



August 23, 2016

SUBMITTED ELECTRONICALLY

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: (CMS-1651-P) Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and 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 Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model

Dear Acting Administrator Slavitt:

The undersigned members of the Independence through Enhancement of Medicare and Medicaid (“ITEM”) Coalition, as well as other supporting organizations, appreciate the opportunity to comment on the above-referenced proposed [rule](#) (the “Proposed Rule”). 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.

We write to express our comments and concerns with the Proposed Rule regarding access to care for those needing durable medical equipment (DME), including people eligible for both Medicaid and Medicare benefits (“dually-eligible beneficiaries”). We will not be addressing the provisions of the proposed rule that pertain to End Stage Renal Disease (ESRD).

Overall, many of the changes proposed to the DMEPOS Competitive Bidding Program (CBP) are systematic improvements from the current bidding process that address some of the most

egregious aspects of the program. For that, we thank CMS for recognizing some of the many concerns raised with the CBP in recent years that, we believe, has led to “predatory pricing” and a resulting negative impact on Medicare beneficiary access to quality DME and related services.

I. DMEPOS Competitive Bidding Program (CBP)

a. State Licensure Requirement

CMS has proposed revising the regulatory language to state that a contract will not be awarded to a bidding entity unless the entity meets applicable state licensure requirements.

ITEM Coalition Comment: The ITEM Coalition supports and appreciates CMS’s efforts to ensure that contract suppliers meet state licensure requirements and that Medicare beneficiaries in each Competitive Bidding Area (CBA) are served by fully qualified suppliers for the relevant product category. We encourage CMS to take steps to verify that mechanisms and processes are in place to confirm supplier achievement, improve coordination between the responsible contractors, and validate reliability of data regarding state and local licensure requirements. During the last round of competitive bidding, multiple suppliers who received offers to contract under the CBP were not in compliance with their own state licensure laws. We hope that CMS is aware of this issue, and request assurances that CMS will only offer CBP contracts to future bidders that are compliant with state licensure laws, where applicable.

b. CBP Limits Choice, Access, and Quality

The ITEM Coalition has had a long-standing concern that the CBP limits access, choice and quality of care. As an example, one member of the ITEM Coalition recently confirmed these concerns and expressed that at a hospital he consults with has substantial difficulty with the limited DME supplier pool even for something as simple as walkers. Therapists at his hospital want to send their patients home from a rehabilitation hospital stay with timely-delivered, appropriate assistive devices to help them ambulate. But the lack of suppliers willing to provide certain DME at such low reimbursement levels compromises patient care in the way of delays and substandard devices.

ITEM Coalition Comment: CMS must better monitor access, quality and choice problems with the competitive bidding program. Simply monitoring the 1 (800)-Medicare phone line is not enough to gain an accurate assessment of how this program is impacting beneficiary care.

II. Bid Surety Bond

The Proposed Rule requires bidding entities to obtain a bid surety bond from an authorized surety, for each competitive bidding area for which suppliers submit bids. The Proposed Rule sets the minimum amount of the bid surety bond at \$100,000, and requires that the bond indicate the CBA specific to that bond, in addition to other requirements.

The Proposed Rule also stipulates when a bid surety bond would be forfeited. The bid surety bond(s) for the applicable CBA(s) will be forfeited, and CMS will collect on these surety bonds, when a bidding entity fails to accept a contract offer(s) when its composite bid is at or below the median composite bid rate for suppliers used in the calculation of the single payment amount(s). The Proposed Rule also forbids giving a falsified bid surety bond.

ITEM Coalition Comment: The above-referenced surety bond language begins to address beneficiary concerns that some suppliers were engaging in a fundamentally unfair bidding system. This bidding system, discussed more in the next section of this letter, drives DME fee schedules to unrealistic lows, and contributes to serious problems with access, choice and quality of care. While the proposed bid surety bond provisions will likely serve as a deterrent against predatory bidders offering small bids on which they cannot possibly perform, it is not clear whether these surety bonds will be sufficient to correct the fundamental unfairness of the DMEPOS bidding system. Therefore, the ITEM Coalition seeks further clarification from CMS as to how it will protect beneficiary access, choice, and quality of care in the DMEPOS bidding system moving forward.

