

DMEPOS Update: CMS Issues Then Delays Interim Final Rule On Competitive Bidding, Issues Final Rule Requiring Surety Bonds and Reverses on Exempting Pedorthists From Accreditation

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CMS Issues Then Delays Interim Final Rule Regarding Competitive Bidding

According to an announcement on February 13, 2009, the Centers for Medicare and Medicaid Services (“CMS”) is postponing the effective date of the durable medical equipment, prosthetics, orthotics and supplies (“DMEPOS”) Competitive Bidding Program (the “New Competitive Bidding Program Rule”) from February 17, 2009, until **April 18, 2009**.¹ The original comment period on the New Competitive Bidding Program Rule remains unchanged and the public has until **March 17, 2009** to submit comments on the substantive policy issues covered in the Rule, which is discussed below. The reason for the effective date postponement is to allow for agency review, in accordance with a White House memorandum regarding management of the federal regulatory process at the start of the Obama administration. The Obama administration could revise the New Competitive Bidding Program Rule in which case the Rule should be re-released with another comment period.

By way of background, on January 16, 2009, CMS released an interim final rule on the New Competitive Bidding Program.² This New Competitive Bidding Program Rule follows up on the July 2008 enactment of the Medicare Improvements for Patients and Providers Act (“MIPPA”) in which CMS made changes to the Competitive Bidding Program including delaying competitive bidding, terminating competitive bidding contracts effective June 30, 2008, and prohibiting payments based on those awarded

¹ CMS, Latest News: “Medicare Announces Updates to the Competitive Bidding Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies,” *available at* http://www.cms.hhs.gov/DMEPOSCompetitiveBid/01_overview.asp.

² 74 Fed. Reg. 2873 (Jan. 16, 2009).

contracts.³ Among other things, the New Competitive Bidding Program Rule delays Round 1 of the DMEPOS Competitive Bidding Program, requires CMS to conduct a second Round 1 competition in 2009 (the “Round 1 Rebid”), and mandates certain changes for both the Round 1 Rebid and subsequent rounds of the program including a process for providing feedback to suppliers regarding missing financial documentation and requiring contractors to disclose information regarding subcontracting relationships.

Our summary of the New Competitive Bidding Program Rule discusses the *current* version of that rule and its regulatory changes. However, as noted above, the Obama administration could revise the Rule; in which case, we will update this *Client Alert* accordingly.

Temporary Delay of the DMEPOS Competitive Bidding Program

MIPPA delayed the DMEPOS Competitive Bidding Program, postponing the start of Round 1 from 2007 to 2009, and the start of Round 2 from 2009 to 2011.⁴ The Metropolitan Statistical Areas (“MSAs”) originally identified as the Competitive Bidding Areas (“CBAs”) for Round 1 of the program will remain the same for the Round 1 Rebid, with the exception of Puerto Rico, which was eliminated for lack of bids.⁵ Similarly, the Round 1 Rebid will include the same product categories previously identified for Round 1 of the program with the exception of negative pressure wound therapy, which was eliminated from Round 1.⁶ Suppliers wishing to participate in the Round 1 Rebid, **including suppliers that were awarded contracts in the original Round 1 bidding process in 2007**, will need to submit new bid applications for the Round 1 Rebidding process.⁷

³ For more information on these MIPPA changes, please review the September 2008 EBG Client Alert entitled *DMEPOS Update: Physicians and Certain Other Professionals Now Exempt from DMEPOS Accreditation Requirements and MIPPA Delays Competitive Bidding, Terminates Round 1 Contracts*.

⁴ 74 Fed. Reg. at 2876, 2880 (revising 42 C.F.R. §§ 414.410(a)(1) and (2)). The interim final rule also provides that a competition for a national mail order competitive bidding program may occur after 2010. *Id.* (revising 42 C.F.R. § 414.410(a)(3)).

⁵ 74 Fed. Reg. at 2875, 2877; “CMS Issues Interim Final Regulation to Restart Competitive Bidding Program,” BNA’s Health Care Daily Report no. 10 (Jan. 16, 2009). These CBAs are: Cincinnati-Middletown (Ohio, Kentucky and Indiana), Cleveland-Elyria-Mentor (Ohio), Charlotte-Gastonia-Concord (North Carolina and South Carolina), Dallas-Fort Worth-Arlington (Texas), Kansas City (Missouri and Kansas), Miami-Fort Lauderdale-Miami Beach (Florida), Pittsburgh (Pennsylvania) and Riverside-San Bernardino-Ontario (California).

