

March 28, 2014

Marilyn B. Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attention: CMS-1460-ANPRM, Medicare Program; Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Using Information from Competitive Bidding Programs

Dear Administrator Tavenner,

The Disability Rights Education and Defense Fund (DREDF) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) advanced notice of proposed rulemaking (ANPRM) for payment methodologies related to DMEPOS. We present our concerns regarding consumer access to customized equipment and service that will be affected by CMS's competitive bidding rental and bundled payment proposals and emphasize the urgent need for individualized consideration due to long-term medical need.

For individuals with disabilities such as cerebral palsy, polio, multiple sclerosis, muscular dystrophy, spinal cord injury and other disorders that can dramatically and permanently affect mobility, dexterity, and even speech, uninterrupted access to the appropriate technology and devices can make the difference between dependency, isolation, ill-health, and the experience of chronic pain, and independence, effective pain management, and community participation. Appropriate technology and devices therefore play a critical role in an effective continuum of care that cannot be compromised.

Approximately 8 million Medicare beneficiaries are under age 65 and have a disability.¹ Over half of these beneficiaries acquired their disability before age 54. Thanks to advances in technology and medicine, they often live for decades with significant physical limitations, which, if managed appropriately, do not have to limit their ability to live active, productive lives. Appropriate medical equipment and devices can enable an individual with a disability to live in their own home in the community rather than in a hospital or other restrictive and impersonal institutional setting. Such equipment can also improve or maintain an individual's functional ability, enable employment, and

¹ Medicare & Medicaid Research Review/2011 Statistical Supplement. Table 2.3. Centers for Medicare and Medicaid Services.

facilitate educational and recreational pursuits that improve quality of life and health status.

The Disability Rights Education and Defense Fund (DREDF) is a leading national law and policy center that advances the civil and human rights of people with disabilities through legal advocacy, training, education, and public policy and legislative development. As a cross-disability law and policy organization led by people with disabilities and parents who have children with disabilities, we are acutely aware of the need for timely access to appropriate DMEPOS. We are also personally aware of the ongoing need for ready access to skilled and seasoned rehabilitation professionals who can assess complex mobility, dexterity and communication needs, engineer effective solutions, and remain available for follow-up and refitting when necessary.

Competitive Bidding Program

DREDF opposes any attempts to expand the competitive bidding program to include either additional regions or additional product categories. We oppose any proposal to expand the program for the following reasons: 1) competitive bid pricing can drive smaller, community-based durable medical equipment (DME) providers on whom people with disabilities rely, out of business, and 2) force DME providers to have smaller product inventories in stock, which has an impact on consumer choice, product quality and the speed with which urgent, emergency repairs can be made.

CMS has statutory authority to apply competitive bidding pricing from the competitive bid areas to other areas of the country, but cannot make payment adjustments based on competitive bidding for items that were not competitively bid. Congress excluded rural areas from competitive bidding before 2015 and gave CMS the discretion to carve rural areas out of competitive bidding altogether. We think that too few beneficiaries reside in rural areas to offset price reductions for DME and other competitive bid items. Thus competitive bidding is not appropriate for rural areas. Moreover, DREDF specifically opposes expanding competitive bidding pricing to noncompetitive bid areas, notwithstanding the statutory mandate.

CMS continues to implement the Medicare DMEPOS competitive bidding program even as beneficiaries have repeatedly voiced serious concerns about the lasting impact of this program on access, choice, and quality. DREDF therefore recommends that Congress incorporate further beneficiary safeguards into the Medicare competitive bidding program, including:

- A requirement that CMS work with independent, third party non-profit organizations familiar with consumers with disabilities and chronic illnesses who require the long term use of Complex Rehabilitation Technology (CRT) to develop, modify and implement:
 - A continuous survey of the Medicare beneficiary experience with the DMEPOS benefit, including functional outcome measures; and

- A continuous quality control 'secret shopper' survey over time of contract suppliers.
- Safeguards regarding implementation of provisions of H.R. 1717, the Medicare DMEPOS Market Pricing Program Act of 2013, specifically:
 - The establishment of an independent market mechanism to set DME pricing and establish binding bids from participating suppliers of durable medical equipment, supplies and related services
 - The development of auction systems in geographic areas that are smaller and more homogeneous than bidding areas under CMS's current bidding program, facilitating improved access to devices for people with disabilities and chronic illnesses
- A requirement that CMS reactivate and make permanent the Program Advisory and Oversight Committee (PAOC). The Medicare Modernization Act required Medicare to establish and administer a PAOC to provide advice on the development and implementation of CMS' Competitive Acquisition Program.

