September 7, 2018

Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
CMS-1691-P
Room 445-G
Hubert Humphrey Building
200 Independence Ave, SW
Washington, DC 20201

Submitted electronically

RE: 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 Competitive Bidding Program and Fee Schedule Amounts, and Technical Amendments to Correct Existing Regulations Related to the CBP for Certain DMEPOS [CMS-1691-P]

Dear Administrator Verma:

On behalf of our more than 100,000 member physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to submit comments on the Centers for Medicare and Medicaid Services’ (CMS) Calendar Year (CY) 2019 End-Stage Renal Disease Prospective Payment System and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) and Fee Schedule Amounts proposed rule. The mission of APTA is to build a community to advance the physical therapy profession to improve the health of society. Physical therapists play a unique role in society in prevention, wellness, fitness, health promotion, and management of disease and disability by serving as a dynamic bridge between health and health services delivery for individuals across the age span. While physical therapists are experts in rehabilitation and habilitation, they also have the expertise and the opportunity to help individuals improve overall health and prevent the need for otherwise avoidable health care services. Physical therapists’ roles may include education, direct intervention, research,
advocacy, and collaborative consultation. These roles are essential to the profession’s vision of transforming society by optimizing movement to improve the human experience.

The clinical judgment and expertise of the physical therapist is critical in selecting a particular DMEPOS, including complex rehabilitation technology (CRT) for the patient, and is based on the physical therapist’s evaluation of the individual. These services, which include determining the appropriate DMEPOS for the patient, are crucial to expanding a beneficiary’s ability to function, maintaining productivity, and improving the quality of health outcomes. Access to the appropriate DMEPOS also allows beneficiaries to safely and productively continue their activities of daily living. These services and supplies are particularly important for Medicare, Medicaid, and dual-eligible beneficiaries, who often are dealing with multiple health issues and co-morbidities that impact their quality of life, as well as the commercially insured population. Proper provision and access to DMEPOS and CRT by qualified suppliers reduce medical complications, clinical interventions, hospitalizations, institutionalization, caregiver assistance, and other health care costs.

APTA encourages CMS to continue to focus on improving the coding and payment processes for DMEPOS, complex rehabilitation and assistive technology, as well as the broader Medicare DMEPOS benefit. Please find below our detailed comments on the proposed rule.

**CBP Harms Beneficiary Access to DMEPOS**

The DMEPOS CBP has resulted in payment reductions for DME and CRT which, in turn, harm beneficiary access to high quality devices and related services. APTA supports the continued exemption of complex rehabilitation manual and power wheelchairs and related accessories and seating from the CBP. It is imperative that the specific products determined to meet the medical needs of beneficiaries be protected in order to prevent injuries and permanent deformities. Therefore, APTA urges CMS to continue to exclude these items and any other related products from the CBP in the future.

**Changes to the DMEPOS CBP**

APTA appreciates CMS’s recognition of the need for revisions to the CBP and for proposing important improvements. However, additional changes beyond those described are necessary. We strongly encourage CMS to make the appropriate modifications to ensure beneficiary access to the products and the related services that they depend upon.

Proposed use of lead item pricing for all product categories under the DMEPOS CBP

APTA appreciates CMS’s proposal to revise the DMEPOS CBP by implementing lead item pricing, as lead item pricing may help to address issues of price inversion currently affecting the DMEPOS CBP. However, we have concerns regarding how this process will impact pricing associated with non-lead items and urge CMS to closely analyze potential categories. To that end, we recommend CMS develop and implement a methodology that ensures appropriate payment rate outcomes. Given that a lead item will dictate the price for all items in a category, we also encourage CMS to create small, item-specific categories. For instance, the standard mobility group of items is large and contains a broad array of unrelated items. Accordingly, a lead item chosen from a manual wheelchair category will not accurately reflect the cost of a power wheelchair component. We recommend these items be segmented into two main product
categories, which would then be comprised of related subcategories. Each sub-category would then have a lead item based on the highest allowed charges of the items within that subcategory. We recommend CMS engage with stakeholders, including beneficiaries, clinicians who evaluate or recommend DMEPOS, suppliers, manufacturers, and national associations, including APTA, to ensure categories and subcategories are accurately and realistically identified.

