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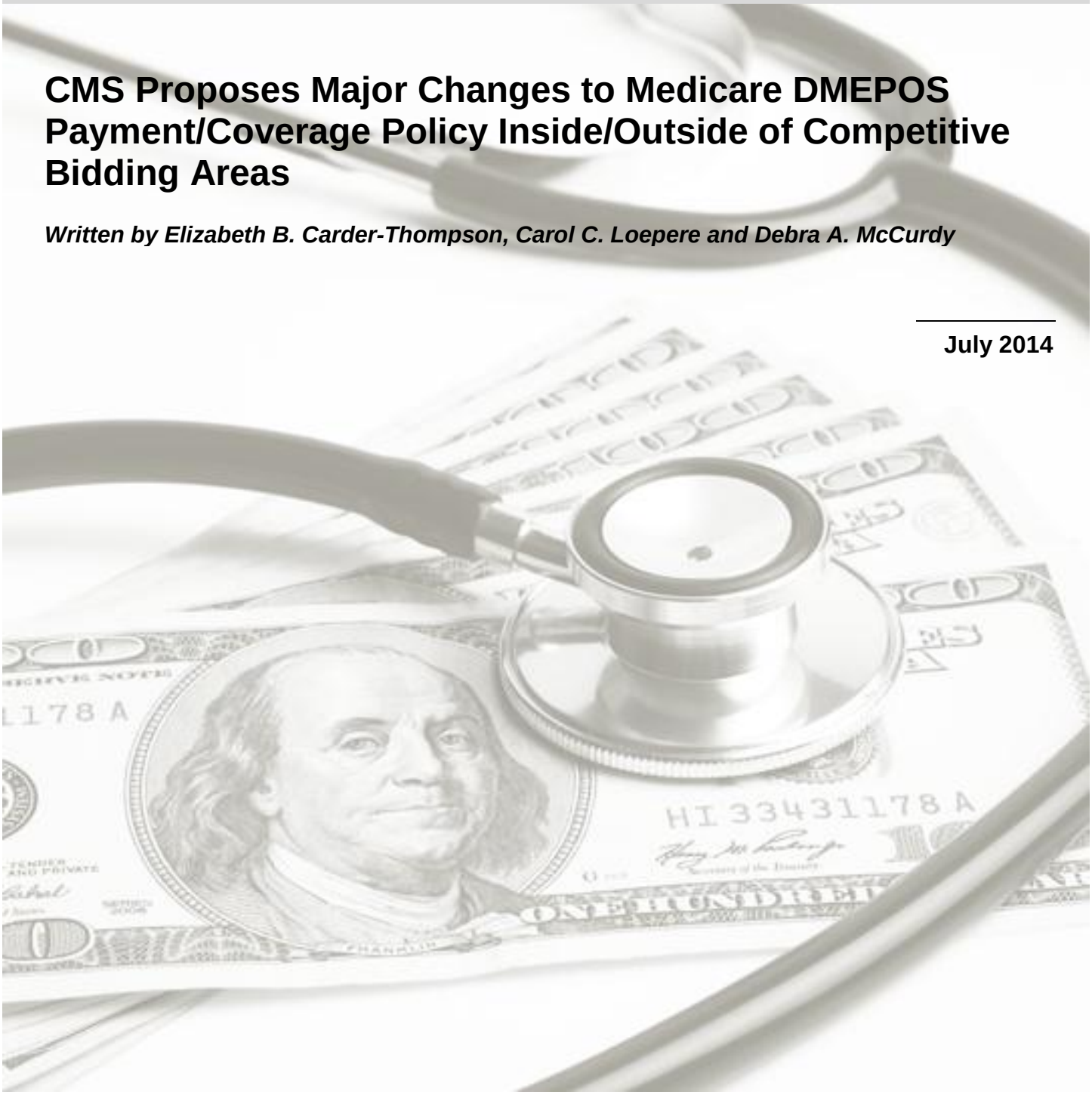
CMS Proposes Major Changes to Medicare DMEPOS Payment/Coverage Policy Inside/Outside of Competitive Bidding Areas

