September 10, 2018

VIA ELECTRONIC SUBMISSION

Administrator Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1691-P
P.O. Box 8010
Baltimore, Maryland 21244-8010

Re: CY 2019 Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System, Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) CMS-1691-P

Dear Administrator Verma:

The Medicare Rights Center (Medicare Rights) is pleased to submit comments in response to CMS-1691-P. Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Each year, Medicare Rights provides services and resources to nearly three million people with Medicare, family caregivers, and professionals. The following comments are informed by our experience assisting beneficiaries, their family members, and health care professionals.

History of DMEPOS CBP and Fee Schedule Payment Rules

In light of some of the proposed changes to the Competitive Bidding Program and the timing and implementation of those changes, it is important to highlight the statutory framework within which the agency must operate.

The Medicare payment rules for durable medical equipment (DME) are set forth in sections 1834(a) and 1847(a) of the Social Security Act (the Act). The Act was amended by section 302(b)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), to require the Secretary of the Department of Health and Human Services (the Secretary) to establish and implement Competitive Bidding Programs (CBPs) in Competitive Bidding Areas (CBAs) throughout the United States for contract award purposes for the furnishing of certain competitively priced Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items and services. The 21st Century Cures Act (the Cures Act) (Pub. L. 114-255) was enacted on December 13, 2016, and amended section 1834(a)(1)(G) of the Act to require, in the case of items and services furnished on or after January 1, 2019, that in making adjustments to the fee schedule amounts for non-CBAs, the Secretary shall: (1) solicit and take into account stakeholder

Washington, DC Office:
1444 I Street NW, Suite 1105
Washington, DC 20006
202.637.0961

www.medicarerights.org www.medicareinteractive.org

input; and (2) take into account the highest bid by a winning supplier in a CBA and a comparison of each of the following factors with respect to non-CBAs and CBAs:

- The average travel distance and cost associated with furnishing items and services in the area.
- The average volume of items and services furnished by suppliers in the area.
- The number of suppliers in the area.

Proposals for the DMEPOS CBP and Fee Schedule Payment Rules

This rule proposes changes to bidding and pricing methodologies under the DMEPOS Competitive Bidding Program; adjustments to DMEPOS Fee Schedule amounts using information from competitive bidding for items furnished from January 1, 2019 through December 31, 2020; new payment classes for oxygen and oxygen equipment; and special payment rules for multi-function ventilators or ventilators that perform functions of other durable medical equipment.

General CBP Comments

Consistent with our previous public statements,[1] Medicare Rights strongly supports the DMEPOS Competitive Bidding Program. We believe it represents an important advancement in how Medicare pays for medical equipment and services. The program serves a triple aim—contributing to lower costs for older adults and people with disabilities, as well as the right prices for Medicare, and a better deal for American taxpayers. According to the U.S. Department of Health and Human Services, "The program saved more than $580 million for beneficiaries and taxpayers in its first two years of operation, and it is projected to save the Medicare Part B Trust Fund $25.8 billion and beneficiaries $17.2 billion over ten years."[2]

Through the DMEPOS bidding program, medical equipment suppliers compete for Medicare's business on the basis of quality and price, by submitting bids to serve beneficiaries in a specified region. In the proposed rule, the Centers for Medicare & Medicaid Services (CMS) cites concerns about undue barriers to accessing needed medical equipment and supplies under the program, but available evidence reflects the contrary. An initial report by the Government Accountability Office (GAO) determined beneficiary access and satisfaction were not negatively affected by the bidding program in 2011, though careful monitoring was needed as the program expanded.[3] Similar findings were reported in 2012 through a subsequent GAO analysis.[4]

Trends heard on our national helpline are reflective of these findings. Our most common calls involve questions about coverage rules and concerns about denials of coverage. None of these inquiries are unique to the DMEPOS bidding program. We hear the same questions and concerns from those with Traditional Medicare in bidding areas, those in non-bidding areas, and among Medicare Advantage enrollees. We believe these trends reflect a general need for enhanced oversight of suppliers and education of beneficiaries across all Medicare coverage types.

This is not to say that no changes or alterations to the program are warranted. While additional oversight would be welcome,[5] the abrupt, albeit temporary, termination of the program contemplated by this

[1] Testimony of Joe Baker before the House Committee on Ways & Means, (May 19, 2015).
[2] GAO, "Bidding Results from CMS's Durable Medical Equipment Competitive Bidding Program," (November 2014), available at: http://www.gao.gov/assets/670/666806.pdf
[3] GAO, "Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid," (May 2012), available at: http://www.gao.gov/assets/600/590712.pdf
[4] GAO, "Second Year Update for CMS's Durable Medical Equipment Competitive Bidding Program Round 1 Rebid," (March 2014), available at: http://www.gao.gov/assets/670/661474.pdf
[5] *Id.*

proposed rule and CMS's delay in re-bidding these contracts is outsize in relation to the program's modest problems and significant benefits.