Bundled Payments and Competitive Bidding Programs

CMS's proposal to "bundle" payment for equipment and supplies is deeply flawed because its focus is on the equipment bundle and not on the clinical needs of the individual using the equipment. It is impossible to separate an individual's need for DME and enteral equipment, nutrients and supplies from his/her clinical condition and the progression of his/her medical condition or disability. Healthcare services and supports should be patient centered and reflect an individual's needs and choices. Therefore, a bundled, continuous rental policy for certain items could adversely affect an individual's ability to direct their own care or follow a plan of care outlined by their physician, nurse practitioner or other medical provider. For these reasons, DREDF opposes bundling payments for DME and enteral equipment, nutrients, and supplies.

The concept of bundling payments as a method to achieve reduced health care spending and improved patient outcomes is an unproven policy to date. However, a number of pilots and demonstrations authorized under existing Medicare law are beginning to test the bundling concept. These reforms must be given time to either achieve their promise or demonstrate their shortcomings. New delivery models that focus on persons with multiple chronic conditions are in their infancy and should also be given time to demonstrate whether they have value. Moreover, CMS has not yet pursued some bundling proposals (i.e., the Continuing Care Hospital pilot program) that could show promise. Before Congress legislates additional bundling requirements, these and other related programs should be given an opportunity to demonstrate whether they can better align financial incentives with coordination of high quality care while promoting home and community-based care, preventing unnecessary institutionalization and readmissions, and promoting person-centered care and decision making.

Capped Rental and Competitive Bidding Programs

The proposal to reclassify a significant number of items of durable medical equipment (DME) into the “capped rental” category instead of treating those items as “inexpensive and other routinely purchased” items raises serious concerns about the impact on beneficiaries who require mobility devices, speech generating devices (SGDs), and bone healing technology. We therefore ask CMS to revisit this aspect of the proposed rule and establish guidelines for what will be included in the “routinely purchased” category.

We are particularly concerned about the impact of the proposed rule on Medicare beneficiaries who, due to complications with their medical condition, may have an extended hospital stay, a nursing home stay, or receive hospice services during the 13-month DME rental period. In these situations, Medicare coverage for the rental equipment would cease. This could result in the medical equipment no longer being covered, leaving beneficiaries without access to critical individually tailored mobility, speech generating or other devices that they require while institutionalized. For example, under this proposal, a beneficiary with spinal muscular atrophy, a condition typified by scoliosis, severe trunk and extremity weakness, and breathing and swallowing limitations, might not have access to her customized wheelchair, even though she will need to use this equipment during an extended hospital or nursing home stay. In fact, her wheelchair, equipped with individualized, custom molded seating, torso restraints and support systems, an arm tray, and special electronics for driving the chair, almost certainly will be a central element in her treatment and recovery. It will allow her to get out of bed and sit upright, and eventually begin to regain functional capability while supported by equipment that is tailored to her body size, shape, level of weakness and other personal factors. Similarly, even if this person is receiving hospice care, she will also likely require her various personalized equipment items for safety and comfort, such as her speech generating device or her customized wheelchair.

By contrast, under the current system, beneficiaries own their medical equipment outright and may keep this equipment when they receive these institution-based services. Moreover, while the person’s need for DME can be just as critical in an institutionalized setting as at home, beneficiary savings are not achieved with a 13-month wheelchair rental agreement. Beneficiaries will pay five percent more out of pocket during a 13-month rental agreement than if they purchased the equipment at the outset.

This proposal also fails to recognize and take into account that certain medical devices and technologies are highly customized to meet the unique, individual needs of beneficiaries whose disability is either permanent or expected to be long-term. We are also concerned that the proposed rule would create a situation where a number of these critical devices would no longer be available at all to Medicare beneficiaries.

Devices that are individually configured to meet the unique needs of the person with either a permanent or long term disability should never be included in the “capped rental” category, but should remain in the “routinely purchased” category. Doing so ensures that these devices can continue to be available and tailored to the unique functional profile and medical needs of the individual. Therefore, CMS should continue to allow for the purchase of devices designed for single use by an individual and for the purchase of such devices, which also can be altered to meet the individual’s needs over a span of years.

Finally, from the supplier standpoint, if one piece of equipment is a capped rental item, where is the incentive for the supplier to provide fully customizable equipment for one individual if that equipment is soon going to be rented to another individual with different customization requirements?

Complex Rehabilitation Technology (CRT)

Complex Rehabilitation Technology (CRT) refers to medically necessary and individually configured manual and power wheelchair systems, adaptive seating systems, alternative positioning systems, and other mobility devices that require evaluation, fitting, design, adjustment and programming. CRT is designed to meet the specific and unique medical and functional needs of individuals with clinical conditions and impairments that are significantly different from those experienced by the traditional senior Medicare population. This population tends to qualify for Medicare based on their disability and not their age, and consists of individuals diagnosed with long term conditions or disabilities such as cerebral palsy, muscular dystrophy, multiple sclerosis, spinal cord injury, amputation, brain injury, stroke, amyotrophic lateral sclerosis (Lou Gehrig’s disease), polio, and spina bifida. (See example of person with spinal muscular atrophy above.) These individuals typically require highly customized CRT devices that are not intended for use by multiple beneficiaries. Therefore, classifying CRT under a “capped rental” category is illogical and inappropriate and the final rule should reflect this.

