, and have appropriate signage.<sup>5</sup> The proposed rule also specifically solicits comments on whether a minimum square footage requirement should be added to the definition of an "appropriate site" and what, if any, appropriate exceptions would apply to such a requirement.

In addition, the proposed rule modifies the standard which currently states that the supplier "[m]aintains a primary business telephone listed under the name of the business locally or toll-free for beneficiaries." The proposed rule specifically excludes the use of cell phones and beepers/pagers as a method of receiving calls, as well as using call forwarding during the posted hours of operation.

### *Insurance Requirements*

CMS also proposes to revise the insurance requirements for DMEPOS suppliers. The proposed rule states that a DME supplier must, prior to submitting its Medicare enrollment application, have comprehensive liability insurance policy in the amount of \$300,000 per incident that covers both the supplier's place of business and all customers and employees of the supplier, and must ensure that the policy remains in force at all times.<sup>6</sup> Additionally, the supplier must list the National Supplier Clearinghouse (NSC) as a certificate holder on the policy and notify the NSC within 30 days of any policy changes or cancellations.<sup>7</sup> If the proposed rule is finalized in its current form, the failure to maintain this insurance at all times will result in revocation of the supplier's billing privileges retroactive to the date the insurance lapsed.

### *Proof of Delivery and DME Instructions*

The final clarification in the proposed rule states that the DMEPOS supplier is solely responsible for delivery of Medicare-covered items and for maintaining proof of delivery in the beneficiary's file. Further, the DMEPOS supplier is responsible for instruction on the use of the durable medical equipment (DME), though CMS may permit the supplier to contract out the instruction, so long as the supplier maintains responsibility for the instruction.<sup>8</sup> All instruction, whether carried out by the supplier or an agent, must be documented in the beneficiary's file.

### **New Enrollment Requirements**

In addition to the clarifications and modifications made by CMS, the proposed rule introduces several new enrollment requirements, some of the more significant of which are summarized below:

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<sup>5</sup> Id. Currently, the rule requires the physical facility to be located on an "appropriate site," but gives little guidance as to what constitutes an appropriate site.

<sup>6</sup> Id. at 4506-07. The current rule does not make it clear that the insurance policy must be in place prior to the submission of the Medicare enrollment application.

<sup>7</sup> Id. at 4507. Currently, the NSC is not required to be listed as a certificate holder on the policy.

<sup>8</sup> Id. at 4507-08. The current rule does not make it clear that the DME supplier remains solely responsible for delivery and instruction regardless of whether it uses a contractor to deliver the items.

### *Documentation of Medical Necessity*

DMEPOS suppliers will be required to maintain ordering and referring documentation (including national provider identifier (NPI) numbers) on the physicians, nurse practitioners, physician assistants, clinical social workers and certified nurse midwives who order DME from the supplier for 7 years after the claim has been paid. The proposed rule specifically indicates that the documentation must be kept with regard to the individual (not the group practice, etc.) who ordered or referred a Medicare beneficiary for the DME and states that the purpose of such a rule is for the DMEPOS supplier to assure itself that the patient's medical record supports the medical necessity for the item. If medical necessity is not adequately documented, the DMEPOS supplier will be liable for the claim unless an advance beneficiary notice (ABN) has been obtained.<sup>9</sup>

### *Prohibition on Space Sharing*

If the proposed rules are enacted in their current form, DME suppliers will not be able to share a practice location with any another Medicare suppliers, including a physician/physician group or other DME supplier.<sup>10</sup> CMS states that such co-mingling of practice locations, operations, staff, and inventory constitutes a "significant risk" to the Medicare program and impedes the ability of CMS and the NSC to ensure that each individual DEMPOS supplier is meeting all the supplier standards.<sup>11</sup> Acknowledging that many physicians and other practitioners have their own DEMPOS supplier number, CMS is soliciting comments on the need to establish an exception to the space sharing proposal for such individuals.