Written by Elizabeth B. Carder-Thompson, Carol C. Loepere and Debra A. McCurdy

July 2014



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IF YOU HAVE QUESTIONS OR WOULD LIKE ADDITIONAL INFORMATION ON THE MATERIAL COVERED IN THIS ALERT, PLEASE CONTACT ONE OF THE AUTHORS:

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Proposed policies estimated to cut DMEPOS payments by $7 billion over 5 years

Written by Elizabeth B. Carder-Thompson, Carol C. Loepere and Debra A. McCurdy

On July 2, 2014, the Centers for Medicare & Medicaid Services (CMS) released a proposed rule that would make a series of significant changes to Medicare coverage and payment policies for durable medical equipment (DME), prosthetics, orthotics, and supplies (DMEPOS). Notably, the proposed rule would establish a methodology for adjusting Medicare DMEPOS fee schedule payment amounts across the country using information from the Medicare DMEPOS Competitive Bidding Program (CBP) – which CMS estimates would cut Medicare DMEPOS reimbursement by more than $7 billion in FYs 2016 through 2020. The proposed rule also would: test the use of bundled monthly payment amounts for DME and enteral nutrition under the CBP; modify CBP change of ownership (CHOW) and termination of contract rules; clarify qualifications for providing custom fitting services for orthotics; and revise Medicare hearing aid coverage policy. These provisions, which were part of a broader proposed rule that would also update the Medicare end-stage renal disease prospective payment system for 2015, are summarized below.

Adjustment to DMEPOS Pricing in Non-CBAs

The Affordable Care Act mandates that CMS use pricing information from the DMEPOS competitive bidding program to adjust DME fee schedule amounts for items furnished in areas where the CBP is *not* implemented by January 1, 2016. CMS also is authorized (but not mandated) to make such adjustments for off-the-shelf (OTS) orthotics and enteral nutrients, supplies, and equipment furnished outside of competitive bidding areas (CBAs). CMS published an Advance Notice of Proposed Rulemaking (ANPRM) on February 26, 2014, which solicited comments on several issues for the agency to consider in developing a proposed methodology to implement its authority.

Under the proposed rule, CMS sets forth three methodologies for making such adjustments, depending on the geographic area and the type of product furnished. The primary methodology, which would apply to items bid in more than 10 CBAs throughout the country beginning January 1, 2016, would be based on the competitive bidding single payment amount (SPA) – i.e., the allowed payment for an item furnished under a CBP derived from the median of successful bids for furnishing items and services in a CBA. In short, adjusted fee schedule amounts for areas within the contiguous United States would be determined based on regional SPAs (RSPAs) calculated from the average SPAs for an item from all CBAs that are fully or partially located in the region. The adjusted payment amount for the item would equal the RSPA limited by a national floor and ceiling of not less

than 90 percent and not more than 110 percent of the national average. CMS notes that this methodology is based on the regional fee schedule payment methodology in effect for prosthetics and orthotics. For areas that are predominantly rural or sparsely populated ("frontier states") and have not been subject to competitive bidding previously, adjusted fee schedule amounts would be no lower than the national ceiling amount. CMS also proposes special rules for adjustments in areas outside of the contiguous United States.

A second proposed methodology would be used for lower-volume items or other items that were bid in no more than 10 CBAs. Payment amounts for these items in non-CBAs would be 110 percent of the average of the SPAs for the areas where CBPs are implemented. CMS suggests that using a straight rather than weighted average of the SPAs gives SPAs equal weight regardless of size of the CBA and prevents giving undue weight to SPAs in more heavily-populated areas. The additional 10 percent adjustment is intended to account for unique costs such as delivering items in remote locations in an administratively simply method. A third methodology applies national mail order CBP payments to mail order items furnished in the Northern Mariana Islands.

