



September 10, 2018

SUBMITTED ELECTRONICALLY

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: ITEM Coalition Comments on Select Proposals in CMS-1691-P, “Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS”

Dear Administrator Verma:

The undersigned members of the Steering Committee of the Independence through Enhancement of Medicare and Medicaid (“ITEM”) Coalition appreciate the opportunity to comment on the above-referenced proposed [rule](#) (the “proposed rule”). We write specifically in reference to proposals to modify the competitive bidding program (CBP) and adjustments to the DMEPOS fee schedule amounts. Above all, the ITEM Coalition wishes to express our comments in light of the importance of ensuring continued access to and choice of quality care for those needing durable medical equipment and related services and devices.

The ITEM Coalition is a national consumer and clinician-led coalition advocating for access to and coverage of assistive devices and technologies for persons with injuries, illnesses, disabilities and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including such conditions as multiple sclerosis, paralysis, hearing and speech impairments, cerebral palsy, visual impairments, spinal cord injuries, brain injury, stroke, spina bifida, myositis, limb loss, Osteogenesis Imperfecta (OI), and other life-altering conditions.

I. Changes to Competitive Bidding Program

The proposed rule includes a proposal to implement “lead item pricing” in the CBP and base single payment amounts (SPAs) on the maximum winning bid. The methodology would apply to all items in the product category rather than groupings of items within a product category. CMS proposes that the “lead item” would be identified based on total national allowed charges rather than total national allowed services. Under this proposal, the SPA for the lead item in each product category and competitive bidding area (CBA) would be based on the maximum or highest amount bid for the item by suppliers in the winning range. The SPAs for all other items in the product category would be based on a percentage of the maximum winning bid for the lead item.

The ITEM Coalition supports CMS’ efforts to make the CBP more equitable and fair for all stakeholders. CMS’ proposed lead item pricing scheme may have the potential to help improve beneficiary access to quality DMEPOS devices and services. However, CMS should ensure that all stakeholders, including Medicare beneficiaries, have an opportunity to work with the agency to formulate the new product categories upon which this new system will be based. Ideally, similar DMEPOS items and services would be grouped in a way that would allow for ease of access for beneficiaries. Similarly, product categories need to be constructed in ways that allow for beneficiaries to have true choice among products and services. To that end, the ITEM Coalition urges CMS to establish a process that allows for stakeholders to work with CMS on the implementation of the changes to the CBP.

II. Adjustments to the DMEPOS Fee Schedule

The proposed rule includes adjustments to DMEPOS Fee Schedule amounts for items furnished from January 1, 2019 through December 31, 2020. CMS proposes that the fee schedule amounts in all areas that are currently rural or non-contiguous, non-CBAs (competitive bidding program areas) be based on a blend of 50 percent of the adjusted fee schedule amounts and 50 percent of the unadjusted fee schedule amounts. CMS indicates the proposal is in response to a number of factors including stakeholder comments, the higher costs for non-contiguous areas, the increased average travel distance in certain rural areas, the significantly lower average volume per supplier in non-CBAs (especially in rural and non-contiguous areas), and the decrease in the number of non-CBA supplier locations.

The ITEM Coalition is very supportive of the extension of the transition period for the phase-in of fee schedule adjustments because of the potential positive impact this will have on access, quality, and choice of durable medical equipment for Medicare beneficiaries. Over the past several years, CMS has made significant policy and regulatory changes to the Medicare DME benefit. Many of these changes have been intended to save taxpayer money; however, many ITEM Coalition members report substantial negative effects on beneficiary access to vital DME items and services that improve health and function. The proposal to extend 50/50 pricing within the proposed rule would actually promote beneficiary access to and choice of quality DME for the time it remains in effect.

a. Access and Choice

There are fundamental differences in providing DME in urban/suburban areas compared to rural areas, differences that add cost to the provision of DME to Medicare beneficiaries. Medicare beneficiaries in rural areas are geographically dispersed, hard to reach, and do not have the same access to systems of care available in more populated areas. Tough terrain, long distances between patients and providers/suppliers, and fewer health care resources mean that DME suppliers must incur added costs to deliver the right medical equipment and supplies to patients on a timely basis. Rural DME suppliers, quite literally, have to go the extra mile for their Medicare patients. This translates into added costs for transportation, delivery and clinical staff, fuel, and other expenses.

With the introduction of competitively bid fees in rural areas, suppliers are being forced to shut down because they cannot afford to provide DME to patients in rural areas. This exacerbates the problem of already-low numbers of DME suppliers in rural and non-contiguous areas, which creates an access problem for rural Medicare beneficiaries. Medicare beneficiaries have experienced interruptions in continuity of care and barriers to DME access as a result of this flawed approach to reimbursement of DME in rural areas. The extension of the blended rates promotes access for beneficiaries in rural areas, as it will be less likely suppliers will be forced to close or stop providing DME to Medicare beneficiaries. The blended rates also help to provide choices to beneficiaries to select from among a greater number of DME suppliers, as well as a greater variety of brand name items and services.

b. Quality

Facing increased challenges of operating in rural areas, suppliers have to cut costs elsewhere to make ends meet. This means limiting the range of DME provided to beneficiaries to less expensive, often lower quality DME, reducing staff, making home deliveries less often, and other methods of reducing supplier cost. All of these cost saving measures potentially compromise the quality of the existing Medicare DME benefit. The extension of blended pricing in the proposed rule will increase the likelihood that beneficiaries will receive quality DME, as rural suppliers will be properly reimbursed for the costs of providing DME. Receiving DME as prescribed is essential, as patients depend on DME to live and function as independently as possible. The Medicare DME benefit has a profound impact on patients' quality of life.

