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Leslie Demaree Goldsmith

Carel T. Hedlund

S. Craig Holden

Julie E. Kass

Paul W. Kim

Robert E. Mazer

Christine M. Morse

Laurence B. Russell

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Surety Bonds and Accreditation: Is it Worth the Cost to be a DMEPOS Supplier?

Donna J. Senft 410-347-7336 djsenft@ober.com

Recent requirements for DMEPOS suppliers to obtain a surety bond and accreditation have increased the cost of doing business. In implementing these requirements, CMS noted that these increased costs "will require some DMEPOS suppliers to reconsider their participation in the Medicare program." CMS estimated that approximately 40% of the suppliers with annual Medicare revenues of less than \$10,000 and 30% of the suppliers with annual Medicare revenues between \$10,000 and \$24,999 will exit the Medicare program. CMS cautioned new suppliers to develop a business plan and marketing analysis "to determine whether it makes business sense to open and establish a new DMEPOS supplier business."

Surety Bond

The surety bond requirement for DMEPOS suppliers was part of the Balanced Budget Act (BBA) of 1997. In the proposed rule to effect the BBA changes, CMS indicated its intent to implement the surety bond requirements. Prior to the publication of the final rule in October 2000, CMS decided not to proceed with any surety bond requirements at that time. Due to the length of time of the delay in implementing the requirements, CMS had to initiate the process by publishing a second proposed rule, which it did on August 1, 2007. The proposed rule is available on the Internet at:

edocket.access.gpo.gov/2007/pdf/07-3746.pdf. CMS published the final rule in the Federal Register on January 2, 2009. The final rule is available at: edocket.access.gpo.gov/2009/pdf/E8-30802.pdf. Additionally, CMS added Section 21.7 to Chapter 10 of the Medicare Program Integrity Manual to highlight the new requirements related to surety bonds.

As a general rule, DMEPOS suppliers will be required to obtain a \$50,000 surety bond **for each** DMEPOS practice location and each assigned NPI number to which Medicare billing privileges have been granted. There are a few exempted categories of DMEPOS suppliers, mostly licensed professionals that otherwise are subject to disciplinary proceedings and other actions for fraudulent conduct. Government-owned suppliers are also exempt from the surety bond requirements. Additionally, DMEPOS suppliers that pose an elevated risk will be required to obtain a bond in a higher amount.

Donna J. Senft

Susan A. Turner

Associates

Kristin C. Cilento

Joshua J. Freemire

Mark A. Stanley

Lisa D. Stevenson

Emily H. Wein

CMS estimates that the average cost of the \$50,000 surety bond will be \$1,500 annually. A listing of authorized sureties approved to provide the required bond is available on the Department of the Treasury's website at: fms.treas.gov/c570/c570_a-z.html. DMEPOS suppliers that fail to comply with the surety bond requirements are subject to a revocation of billing privileges.

Provisions in the Final Surety Bond Rule:

- An elevated surety bond amount is required for DMEPOS suppliers that
 "pose a significantly higher risk to the Medicare program," i.e.,
 suppliers "with at least one adverse legal action within the 10 years
 preceding enrollment, revalidation, or re-enrollment."
 - o "Adverse legal action" is defined to include:
 - A Medicare-imposed revocation of any Medicare billing privileges;
 - Suspension or revocation of a license to provide health care by any State licensing authority;
 - Revocation or suspension by an accreditation organization;
 - A conviction of a certain Federal or State felony offenses (as defined in 42 C.F.R. § 424.535(a)(3)(A)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or
 - An exclusion or debarment from participation in a Federal or State health care program.
 - The increased bond amount would be an additional \$50,000 for each adverse legal action.
 - Payment of the elevated bond would continue for a three-year duration.
- The bond must guarantee that the surety will pay CMS, within 30 days
 of receipt of a written notice requesting payment, a total of up to the full
 penal amount of the bond in the following amounts:
 - The amount of any unpaid claim, plus accrued interest, for which the DMEPOS supplier is responsible.
 - The amount of any unpaid claims, CMPs, or assessments imposed by CMS or the OIG on the DMEPOS supplier, plus accrued interest.

The written notice must containing sufficient evidence to establish the surety's liability under the bond.

Requirements in Response to Solicited Comments Regarding Exemptions

In the proposed rule, CMS solicited comments on which categories of DMEPOS suppliers should be granted an exception from the surety bond requirements. Among the various categories of suppliers that commenters recommended, CMS provided the following exceptions:

 Exception for physicians and nonphysician practitioners, if the devices are for the practices' own patients and are part of the professional services rendered.

- Exception for state-licensed orthotic and prosthetic personnel in private practices or businesses solely owned by the orthotists and prosthetists and who provide custom-made orthotics, prosthetics or the related supplies.
- Exception for physical therapist and occupational therapists in private practice or businesses solely owned by the therapists if they provide orthotics, prosthetics, and supplies to the therapist's own patients as part of the therapy service.