⁶ 74 Fed. Reg. at 2875. These product categories are: Oxygen Supplies and Equipment; Standard Power Wheelchairs, Scooters and Related Accessories; Group 2 Complex Rehabilitative Power Wheelchairs and Related Accessories; Mail-Order Diabetic Supplies; Enteral Nutrients, Equipment and Supplies; CPAP, RADs and Related Supplies and Accessories; Hospital Beds and Related Accessories; Walkers and Related Accessories; and Group 2 Support Surfaces (mattresses and overlays) in Miami only. MIPPA also permanently excluded Group 3 complex rehabilitative wheelchairs as a possible category for inclusion in the program and this interim final rule amends 42 C.F.R. § 414.402 to incorporate this exemption. See 74 Fed. Reg. at 2877, 2880 (revising 42 C.F.R. § 414.402).

⁷ 74 Fed. Reg. at 2875; CMS Fact Sheet, “Changes to the Competitive Bidding Program for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (CMS-1561-IFC)” (Jan. 15, 2009), available at <http://www.cms.hhs.gov> (hereinafter “January 15, 2009 CMS Fact Sheet”).

Supplier Feedback Regarding Missing Financial Documentation

Under the New Competitive Bidding Program Rule, Suppliers must submit the same categories of financial documents that were requested for the original Round 1 bidding process. However, unlike the original bidding process, CMS will only require that suppliers provide one (1) year of such documentation rather than the three (3) years originally required. Under the new rule, CMS must notify suppliers that submit their bids within a specific time period whether their bid submissions are missing any of the required financial documentation.⁸ CMS will provide this notification within forty-five (45) days after the end of the “covered document review date,” defined as the later of (i) the date that is thirty (30) days before the final date for the closing of the bidding window or (ii) the date that is thirty (30) days after the opening of the bid window.⁹ For all subsequent rounds of the program, CMS will have ninety (90) days after the end of the covered document review date to provide this notification to suppliers. For all rounds of the program, CMS will allow suppliers to submit any missing information within ten (10) business days after receiving such notice.

Disclosure of Subcontracting Relationships and Accreditation Status

Under the New Competitive Bidding Program Rule, all contract suppliers must notify CMS of any subcontracting relationships they have entered into for the purpose of furnishing items and services under the Medicare contract and whether the subcontractor meets accreditation requirements.¹⁰ These notifications must be made no later than ten (10) days after the date on which the supplier enters into a contract with CMS. If a contract supplier subsequently enters into any subcontracting relationships, the supplier must disclose these relationships to CMS no later than ten (10) days after entering into these relationships. CMS stated that it will issue guidance in the near future regarding this subcontractor notification requirement.

Exemptions for Certain Items

MIPPA requires an exemption from the Competitive Bidding Program for certain DMEPOS items when they are furnished by a hospital to the hospital’s own patients during an admission or on the date of discharge. The New Competitive Bidding Program Rule implements this MIPPA exemption, which applies to the same items that are exempt from the Competitive Bidding Program when they are furnished by physicians to their own patients as part of their professional services including crutches, walkers, canes, folding manual wheelchairs, blood glucose monitors and infusion pumps that are considered durable medical equipment. DMEPOS items provided under this exemption

⁸ 74 Fed. Reg. at 2876-77, 2880-81 (revising 42 C.F.R. § 414.414(d)). The interim final rule includes the definition of “covered documents” provided by MIPPA: financial, tax or other documents required to be submitted by a bidder as part of an original bid submission in order to meet required financial standards.

⁹ 74 Fed. Reg. at 2876, 2880; January 15, 2009 CMS Fact Sheet, *supra* note 7.

¹⁰ *Id.*

will be paid at the single payment amounts established for these items, not at the Competitive Bidding Program rate.¹¹

CMS Issues Final Rule Requiring Posting of \$50,000 Surety Bonds

In the January 2, 2009 *Federal Register*, CMS published a final rule that requires DMEPOS suppliers to post \$50,000 surety bonds as a condition of participating as a Medicare provider (the “Bond Requirement Rule”).¹² The Bond Requirement Rule amends the Medicare Supplier Standards at 42 C.F.R. § 424.57. This Bond Requirement Rule takes effect on **May 4, 2009**, for DMEPOS suppliers seeking enrollment or a change in ownership, and will be effective on **October 2, 2009**, for Medicare-enrolled DMEPOS suppliers.

Certain entities are exempt from the bond requirement, including government-operated suppliers that have provided CMS with a comparable bond under State law; state-licensed orthotic and prosthetic personnel in private practice making custom-made orthotics and prosthetics; physicians and non-physicians providing items only to their own patients as part of their physician or non-physician services; and physical and occupational therapists in private practice.¹³

For new suppliers, the initial bond must be effective on the date the application is submitted to the National Supplier Clearinghouse (“NSC”). If submitting an application pursuant to a change of ownership, the bond may be effective from the date of the purchase or transfer, but if it is effective at a later date, the effective date of the new DMEPOS supplier billing privileges would be the effective date of the bond as validated by the NSC. Suppliers enrolling new practice locations must submit to the NSC a new surety bond or an amendment or rider to an existing bond, showing that the new practice location is covered by an additional base bond of \$50,000 or, if required by the NSC, an elevated bond amount.