III. Impact on Beneficiaries' Costs of Obtaining Durable Medical Equipment

CMS estimates that this proposed rule will create significant costs for Medicare beneficiaries via cost sharing. While we recognize that this rule may increase costs for certain Medicare beneficiaries, potentially impacting those on the margin, we believe that the increased access to quality DME and supplier/brand name choice is a beneficial trade-off. In addition, the true impact of this forecasted cost-sharing is unclear due to the widespread existence of secondary insurance. Over 80% of traditional Medicare beneficiaries have some type of supplemental coverage, whether it is employer-sponsored, Medigap, or Medicaid.¹ For beneficiaries who are dually eligible for both Medicare and Medicaid, Medicaid will typically pay the cost sharing,

¹ *An Overview of Medicare*, KAISER FAMILY FOUNDATION (Nov. 2017), <https://www.kff.org/medicare/issue-brief/an-overview-of-medicare/>.

offsetting this total amount. In addition, many beneficiaries who do not qualify for Medicaid but cannot afford secondary insurance do not end up paying for DME cost sharing out of pocket. It is common practice for suppliers to write off co-payments when beneficiaries cannot afford to pay after the supplier has made reasonable attempts to collect the balance.

We encourage CMS to monitor how this cost increase impacts beneficiaries, but we believe the increase in access, quality, and choice will offset the legitimate concerns of increased beneficiary cost-sharing.

Overall, the resumption of the transition period for the phase-in of fee schedule adjustments for non-competitive bidding areas has the potential to improve access for beneficiaries, improve choice for beneficiaries, and maintain the quality of durable medical equipment for beneficiaries. For that, we thank CMS for recognizing the negative impact of the full fee schedule adjustment on beneficiaries in rural and non-contiguous CB areas, and taking proactive steps to ameliorate this impact.

IV. Non-CBA, Not Rural or Non-Contiguous Areas

In the proposed rule, for all areas that are currently non-CBAs, but are not rural or non-contiguous areas, CMS believes that fee schedule amounts should be based on 100 percent of the adjusted fee schedule amounts. CMS states that although the average volume of items and services furnished by suppliers in non-rural non-CBAs is lower than the average volume of items and services furnished by suppliers in CBAs, the travel distances and costs for these areas are lower than the travel distances and costs for CBAs. As a result, because the travel distances and costs for these areas are lower than the travel distances and costs for CBAs, CMS believes the fully adjusted fee schedule amounts are sufficient. CMS specifically requests comment on the issue of whether the 50/50 blended rates should apply to these areas as well.

The ITEM Coalition strongly believes that CMS should extend the same 50/50 blended rates to all non-CBAs to ensure that beneficiaries have appropriate access and choice of quality DMEPOS products and services. An extension of the 50/50 blended rate to all non-CBAs would be consistent with Congressional intent recently expressed in the 21st Century Cures Act (P.L. 114-255), in which Congress provided retrospective reimbursement for all non-CBAs for the period between July 1 through December 31, 2016. Overall, such an extension of the 50/50 blended rate would help ensure beneficiary access to DMEPOS products and services is more fair and equitable.

V. Conclusion

The ITEM Coalition appreciates the opportunity to comment, and CMS' attention to these important matters. The ITEM Coalition supports CMS' efforts to make the CBP more fair and equitable, and looks forward to working with the agency to establish effective product categories that ensure beneficiary access and choice of quality DMEPOS products and services. Additionally, the ITEM Coalition strongly supports the resumption of the extension period for the phase-in of fee schedule adjustments in rural and non-contiguous CB areas. As noted above,

we urge CMS to extend the 50/50 blended rates to all non-CBAs to improve access, choice and quality of durable medical equipment for Medicare beneficiaries.

We greatly appreciate your attention to this important issue. Should you have further questions regarding the information contained in our letter, please contact the ITEM Coalition Steering Committee, listed below, or Peter Thomas, ITEM Coalition staff, via email at Peter.Thomas@PowersLaw.com or by calling 202-872-6730.

Sincerely,

ITEM Coalition Steering Committee

Mark Richert, American Foundation for the Blind

(MRichert@afb.net)

Dan Ignaszewski, Amputee Coalition

(dan@amputee-coalition.org)

Kim Beer, Christopher and Dana Reeve Foundation

(KBeer@christopherreeve.org)

Laura Weidner, National Multiple Sclerosis Society

(Laura.Weidner@nmss.org)

Lee Page, Paralyzed Veterans of America

(LeeP@pva.org)

Alexandra Bennewith, United Spinal Association

(ABennewith@unitedspinal.org)