Changes from the Proposed Rule:

- CMS did not implement the provision generally requiring a \$65,000 bond, an increase from the \$50,000 bond proposed in 1997 based on the Consumer Price Index. CMS confirmed that any increase in the bond amount would occur through future rulemaking rather than incorporating rules for an annual adjustment.
- CMS extended the grace period for existing providers to comply with the surety bond requirement from the proposed 60-day period to a nine-month grace period. Compliance for new enrollees was set at 120 days from the effective date of the final rule. Refer to the compliance dates appearing below.
- CMS modified the provisions to indicate that liability is on the surety whose bond was in effect when the payment, overpayment, or other event giving rise to the claim occurred.
- CMS deleted the option for providing evidence of an annual surety bond, requiring compliance through a continuous bond.
- CMS revised the provisions related to cancellation of the bond to reflect
 that it is the DMEPOS supplier's right alone to cancel the bond. If a
 DMEPOS supplier chooses to change sureties, it must provide notice
 to both the surety and the NSC 30 days prior to the cancellation
 effective date. Under the revised rule, the surety is only obligated to
 notify the NSC if its coverage of the DMEPOS supplier has lapsed.
- CMS removed certain definitions and revised others in response to comments to the proposed definitions.

Accreditation

CMS initially implemented a requirement for DMEPOS suppliers to be accredited in an August 18, 2006 final rule that also laid the groundwork for timely implementation of the Medicare DMEPOS Competitive Bidding Program. This final rule is available on the CMS website at: cms.hhs.gov/inpatientrehabfacpps/downloads/cms_1540f.pdf. Due to legislation that delayed expansion of the Competitive Bidding Program, the accreditation requirements were not initiated as planned.

The requirement for accreditation was then included among the DMEPOS quality standards that were implemented as part of the Medicare Improvements for Patients and Provider Act of 2008 (MIPPA). The Act, however, gave CMS the authority to exempt certain professionals from the accreditation requirement. In an October 2, 2008 Payment Matters, we highlighted the professionals that CMS has exempted from accreditation. Refer to the article entitled "Practitioners Get Relief from DMEPOS Accreditation Requirements" available on the Ober|Kaler website at:

ober.com/shared_resources/news/newsletters/
payment-matters/2008/paymentmatters-100208-p01.html.

In addition to exempting certain DMEPOS suppliers, certain products are excluded from accreditation, including:

- Drugs used with DME (inhalation drugs and drugs infused with a pump;
- Implantable items; and
- Immunosuppressive drugs and anti-emetic drugs.

In its publications and announcements, CMS has warned DMEPOS suppliers about the time constraints in obtaining accreditation, which takes, on average, four to six months and can be up to nine months. CMS has assured existing suppliers who submitted an application to an accrediting organization, on or before January 31, 2009, that an accreditation decision (either full accreditation or denied accreditation) will be made before the September 30, 2009 deadline.

In implementing the accreditation requirement, CMS recognized the increased burden on DMEPOS suppliers and attempted to minimize the burden by:

- Selecting several accreditation organizations to induce competition and assist in decreasing accreditation costs. A list of approved accrediting organizations and the categories of products and services for each accrediting organization is available on CMS' website at: cms.hhs.gov/MedicareProviderSupEnroll/ Downloads/DeemedAccreditationOrganizations.pdf.
- Asking accreditation organizations, during the selection process, to include a plan that outlined the organization's methodology to reduce accreditation fees for small/specialty suppliers and suppliers that have multiple locations. Requiring accreditation organizations to ensure compliance with the quality standards and to not make accreditation contingent on using consultation services or purchasing manuals.
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Accreditation is not transferable in a change of ownership. The buyer must seek its own accreditation, thus creating timing issues especially if the buyer does not operate any other DMEPOS businesses that are accredited. Since the accreditation approval must be included with the enrollment application, the buyer must obtain accreditation before submitting its application to obtain billing privileges. Under the enrollment rules, the buyer has only 30 days following the change in ownership (CHOW) to be able to bill for services provided after the effective date of the CHOW once billing privileges are granted.

CMS estimates the cost of accreditation to be approximately \$3,000 for a 3-year accreditation, or an annual cost of \$1,000. DMEPOS suppliers that fail to comply with the accreditation requirements are subject to a revocation of billing privileges. Additional information on DMEPOS accreditation is available at: cms.hhs.gov/MedicareProviderSupEnroll/03_DeemedAccreditation Organizations.asp.

New Enrollment Form

The CMS 855S enrollment application has been revised to include new sections for reporting surety bond information and accreditation exempt drugs and pharmaceuticals. The new form is to be used for initial enrollments, reactivations, reenrollments, and to report changes of information. The revised CMS 855S enrollment application is available on the CMS website at: www.cms.hhs.gov/cmsforms/downloads/cms855s.pdf.

Compliance Dates

- Suppliers who applied to participate in the Medicare program after March 1, 2008, were required to submit proof of accreditation with the enrollment application. This included both new suppliers and suppliers acquiring an existing DMEPOS business through a CHOW. Failure to submit proof of accreditation results in a rejection of the enrollment application.
- New suppliers and suppliers who have acquired an existing DMEPOS business through a CHOW will be subject to the surety bond rule effective May 4, 2009.
- Existing suppliers adding a new practice location must provide documentation of a new *surety bond*, or an amendment or rider to the existing bond, showing the new practice location is covered by its own \$50,000 surety bond.
- Existing suppliers have until September 30, 2009, to become accredited.
- Existing suppliers have until October 2, 2009, to comply with the surety bond requirements.

Ober|Kaler's Comments: The combined effect of the surety bond and accreditation requirements, designed to prevent fraudulent conduct, may result in existing DMEPOS suppliers deciding to exit the Medicare program. New DMEPOS suppliers and entities acquiring an existing DMEPOS business need to plan for the extra time, in addition to the expense, required to comply with these new requirements.

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