### *Hours of Operation*

In addition to the revision of the "appropriate site" requirements listed above, CMS proposes to require DMEPOS suppliers to be open to the public for a minimum of 30 hours per week, except for those suppliers who are working with custom-made or fitted orthotics and prosthetics. CMS affirms that "all legitimate DEMPOS would need to be open a minimum of at least 30 hours per week in order to attract, retain and serve Medicare beneficiaries."<sup>12</sup> Further, CMS proposes to revise the CMS-855S Medicare enrollment application to ensure that suppliers are able to report changes to their normal operating hours and to indicate that they are meeting the 30-hour requirement.

### *No Tax Delinquencies*

The proposed rule further requires DMEPOS suppliers to certify that they have no IRS or state tax delinquency.<sup>13</sup> With this new requirement, CMS desires to "ensure that Medicare payments are only being made to organizations and individuals who have satisfied existing tax debts...[by having] a basis to revoke the billing privileges of a DME supplier, including physicians and non-physician practitioners who are also enrolled as DME suppliers." Moreover, in order to more fully implement this requirement, CMS will revise the CMS-855S form to require that DME suppliers (1) certify that the supplier does not have an IRS or state tax delinquency, and (2) consent to having CMS verify that

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<sup>9</sup> This requirement will be added at 42 C.F.R. § 424.57(c)(28).

<sup>10</sup> This requirement will be added at 42 C.F.R. § 4242.57(c)(29).

<sup>11</sup> 73 Fed. Reg. at 4508.

<sup>12</sup> Id.

<sup>13</sup> This requirement will be added at 42 C.F.R. §424.57(c)(31).

the information submitted by the supplier regarding the tax delinquency is correct. CMS proposes to define "tax delinquency" as "an amount of money owed to the United States or a State: a conviction or civil judgment for tax evasion, a criminal or civil charge for tax evasion, or the filing of a tax lien."<sup>14</sup>

### *Oxygen*

DMEPOS suppliers will be required to obtain oxygen from a state-licensed oxygen supplier if the state in which the DME supplier is located licenses oxygen suppliers.<sup>15</sup>

### *Overpayments*

Finally, CMS proposes to add a new paragraph specifying that CMS may establish a Medicare overpayment from the date of an adverse legal action or felony conviction (including felony convictions within the 10 years preceding enrollment or revalidation of enrollment) that precludes payment.<sup>16</sup> This aspect of the proposed rule allows CMS to assess and collect overpayment from the date of the reportable event, which CMS indicates is necessary because some DMEPOS suppliers fail to report adverse legal actions and felony convictions within the required 30-day period.

### **Conclusion**

When and if finalized, the new standards would affect DMEPOS suppliers upon application for enrollment, or if they are already enrolled, upon the effective date of the final rule (suppliers who are already enrolled would have to meet all of the new and revised standards when finalized in order to maintain their enrollment).<sup>17</sup>

Comments to the proposed rule must be received by the appropriate CMS office by March 25, 2008. If you have any questions about the proposed rule addressed by this Health Law Update, please contact any of the attorneys in our Healthcare Industry Practice Area, listed on the following page.

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<sup>14</sup> 73 Fed. Reg. at 4508-09.

<sup>15</sup> This requirement will be added at 42 C.F.R. §424.57(c)(27).

<sup>16</sup> 73 Fed. Reg. at 4509.

<sup>17</sup> In addition to the enrollment standards, detailed quality standards for DMEPOS suppliers appear on CMS' website at: <http://www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DMEPOS AccreditationStandards.pdf>. On February 15, 2008, CMS posted what it called "minor changes" to these quality standards, with a deadline for comments of March 15, 2008. See [http://www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DRAFT\\_DMEPOSQualityStandards.pdf](http://www.cms.hhs.gov/MedicareProviderSupEnroll/Downloads/DRAFT_DMEPOSQualityStandards.pdf)

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