CMS proposes updating adjusted payment amounts each time an SPA changes following new competitions, which may occur at the end of a contract period, as additional items are phased in, or as new programs are phased in. The adjusted fee schedule amounts would become the new bid limits for future rounds of competitive bidding. CMS also proposes a number of policies to address special circumstances, such as accessories that are used with different types of base equipment, and when SPAs for lower levels of service are higher than SPAs for higher levels of service.

Special Bundled Payment Rules for Certain DME and Enteral Nutrition under the CBP

CMS is proposing to test a limited phase-in of bundled payments for certain types of DME and enteral nutrition subject to competitive bidding, under the auspices of the CMS Center for Medicare and Medicaid Innovations' demonstration authority. CMS would initially test this payment model in no more than 12 CBAs in conjunction with competitions that begin on or after January 1, 2015; any expansion of the program would follow program evaluation and future notice and comment rulemaking.

Under the proposed program, CMS would make bundled monthly payment amounts on a continuous monthly rental basis (rather than on a capped-rental basis) for one or more of the following categories of items and services: enteral nutrition, oxygen and oxygen equipment, standard manual wheelchairs, standard power wheelchairs, hospital beds, continuous positive airway pressure (CPAP) devices, and respiratory assist devices. CMS believes that such ongoing, uncapped monthly payments could both help ensure that medical equipment is "kept in good working order" for the duration of medical need, and make it easier for beneficiaries to change suppliers since the new supplier would not be faced with a limited number of rental payments.

CMS proposes that the SPA for the monthly rental of DME would include payment for each item and service associated with the rental equipment, including ongoing maintenance and servicing of the rental equipment, and furnishing and replacing supplies and accessories that are necessary for the effective use of the equipment. For example, a contract supplier furnishing a CPAP would be responsible for furnishing the CPAP device, accessories used with the device such as masks, tubing, headgear, and humidifiers, and all maintenance and servicing of the equipment under the single monthly payment. In the case of enteral nutrition, CMS would include payment for all nutrients, supplies, and equipment in the monthly SPA. The preamble includes CMS's rationale for including the specific types of equipment in the demonstration, and special considerations for suppliers of each type of product.

The proposed rule provides that separate payment for all repairs, maintenance and servicing, and replacement of supplies and accessories for beneficiary-owned DME or enteral nutrition equipment would end in the CBAs where the special payment rules are in effect. Instead, if the beneficiary has a medical need for the equipment, the contract supplier would be responsible for furnishing new equipment and servicing that equipment. CMS also proposes various special transition policies, rules regarding beneficiary-owned power wheelchairs, and rules to ensure that bids submitted for items paid on a continuous rental basis are less than would otherwise be paid.

CMS would provide advance notice to suppliers and beneficiaries about any special payment rules to be included in a CBP. CMS states that because suppliers' bids would reflect the cost of furnishing items in accordance with the new payment rules, overall savings generally are expected to be the same as they are under the current payment rules.

DMEPOS CBP CHOW Rules

Current competitive bidding rules prohibit the sale of a competitive bidding contract. CMS may permit the transfer of a contract to an entity that merges with or acquires a competitive bidding contract supplier, however, if the new owner assumes all rights, obligations, and liabilities of the entire competitive bidding contract. CMS now acknowledges that "requiring a transfer of the entire contract to a successor entity in all circumstances may be overly restrictive, and may be preventing routine merger and acquisition activity."

CMS therefore is proposing to permit transfer of part of a competitive bidding contract under specific circumstances. Specifically, a contract supplier would be permitted to sell a distinct company (e.g., an affiliate, subsidiary, sole proprietor, corporation, or partnership) that furnishes one or more specific product category (PC) or serves one or more specific CBAs and transfer the portion of the contract initially serviced by the distinct company, including the PC(s), CBA(s), and location(s), to a qualified successor entity that meets all competitive bidding requirements.