Beneficiary Protections in the Gap

The proposed rule states that:

> The proposed changes to the CBP would be effective for competitions beginning on or after January 1, 2019. The Round 2 Recompete, National Mail-Order Recompete, and Round 1 2017 contract periods of performance will end on December 31, 2018. Competitive bidding for items furnished on or after January 1, 2019 has not yet begun, and therefore, we do not expect that CBP contracts would be in place on January 1, 2019. Thus we anticipate that there would be a gap in the CBP beginning January 1, 2019. During a gap in the CBP beginning January 1, 2019, there would be no contract suppliers and payment for all items and services previously included under the CBP would be based on the lower of the supplier's charge for the item or fee schedule amounts adjusted in accordance with sections 1834(a)(1)(F) and 1842(s)(3)(B) of the Act. We are proposing specific fee schedule adjustments as a way to temporarily pay for items and services in the event of a gap in the CBP due to CMS being unable to timely recompete CBP contracts before the current DMEPOS competitive bidding contract periods of performance end.[6]

This passive language belies the fact that the creation of this "gap" and the effective cancellation of the existing competitive bidding process until new bids could be taken is entirely within the agency's control. Further, the proposed payment strategy in this period is complicated and confusing, in part because the law requires CMS to take the competitive bidding payment amounts in CBP areas into account when setting the rates for non-CBP areas, but CMS has effectively eliminated all CBP areas for this "temporary" period of time, in direct contravention of plain congressional intent.

Medicare Rights is deeply concerned about the lack of transparency around the agency's decision not to solicit bids under the existing program, creating a void that must be filled by stop-gap methodologies like those outlined in this proposed rule. Reverting to non-competitive bid price setting in CBAs for an undetermined period of time is likely to cause significant consumer and supplier confusion, as well as create lapses in important beneficiary protections. This gap is also estimated to cost "$1,050 million dollars in Medicare benefit payments and $260 million dollars in Medicare beneficiary cost sharing for the 2-year period beginning January 1, 2019 and ending December 31, 2020," plus over "$45 million dollars and $30 million dollars" in federal and state Medicaid costs.[7]

Important beneficiary protections—like the requirement that a contract supplier serve any beneficiary and perform needed maintenance, as well as the protection against balance billing, and the existence of the Competitive Acquisition Ombudsman, who can investigate, track, and address problems—will all vanish in this indeterminate gap period. Beneficiaries who have come to rely on the availability of their equipment, orthotics, and supplies for a fair, market-set price will again be forced to extensively comparison shop, and will again be at risk of overpaying and of facing significantly increased out-of-pocket costs. All parties will need to be educated about this "new normal," which will be temporary.

[6] 82 FR 34380
[7] 82 FR 34308

This level of disruption may be warranted in situations where a program is failing dramatically and where the agency contemplates a complete overhaul. This is not, however, the case for the current Competitive Bidding Program, as evidenced by the fact that the proposed changes—largely to base single payment amounts on the maximum winning bid, and to implement lead item pricing in the Medicare—have significantly more modest estimated costs over a five year period than the gap does over an estimated two years. The actual programmatic changes are expected to cost $10 million in Medicare benefit payments and $3 million over the first five years of implementation, compared to the existing scheme.[8]

We strongly urge CMS to revisit this proposed strategy and to immediately open bidding for service provision under the current methodology for the 2019 plan year. If CMS wishes to move forward with the remainder of the proposed rule and establish a new methodology for choosing winning bids for those received in later plan years, it can do so without causing the level of disruption and confusion that this rule and this proposed course of action would bring about. Such a revised approach would preserve beneficiary protections and the status quo, honor congressional intent, and allow for time to smoothly transition to a new CBP methodology.

At minimum, however, CMS must revise this proposal to preserve the essential beneficiary protections—including the existence of the Competitive Acquisition Ombudsman—during any gap period.

Other Provisions of the Proposed Rule

CMS also solicits comments about the proposal to add payment classes for portable liquid oxygen equipment only, portable gaseous oxygen equipment only, and high flow portable liquid oxygen contents. The agency also proposes to establish a new methodology for ensuring that all new payment classes for oxygen and oxygen equipment added since 2006 are budget neutral, as well as new rules regarding how to pay for certain ventilators that also perform the function of other items of durable medical equipment. Medicare Rights supports these changes.

Thank you for opportunity to provide comments. For additional information, please contact Lindsey Copeland, Federal Policy Director at LCopeland@medicarerights.org or 202-637-0961 and Casey Schwarz, Senior Counsel for Education & Federal Policy at CSchwarz@medicarerights.org or 212-204-6271.

Sincerely,

Joe Baker
President
Medicare Rights Center

[8] *Id.*