APTA also has concerns that the lead item pricing method effectively makes it possible for suppliers to submit bids on lead items without verifying they are capable of furnishing the entire category. Although various items may be grouped into a single category, this does not equate to one supplier being able to provide all of the items in that category. Accordingly, to safeguard beneficiary access, we encourage CMS to develop the categories in a way that ensures beneficiaries are able to access related items from a single CBP supplier. We recommend that when awarding contracts, CMS take into account not only bid price, but also a supplier’s range of available supplies and devices.

\textit{Calculation of Expected Beneficiary Demand}

CMS proposes that under the lead item pricing methodology, the agency would calculate expected beneficiary demand and total supplier capacity based on the lead item in the product category when evaluating bids. Currently, beneficiary demand for items in a product category and supplier capacity for furnishing items in the product category are calculated based on historic utilization of the items making up at least 80% of the total expenditures for the product category as a whole.

APTA has concerns that the beneficiary demand calculation is frequently underestimated compared to the actual need. APTA encourages CMS to consider amending the historic utilization percentage in establishing demand for the product category. Given the growing aging population, it is critical that there are an adequate number of qualified suppliers able to exceed the population’s needs.

\textit{Proposed calculation of single payment amounts (SPAs) using maximum winning bids for lead items}

APTA appreciates CMS’s proposal to calculate SPAs using the maximum winning bid for lead items. We agree with CMS that using the maximum winning bid will ensure appropriate reimbursement is paid to suppliers and will encourage more suppliers to participate and compete for contracts, knowing they will not have to accept a lower rate should they win a contract. Previously, when CMS calculated the SPA using the median winning bid, it essentially ensured half of the winning suppliers would be entering into contracts for reimbursement less than for their bid amount. This caused many suppliers to refuse to accept such contracts, consequently contributing to many of the access issues facing Medicare beneficiaries today.

\textbf{Adjustments to DMEPOS Fee Schedule Amounts Based on Information from the DMEPOS CBP}

\textit{Proposed Fee Schedule Adjustments for Items and Services Furnished in Non-Competitive Bidding Areas During a Gap in the DMEPOS CBP}

APTA supports CMS’s proposal to adjust the fee schedule amounts for items and services furnished in rural and non-contiguous non-competitive bidding areas (CBAs) by extending
through December 31, 2020 the current methodology which bases the fee schedule amounts on a blend of 50% of the adjusted fee schedule amounts and 50% of the unadjusted fee schedule amount in accordance with the current methodologies under paragraphs (1) through (8) of 42 CFR §414.210(g). Such amounts will help to better ensure beneficiary access to items and services in rural and non-contiguous non-CBAs.

However, we encourage CMS to further examine the specific challenges faced by patients and providers in these areas. We recommend the agency take time and distance into account when awarding contracts. For example, the location of a non-CBA supplier determines how quickly a patient can obtain a product. Frequently, hospitals and clinics in rural geographies do not have these supplies on site and must order them from the supplier at the time of prescription. Consequently, the lack of suppliers in these regions results in patients waiting inordinately long periods of time to obtain the supplies and devices they need. Although CMS’s analysis found the average distance was longer in CBAs than non-CBAs, we agree with CMS’s rationalization that the results are skewed by a number of factors. Our members’ firsthand experience is that in non-CBAs, rural and non-contiguous areas, the time it takes to obtain a device is a considerable problem. Accordingly, we encourage CMS ensure there are a sufficient number of qualified suppliers within certain distances of rural and non-contiguous service areas to ensure products are available within acceptable time frames.

Additionally, as stated above, we have concerns that the predicted demand for supplies and devices in these areas is often underestimated compared to the actual need. Considering the rapidly aging population and the influx of baby boomers into the Medicare system, the demand for DMEPOS will continue to dramatically increase in the coming years. Accordingly, to ensure patients in rural and non-contiguous areas can continue to receive appropriate care, we recommend CMS ensure suppliers have the capacity to exceed expected demands prior to awarding contracts.