If a supplier fails to obtain, file timely or maintain a surety bond, CMS may revoke the supplier’s Medicare billing privileges. The revocation would be effective the date the bond lapsed, so that any payments for items and services furnished on or after that date would need to be repaid to CMS by the supplier. Suppliers that have had “adverse legal actions” may be required to obtain surety bonds of more than \$50,000 if they pose a significantly higher than average risk to the Medicare Trust Funds. “Adverse legal actions” are defined in the regulation as a Medicare-imposed revocation of any Medicare billing number; suspension of a license to provide health care by any State licensing authority, a revocation or suspension of accreditation, a conviction for a Federal or State felony offense within the last ten (10) years preceding enrollment,

¹¹ 74 Fed. Reg. at 2877, 2880 (revising 42 C.F.R. § 414.404).

¹² 74 Fed. Reg. 166 (Jan. 2, 2009).

¹³ Subsection (d)(15)(ii) provides that suppliers that no longer qualify for these exceptions must submit surety bonds to the NSC in accordance with the requirements of subsection (d) within sixty (60) days after it knows or has reason to know that it no longer meets the criteria for an exception.

revalidation or reenrollment; or an exclusion or disbarment from participation in Federal or State health care programs.¹⁴

Surety bonds must include the surety's name and address and must name the supplier as "Principal," CMS as "Obligee" and the surety and its heirs, executors, administrators, successors and assignees, jointly and severally, as "Surety."¹⁵ The bond must declare that actions under the bond may be brought by CMS or CMS contractors. Suppliers must submit bonds that are continuous and contain a guarantee that the surety will, within thirty (30) days of receiving written notice from CMS containing sufficient evidence to establish the surety's liability under the bond of unpaid claims, civil money penalties ("CMPs") or assessments, pay CMS a total of up to the full penal amount in (a) the amount of any unpaid claims, plus accrued interest, for which the supplier is responsible, and (b) the amount of any unpaid claims, CMPs or assessments imposed by CMS or the Office of Inspector General ("OIG") on the supplier, plus accrued interest. Bonds must provide that the surety is liable for unpaid claims, CMPs or assessments that occur during the term of the bond.

If a supplier fails to furnish a bond meeting these requirements listed above or fails to submit a rider when required, or if the supplier's billing privileges are revoked, the last bond or rider submitted by the supplier remains in effect until the last day of the bond coverage period and the surety remains liable for unpaid claims, CMPs or assessments that (a) CMS or OIG imposes or asserts against the supplier based on overpayments or other events that took place during the term of the bond or rider, and (b) were imposed or assessed by CMS or OIG during the two (2) years following the date the supplier failed to submit a bond or required rider, or the date the supplier's billing privileges were terminated, whichever is later.¹⁶

Suppliers may cancel surety bonds, but must provide written notice at least thirty (30) days before the effective date of such cancellation to the NSC and to the surety.¹⁷ Cancellation of a bond is grounds for revocation of the supplier's Medicare billing privileges unless the supplier provides a new bond before the effective date of the cancellation. The liability of the surety continues through the termination effective date. If CMS is notified by a surety regarding a lapse in bond coverage, CMS will revoke the supplier's Medicare billing privileges and, during this lapse, will not pay for items or services furnished by the supplier. Instead, the supplier will be held liable for the items or services and would not be permitted to charge Medicare beneficiaries for such items and services. A surety must immediately notify the NSC regarding any lapse in its coverage of the DMEPOS supplier's coverage.

DMEPOS suppliers that obtain a replacement surety bond from a different surety to cover the remaining term of a previous bond must submit the new bond to the NSC at least thirty (30) days prior to the expiration of the previous bond, so that there is no gap

¹⁴ 74 Fed. Reg. at 187.

¹⁵ *Id.* at 199.

¹⁶ *Id.*

¹⁷ *Id.*

in coverage.¹⁸ If a gap in coverage occurs, the NSC will revoke the supplier's Medicare billing privileges and will not pay for any items or services furnished by the supplier during the gap period. If a supplier changes its bond during the term of an existing bond, the new surety would be responsible for any overpayments, CMPs or assessments incurred by the supplier as of the effective date of the new bond, while the former surety would be responsible for these amounts incurred up to the date of the change of surety.