The proposed exception would not apply to existing contracts, but would apply to contracts issued in all future rounds of the program, starting with the Round 2 Recompete. CMS would require a contract supplier that wants to sell a distinct company with a CBP contract to notify CMS 60 days before the anticipated date of a CHOW, and submit any required documentation within 30 days of the anticipated CHOW. For CMS to approve the transfer, several conditions would have to be met. For instance:

- Every CBA, PC, and location of the company being sold must be transferred to the new owner.
- All CBAs and PCs in the original contract that are not explicitly transferred by CMS must remain unchanged in that original contract for the duration of the contract period (unless subject to a subsequent CHOW).
- All current CHOW requirements set forth at 42 CFR § 414.422(d)(2) must be met.
- The sale of the company must include all of the company's assets associated with the CBA and/or PCs.
- CMS must determine that transferring part of the original contract will not result in disruption of service or harm to beneficiaries.
- The new supplier must meet all applicable competitive bidding requirements.
- The contract supplier and successor entity must enter into a novation agreement with CMS and the successor entity must accept all rights, responsibilities, and liabilities under the competitive bidding contract.

CMS suggests that this provision "would impact businesses in a positive way by allowing them to conduct everyday transactions without interference from our rules and regulations." CMS also proposes non-substantive changes to current CHOW regulations to clarify the language.

Termination of a Competitive Bidding Contract

CMS proposes to clarify the effective date of "termination" in the termination notice CMS sends to a contract supplier found to be in breach of a competitive bidding contract. The proposed rule would specify that a contract will automatically be terminated if the supplier does not timely file a hearing request or submit a corrective action plan. CMS also would specify that a supplier whose competitive bidding contract is being terminated must notify affected beneficiaries that it is no longer a contract supplier no later than 15 days prior to the effective date of termination. If implemented as proposed, this rule would underscore the importance of making sure that CMS and the Contract Bidding Implementation Contractor (CBIC) have the current contact information for the contract supplier, and that all communications from CMS and CBIC are promptly addressed to avoid inadvertent contract termination.

Minimal Self-Adjustment of Orthotics

The Social Security Act authorizes the implementation of competitive bidding for OTS orthotics that require "minimal self-adjustment" for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit the individual. Current regulations at 42 CFR § 414.402 define "minimal self-adjustment" as "an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual who is certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training."

CMS proposes to clarify the specialized training that is needed to provide custom fitting services if providers are not certified orthotists. Specifically, CMS would update the definition of minimal self-adjustment in 42 CFR § 414.402 to define an individual with specialized training to include: a physician defined in section 1861(r) of the Act, a treating practitioner defined at section 1861(aa)(5) (physician assistant, nurse practitioner, or clinical nurse specialist), an occupational therapist defined at 42 CFR § 484.4, or physical therapist defined at 42 CFR § 484.4, who is in compliance with all applicable federal and state licensure and regulatory requirements. CMS states in the preamble that clinical providers such as assistants, fitters, and manufacturer representatives "are not considered to have specialized training for the purposes of providing custom fitting; therefore, orthotics adjusted by these individuals but not by individuals with specialized training would still be considered OTS."

Hearing Aid Coverage

The proposed rule would clarify when a hearing aid can be considered a prosthetic device and not subject to the statutory exclusion of hearing aids from Medicare coverage. CMS proposes to interpret the term "hearing aid" to include all types of air or bone conduction hearing aid devices, whether external, internal, or implanted, including, but not limited to, middle ear implants, osseointegrated devices, dental anchored bone conduction devices, and other types of external or non-invasive devices that mechanically stimulate the cochlea. This definition would have the effect of withdrawing coverage for bone anchored hearing aid (BAHA) devices. CMS does not propose changing the current coverage status of cochlear implants and brain stem implants under the prosthetic device benefit; they are not considered hearing aids subject to the statutory exclusion and thus would continue to be covered.

* * *

CMS is requesting comments on numerous policy issues and technical considerations raised by its proposed DMEPOS policies. CMS will accept comments on the proposed rule until ***September 2, 2014***.

The official version of the proposed rule will be published in the *Federal Register* on July 11, 2014; the advance version is available at http://www.ofr.gov/(S(wpgenyhew2nba1jb12jat5fs))/OFRUpload/OFRData/2014-15840_PI.pdf.

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