The diagnoses that commonly lead to the need for CRT manual wheelchairs and other CRT items are congenital disorders, neuromuscular diseases, or injuries or traumas that result in significant physical or functional limitations. Given the nature of CRT, these items should not be classified as “capped rental” and must be classified as “routinely purchased.” This would include all CRT manual wheelchairs (codes E1161, E1232 to E1238, K0005) and related options and accessories used with these wheelchairs. Appropriately, the CRT ultra lightweight manual wheelchair (code K0005) is currently classified as “routinely purchased” and will remain so. However this same treatment should be accorded to CRT manual wheelchair codes E1161 and E1232 to E1238. These CRT items are individually configured to beneficiary’s medical and functional needs and are used by people who use wheelchairs permanently. This classification would follow the precedent and policy set by Congress and CMS whereby CRT power wheelchairs are eligible to be paid for as a routinely purchased item.

Many people who use this equipment also use pressure-relieving cushions, postural supports, and custom-molded seating systems that are permanently fitted to the wheelchair chassis. These are items that are currently categorized as “routinely purchased equipment” and that can only be provided and maintained by highly trained and skilled rehabilitation professionals. Consequently, the final rule should establish that all CRT manual wheelchairs are classified as “routinely purchased” items. Wheelchair options and accessories provided with or for a “routinely purchased” wheelchair base should be considered “routinely purchased” as well. The final rule should also confirm that repairs and replacements related to “routinely purchased” DME would be treated as “routinely purchased” items.

Reclassification of these items would require a complete change in the service delivery model of this important technology. This technology is manufactured and/or modified to meet the specific needs of each individual; it is not stocked on a shelf, issued, and reissued to beneficiaries on a rental basis.

The capped rental rule also recommends moving many wheelchair accessories to capped rental. The largest portion of these items are used only with power mobility devices and specifically with CRT power wheelchairs. Given that a purchase option is currently available to consumers when these items are provided on a Group 3 power wheelchair base, the proposed rule change would add unnecessary administrative complication in order to reclassify these items as capped rental and thus hinder consumer access to medically necessary equipment. Beneficiaries who qualify for this level of power mobility are full time and permanent CRT consumers who use the items for five or more years, until a replacement product is required.

Additionally, code E0986 (manual wheelchair push-rim power assist) is only available on CRT manual wheelchairs (code K0005), which are classified as “routinely purchased.” Reclassification as capped rental would result in the need to rent this component, which would then be used on a beneficiary-owned base. The local coverage decision policy already requires that the beneficiary use a manual wheelchair for one year before qualifying for the power assist. We therefore urge CMS to categorize the push-rim power assist as a “routinely purchased” item when provided on a purchased or beneficiary owned base.

Speech Generating Devices

Only 2700 Medicare beneficiaries use speech-generating devices (SGDs) but this is a critical benefit for those who need these assistive devices. SGDs are determined to be medically necessary by a speech-language pathologist and physician when a beneficiary cannot effectively communicate without assistance. These devices enable beneficiaries with sensory impairments to communicate with the world around them, which is critical for functional independence as well as communicating needs while hospitalized or in an inpatient setting. SGDs cannot be readily substituted with rental units because they require a high level of customization. Devices, which assist people

with long-term speech impairments, are individually configured to the unique needs of each beneficiary. One SGD supplier reports that 100% of SGD users surveyed continued to have a severe speech deficit well beyond 13 months, which is not unexpected given many SGD recipients have chronic or degenerative conditions such as ALS and Parkinson's disease. Interruptions in access to SGDs as a result of an institution-based stay during the 13-month rental period are particularly problematic for this beneficiary population with their limited ability to communicate. For example, a patient without access to the SGD is unable to articulate needs or concerns, and inpatient staff, typically untrained in the needs of people with significant impairments involving speech limitations, might interpret gestures and attempts to communicate as agitation or restlessness.

Ultrasonic Osteogenesis Stimulators

Among the items proposed for reclassification are ultrasonic osteogenesis stimulators. These devices are currently approved by the Food & Drug Administration as Class III medical devices and are stipulated for single-patient-use only. The design of these devices complies with this FDA requirement. These devices are critical in stimulating bone growth and healing and are particularly useful to individuals with conditions that involve frequent bone fractures such as osteogenesis imperfecta. Reclassification as a rental product would significantly compromise access to this device by permanently or temporarily disrupting patient care while a new FDA approval process unfolds and manufacturers develop a rental program.