III. Bid Limits for Individual Items under the DMEPOS CBP

Current regulations require that bids submitted by suppliers under the CBP be lower than the fee schedule amount. In rounds of competitive bidding subsequent to the first three-year round, the current regulations create a race to the bottom, where fees for DME would be lower in each future round of competitive bidding. These increasingly lower fees negatively impact DMEPOS beneficiaries, as the dwindling fees threaten the existence of a viable DMEPOS benefit.

The Proposed Rule limits bids for future competitions to the fee schedule amounts that would otherwise apply as if CBPs had not been implemented.

ITEM Coalition Comment: This proposal is a very positive development for DMEPOS beneficiaries, and for the preservation of the DMEPOS benefit generally.

IV. Access to Care Issues for DME for Dually-Eligible Beneficiaries

a. Impacts on Beneficiaries from Delayed Access to Needed Equipment and Repairs
CMS requested in the Proposed Rule that stakeholders provide comments on impacts on dually-eligible beneficiaries from delayed access to needed equipment and repairs, related to DME access for dually-eligible beneficiaries.

ITEM Coalition Comment: Delayed access to needed complex rehab technology (CRT) wheelchairs and seating, or repairs to CRT, impacts the health, function and quality of life for beneficiaries with permanent disabilities. The lack of needed mobility devices and seating and positioning products may increase the risk of: being confined to a bed; skin injury; blood clots, urinary tract infections; decreases in respiratory and digestive function; and other health related issues associated with inactivity for people with disabilities, in addition to loss of independence and reduced access to the community. In addition, beneficiaries may experience increased pain if they lack seating technology.

b. General Suggestions

In the Proposed Rule, CMS seeks to obtain additional information to help target efforts to promote timely access to DME benefits for dually-eligible beneficiaries.

ITEM Coalition Comment: To promote timely DME access for dually-eligible beneficiaries, CMS should promote and encourage program policies specifically aimed at serving dually eligible beneficiaries with an emphasis on improved outcomes and reduced cost. CMS should

suggest additional CRT provisions that would improve function, independence, and promote access to community services for dually-eligible beneficiaries.

V. Conclusion

Although we have expressed some concerns and suggestions above, the ITEM Coalition is generally very supportive of the reforms made in this Proposed Rule to access to care for those needing durable medical equipment (DME), including dually-eligible 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 Steve Postal, ITEM Coalition staff, via email at Steve.Postal@ppsv.com or by calling 202-466-6550.

Sincerely,

ITEM Coalition Steering Committee

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Supporting Organizations

Academy of Spinal Cord Injury Professionals

ACCSES

American Academy of Physical Medicine and Rehabilitation

American Association on Health and Disability

American Cochlear Implant Alliance

American Congress of Rehabilitation Medicine

American Foundation for the Blind

American Medical Rehabilitation Providers Association

American Music Therapy Association

American Occupational Therapy Association

American Therapeutic Recreation Association

Amputee Coalition

The Arc of the United States

Association for Education and Rehabilitation of the Blind and Visually Impaired

Association of Assistive Technology Act Programs

Association of University Centers on Disabilities

Board of Certification/Accreditation

Brain Injury Association of America

Caregiver Action Network

Center for Medicare Advocacy

Christopher and Dana Reeve Foundation

Clinician Task Force

Easterseals

Institute for Matching Person & Technology
Lakeshore Foundation
National Association for the Advancement of Orthotics and Prosthetics
National Council on Independent Living
National Multiple Sclerosis Society
Paralyzed Veterans of America
Rehabilitation Engineering and Assistive Technology Society of North America
Spina Bifida Association
The Myositis Association
The Simon Foundation for Continence
United Cerebral Palsy
United Spinal Association