Moreover, it is critical that fee schedule amounts are sufficient to account for the greater resources required to conduct business, taking into consideration travel distance, delivery expenses, and volume of services. APTA encourages CMS to examine the totality of factors impacting beneficiary access to DMEPOS. Many beneficiaries are unable to access the DMEPOS they need due to the unavailability of bid winners in their locality, the lack of a range in products, and the complete absence of certain items in given areas. Further, reliance on HCPCS codes does not always accurately result in appropriate pricing. Although HCPCS codes may be the best way to categorize items at a given time, HCPCS pricing has not kept pace with the rapid technological developments in DMEPOS.

Finally, we support CMS’s intentions to continue monitoring health outcomes, assignment rates, and other information, and to take thoughtful steps to address fee schedule adjustments in non-CBAs for items furnished on or after January 1, 2021 in future rulemaking.

Proposal Fee Schedule Adjustments for Items and Services Furnished in Former CBAs During a Gap in the DMEPOS CBP
APTA supports CMS’s proposal to revise the fee schedule adjustment methodology at 42 CFR §414.210(g)(9) so that for items and services furnished in non-CBAs that are rural or non-
contiguous areas with dates of service from January 1, 2019, through December 31, 2020, the fee schedule amount for the area is equal to 50% of the adjusted payment amount established under this section and 50% of the unadjusted fee schedule amount. We further support the proposal to revise the fee schedule adjustment methodology for items and services furnished in non-CBAs that are not rural or non-contiguous areas with dates of service from January 1, 2019 through December 31, 2020, the fee schedule amount for the area is equal to 100% of the adjusted payment amount. APTA believes this proposal will help to ensure DMEPOS reimbursement is more in line with real prices as well as encourage suppliers to participate and compete.

We recognize the need for CMS to create a fee schedule methodology for former CBAs during temporary gaps in the DMEPOS CBP. While we do not have a specific recommendation regarding how CMS should develop this pricing, we believe the ultimate payment amounts should be more in line with non-bid areas.

Request for Information on the Gap-filling Process for Establishing Fees for New DMEPOS Items

APTA supports restructuring the gap-filling process for establishing fees for newly covered DMEPOS items paid on a fee schedule basis. It is critical that CMS amend the gap-filling methodology used to establish payment rates for new codes. The current process, by which prices are based on average reasonable charges from 1986 and/or 1987 and increased by annual covered item update factors, simply does not accurately reflect today’s costs. The result is that there is no innovation, no new products available, and instead, a race to the bottom by manufacturers struggling to produce supplies and devices efficiently enough to turn a profit given the low reimbursement rate. This leads to less selection as well as lower quality products, which then have a shorter life span, leading to a greater need for maintenance and replacement devices, which in the long run, contributes to higher costs for beneficiaries as well as the Medicare program. APTA encourages CMS to work with Congress to eliminate or modify the 1987 base year requirement for payment for DMEPOS and explore other alternatives.

APTA also recommends that CMS increase its transparency with regards to fee schedule development. Moreover, the agency should take into account certain factors not considered by its methodology, including current tariffs imposed on products and their components, the prices for devices on the private market and internationally, and the life of the product in relation to its price, as well as supplier costs, which include direct labor, indirect labor, and overhead. CMS can also look to other industries to obtain ideas on how to gap fill prices for new technology. Working with industry stakeholders and associations like APTA can help CMS balance the need for affordable yet realistic pricing.

Conclusion

APTA recognizes that oversight of DMEPOS utilization is necessary; however, it is of limited value if delays cause detrimental health impacts on beneficiaries or impose additional administrative and financial burdens on providers and suppliers due to operational and technical issues. The CBP should not delay the provision of care, result in such limited choices that quality is sacrificed, or be overly burdensome to providers or patients. It is vitally important that Medicare beneficiaries are able to access DMEPOS that are medically necessary for their health.
condition(s). The inability to obtain the appropriate equipment or devices results in a substantial cost to beneficiaries, the Medicare program, and the health care delivery system as a whole.

APTA thanks CMS for the opportunity to provide comments on the CY 2019 End-Stage Renal Disease and DMEPOS CBP proposed rule. Should you have any questions regarding our comments, please contact Kara Gainer, director of regulatory affairs, at karagainer@apta.org or 703/706-8547. Thank you for your consideration.

Sincerely,

[Signature]

Sharon L. Dunn, PT, PhD
Board-Certified Clinical Specialist in Orthopaedic Physical Therapy
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