Flawed Data Methodology

The method outlined to classify "routinely purchased" DME is fundamentally and irreversibly flawed and must be revised. Using Medicare claims data from over 27 years ago (for the period July 1986 to June 1987) to identify and classify items as "routinely purchased" indicates a profound lack of understanding of how evolving technology has affected the lives of people with disabilities over the past two and a half decades. This ill-conceived method also fails to take into consideration sea changes in rehabilitation technologies, product innovations, and widespread coding changes over the intervening 27 years.

The proposed rule references the interim final rule from December 7, 1992 (57 FR 57698) and the final rule from July 10, 1995 (60 FR 35492) regarding the definition of "routinely purchased" and how items will be classified into this category. The proposed rule states, "CMS indicated that it selected the period of July 1, 1986 through June 30, 1987, because it is the same 12-month period required by section 1834(a)(2)(B)(i) of the Act for calculating the base fee schedule amount for routinely purchased equipment." No formula or process is proposed that allows either new technology or technology previously not covered by Medicare to meet 1986-87 criteria. Classifying existing HCPCS codes and related products into the then-newly created, routinely purchased payment category might have been appropriate at that time, but that is no

longer the case. Neither the interim final rule nor the final rule contained provisions for classifying new technology or items newly covered by Medicare.

In light of these concerns, we strongly recommend that CMS establish meaningful criteria for determining payment category classification that takes into account advancements in technology and medical treatment.

Identified Potential Savings Are Overstated

The potential savings cited from classifying CRT items from “routinely purchased” to capped rental are inaccurate for CRT items in light of the nature of CRT, how it is provided, and the permanency of the beneficiary’s need. CMS states that to classify expensive items added after 1989 as routinely purchased based on the fact that other payers pay for the item as a purchase, “...does not comply with a fundamental purpose of the capped rental payment methodology to avoid paying full purchase price of costly equipment used only a short time.” There is no evidence that people with permanent disabilities that are significant enough to require CRT use the equipment on a short-term basis. CRT items are classified in the “routinely purchased” category or have an initial issue purchase option with the exception of CRT items grouped into HCPCS codes with DME items.

Ensuring Access to Quality Complex Rehabilitation Technology Act of 2013

Medicare currently does not have “unique device” coverage for the more complex and long-term needs of individuals with disabilities and chronic medical conditions. Therefore, DREDF supports *Ensuring Access to Quality Complex Rehabilitation Technology Act of 2013*, HR 942/S. 948, which would ensure that these individuals can access devices to remain independent in their homes and communities and avoid costly and inappropriate institution-based care. The bill reclassifies an already established category of DME and applies more appropriate rules to meet the needs of beneficiaries.

In conclusion, the concerns we raise, if not resolved by the final rule, will sow confusion and uncertainty in the minds of innovators and serve as a major deterrent to future investments in new technologies. Any rule that slows innovation in medical care and locks in our current level of technology—especially for the population of people with significant disabilities and chronic conditions—should be rejected and replaced, or modified, to ensure that the rule enhances certainty of coverage and stimulates investment in medical innovation. We therefore request that CMS revisit its grandfathering policy and clarify further in the final rule how this new requirement will not stifle invention or breed uncertainty.

We strongly urge CMS to develop policies that identify and classify “routinely purchased” items and that prevent inappropriate payment methods and reductions in access. In addition, because other payers follow Medicare guidelines, it is important to

change Medicare policy now before regulations that harm people with disabilities and chronic conditions are replicated at the state level.

Our recommendations regarding the capped rental rule, which goes into effect April 1, 2014 are the following:

- Temporarily delay the capped rental regulations as they pertain to all mobility devices and SGDs subject to capped rental until additional policy proposals can be assessed and implemented by CMS.
- Exempt all mobility devices for patients whose treating healthcare professional attests to the patient's long term need for the mobility device or SGD in question.
- Exempt all mobility devices and speech-generating devices (SGDs) developed after 1987 as there is no way to assess claims data for these devices for the time period between 1986 and 1987. (If this proposal is not adopted, every new device will be treated as capped rental, placing negative pressure on innovation and leading to restrictions in access to new technologies.)
- Exempt all Speech Generating Devices from capped rental treatment as these devices are highly customized with personal information used in daily communication and are virtually never prescribed for patients with short term speech needs.

Thank you for the opportunity to comment on this ANPRM. Please contact me at shenderson@dredf.org or at 510-644-2555 if you require additional information.

Sincerely,

A handwritten signature in blue ink that reads "Susan R. Henderson" followed by a horizontal line.

Susan R. Henderson
Executive Director