Finally, the Bond Requirement Rule contains guidelines for holding CMS accountable for payments collected from sureties.¹⁹ If a surety has paid an amount to CMS on the basis of liability that occurred under a bond and CMS subsequently collects from the supplier unpaid claims, CMPs or assessments that were the basis for such liability, CMS must reimburse the surety the amount it collected from the supplier up to the amount paid by the surety to CMS, provided the surety has no other liability to CMS under the bond. Furthermore, if a surety has paid CMS on the basis of liability incurred under a bond and the supplier is subsequently successful in appealing the determination that was the basis of the unpaid claim, CMP or assessment that caused the supplier to pay CMS under the bond, CMS must refund the supplier the amount the supplier paid to CMS to the extent that the amount relates to the matter that was successfully appealed, provided all review including judicial review has been completed on the matter.

CMS Reverses Position on Accreditation of Pedorthists

In a December 8, 2008 written clarification, CMS reversed its position on exempting pedorthists and other selected professionals (orthopedic fitters and athletic trainers among others) from the accreditation requirements for DMEPOS suppliers.²⁰ CMS clarified that MIPPA amended Section 1834(a)(20) of the Social Security Act ("SSA") under which eligible professionals and "other persons" are exempt from meeting the September 30, 2009 accreditation deadline that applies to DMEPOS suppliers unless CMS determines that the quality standards are applicable to such professionals.²¹ SSA Sections 1848(k)(3)(B) and 1861(r) outline the specific professionals to whom this exemption applies: physicians, physical therapists, occupational therapists, qualified speech-language pathologists, physician assistants and nurse practitioners.²² Other professionals, including pedorthists, were the "other persons" originally identified by CMS in the wake of its September 2008 directive.²³ As a result of the December 2008

¹⁸ *Id.*

¹⁹ 74 Fed. Reg. at 199-200.

²⁰ Pedorthic Footwear Association ("PFA"), Pedorthists Now NOT Exempt from Accreditation Requirements (last updated Dec. 10, 2008) (quoting a Dec. 8, 2008 CMS Home Health and Hospice Open Door Forum announcement), available at <http://www.pedorthics.org/LatestNews/BreakingNews/PedorthistsNowNOTExemptfromCMSRequirements/tabid/232/Default.aspx>.

²¹ H.R. 6331, P.L. 110-275, § 154.

²² 42 U.S.C. § 1395w-4(k)(3)(B); *id.* § 1395x(r).

²³ Based on a Sept. 17, 2008 phone call to CMS, pedorthists were among the providers exempt from accreditation.

clarification, however, these “other persons” are limited to orthotists, prosthetists, opticians and audiologists.²⁴

The effect of this December 2008 directive is that pedorthic practices and facilities must have submitted their accreditation applications to designated accreditation organizations by **January 31, 2009**, and must be surveyed and fully accredited by **September 30, 2009**, in order to maintain their Medicare supplier numbers and Medicare billing privileges.²⁵ Pedorthic practices and facilities failing to meet the September 30, 2009 deadline risk having their Medicare supplier numbers deactivated and their Medicare billing privileges suspended by CMS.²⁶ The American Board for Certification in Orthotics, Prosthetics & Pedorthics (“ABC”) has made free accreditation resources available on its website at www.abcop.org/pedorthicaccreditation to help pedorthic practices and facilities work to meet these upcoming deadlines.²⁷ Additionally, ABC plans to directly contact certified pedorthists regarding the accreditation requirements.

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²⁴ PFA, CMS Directive Rescinding Pedorthic Exemption: Written Clarification on Medicare for Patients and Providers Act of 2008 (MIPPA) (last updated Dec. 10, 2008), *available at* <http://www.pedorthics.org/LatestNews/BreakingNews/PedorthistsNowNOTExemptfromCMSRequirements/CMSDirectiveRescindingPedorthicExemption/tabid/263/Default.aspx>. H.R. 616 was introduced in the U.S. House of Representatives on January 21, 2009 and proposes to exempt pharmacists and pharmacies from the Medicare DMEPOS accreditation requirements.

²⁵ PFA, Pedorthists Now NOT Exempt from Accreditation Requirements (last updated Dec. 10, 2008), *available at* <http://www.pedorthics.org/LatestNews/BreakingNews/PedorthistsNowNOTExemptfromCMSRequirements/tabid/232/Default.aspx>.

²⁶ *Id.*

²⁷ The American Board for Certification in Orthotics, Prosthetics & Pedorthics, “CMS Reverses Position on Pedorthic Accreditation Exemption; Pedorthic Organizations Now Required to Become Accredited” (last updated Dec. 10, 2008), *available at* http://www.abcop.org/News_Item.asp?news_id=1210200801.

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