CMS Final Rule Revises Durable Medical Equipment Definition and Finalizes DMEPOS Competitive Bidding Program Regulations

November 10, 2011

On November 10, 2011, the Centers for Medicare & Medicaid Services (CMS) will publish in the *Federal Register* a final rule (CMS-1577-F) that revises the definition of durable medical equipment (DME) and finalizes previously made statutorily required changes to the Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) competitive acquisition program. The following is a summary of these provisions, which were included in the final rule on the End-Stage Renal Disease (ESRD) prospective payment system (PPS) for calendar year (CY) 2012.

CMS Finalizes 3-Year 'Minimum Lifetime Requirement' for New DME

In response to concerns that existing regulations and program instructions do not provide guidance on the specific period of time that equipment must function to be considered "durable", CMS earlier proposed revising the definition of DME at 42 CFR 414.202 to establish a 3-year "minimum lifetime requirement" (MLR) that equipment will be expected to meet to be considered DME for Medicare payment determination purposes. CMS expects that equipment provided under the DME benefit will be "quality items that function consistent with industry standards for a 3 year threshold period." The new definition and requirement will be effective with respect to items classified as DME after January 1, 2012.

The revised definition at 42 CFR 414.202 now reads as follows:

§414.202 Definitions
Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:

(1) Can withstand repeated use.
(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
(3) Is primarily and customarily used to serve a medical purpose.
(4) Generally is not useful to an individual in the absence of an illness or injury.
(5) Is appropriate for use in the home.

CMS reviewed information from a variety of sources, including the Rehabilitative Engineering and Assistive Technology Society of North America, product catalogues, product warranty documents and consumer product reviews. CMS determined that conventional DME items typically have a useful life of three or more years before they require major repairs or need to be replaced. CMS noted in the rule that the 3-year MLR is intended to increase the clarity of the current definition of "durable" and

provide "regulatory weight" to a reasonable benchmark for durability. The definitional change also is intended to help CMS and other stakeholders make consistent informal benefit category determinations and national coverage determinations for DME. In addition, the revised definition will help manufacturers understand how long an item must be able to withstand repeated use for Medicare DME payment purposes. However, the MLR requirement is not replacing the reasonable useful lifetime (RUL) rules that are used to determine how often payment can be made for replacement items. Under the RUL, Medicare will pay for a new product after five years.

In instances in which it is unclear if an item can function for the minimum specified timeframe, CMS will review information and evidence consistent with the current benefit category determination process to determine the expected life of the equipment.

In response to comments, CMS defended the 3-year MLR timeframe against complaints that it is "arbitrary and inappropriate" and noted that such a standard is used by other federal agencies, such as the Department of Commerce and Department of Labor, in determining the durability of other consumer goods. CMS also believes that in light of the statutory 5-year RUL requirement, a 3-year MLR will "provide sufficient flexibility to cover new technology items that could be considered durable, but that may not last for 5 years before having to be replaced."

Importantly, the 3-year MLR will be prospective only and will not apply to equipment classified as DME before the rule is implemented on January 1, 2012. CMS will not re-determine payment for any product that currently is covered under the DME benefit. The MLR standard also will not apply to supplies and accessories that are needed for the effective use of DME that is paid under the DME benefit. For example, the standard will not apply to blood testing strips or to infusion therapy supplies. In addition, it will not apply to modified products, including those that have been upgraded but are not new. However, CMS will consider providing additional guidance on this issue if necessary. CMS also noted that while it expects equipment to meet the 3-year standard it will monitor the issue and propose additional rules if necessary.

CMS is considering comments it received on how to apply the 3-year MLR to multi-component devices that have both durable and nondurable components. However, it has neither proposed nor finalized any regulation changes on this issue at this time.

CMS Finalizes DMEPOS Competitive Bidding Provision from Earlier Interim Final Rule

On January 16, 2009, CMS published an interim final rule with comment period that implemented several changes to the DMEPOS competitive bidding program that were mandated by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). In this final rule, CMS responded to the comments it received and finalized the provisions of the interim final rule.

CMS finalized without modification regulatory language based on MIPPA delaying Round 1 of the competitive bidding program to no sooner than 2009 and Round 2 to no sooner than 2011. CMS also finalized language to indicate that competition in

additional Metropolitan Statistical Areas will occur after 2011 (or, in the case of national mail order diabetic testing supplies, after 2010). In response to requests for additional delays, CMS said that it lacked the authority to further delay implementation. CMS also noted that the results of the Round 1 rebid "so far have been very positive" and that the program is "fulfilling its promise as an effective tool" to set Medicare DMEPOS payment rates.

MIPPA modified the "covered document" review procedure that is part of the bid evaluation process. MIPPA established a number of timeframes for suppliers to submit required documents, for CMS to review and notify suppliers of any missing documents, and for suppliers to submit the missing paperwork. The MIPPA covered document review process was incorporated into the interim final rule and CMS is finalizing that rule without modification to reflect that for Round 1 CMS has up to 45 days after the covered document review date to review the covered documents and to notify suppliers of any missing documents. For subsequent rounds, CMS has 90 days after the covered document review date to notify suppliers of any missing covered documents.

MIPPA requires contract suppliers to disclose information on their subcontractor arrangements and any applicable accreditation requirements. CMS modified its regulations in the interim final rule to reflect these requirements. Some comments requested that suppliers not be permitted to subcontract after being selected as a competitive bidding supplier. However, CMS said it does not have the authority to prohibit subcontracting once contract suppliers have been selected. CMS also noted it has a "robust" monitoring program in place and that it has not indentified any problems with the ability of contract suppliers to provide competitively bid items. CMS is finalizing the provisions regarding subcontracting without modification.

MIPPA added a hospital exemption to the competitive bidding program that specifically excluded from the program hospitals that furnish certain competitively bid DME to their own patients during an admission or on the date of discharge. CMS noted that it does not have the authority to provide a broader exception and is finalizing this provision without modification.

MIPPA excluded group 3 complex rehabilitative power wheelchairs and related accessories (when furnished with such wheelchairs) from competitive bidding. In response to comments, CMS said it does not have the authority to exclude Group 2 complex rehabilitative power wheelchairs and is therefore finalizing the language in the interim final rule without modification. MIPPA also excluded negative pressure wound therapy (NPWT) products from the rebid. Some commented that NPWT should be excluded permanently from the program, but CMS said MIPPA did not provide for such action. Except for these two items, MIPPA required that CMS conduct the Round 1 rebid for "the same items and services" that were previously bid. While CMS did exclude some obsolete HCPCS codes and codes that were no longer separately payable, CMS said it did not have the authority to make additional exclusions. Therefore, CMS finalized this provision without modification.

MIPPA amended the areas selected for the first round of the competitive bidding program by excluding Puerto Rico from the Round 1 rebid. While CMS received

comments that requested the Agency exclude additional areas from the rebid, CMS said it lacked the authority to do so. CMS therefore finalized its regulation without modification.

CMS also noted that it received comments that it should have utilized a proposed rule, rather than interim final rule, in implementing the MIPPA changes to the competitive bidding program. CMS disagreed, stating that while it normally publishes a notice of proposed rulemaking, the process may be waived for "good cause." In opting to utilize the interim final rule process, CMS said it was "impractical, unnecessary, and contrary to public interest" to use the proposed rulemaking process because CMS used the interim final rule to conform to MIPPA's specific statutory requirements.

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