



August 30, 2013

VIA ELECTRONIC DELIVERY

Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1526-P  
P.O. Box 8010  
Baltimore, MD 21244-8010

**Re: [CMS-1526-P] Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies**

RESNA, the Rehabilitation Engineering and Assistive Technology Society of North America, is the premier professional organization dedicated to promoting the health and well-being of people with disabilities through increasing access to technology solutions. RESNA advances the field by offering certification, continuing education, and professional development; developing assistive technology standards; promoting research and public policy; and sponsoring forums for the exchange of information and ideas to meet the needs of our multidisciplinary constituency.

RESNA appreciates the opportunity to offer comment on *Section IV. Clarification of the Definition of Routinely Purchased Durable Medical Equipment (DME)*. Regarding the proposed rule that would reclassify certain DME as capped rental items, RESNA expresses concerns about the basis for this decision and its potential implications for both patients receiving that equipment and assistive technology professionals who participate in its provision.

**I. Scope of regulatory authority and responsibility of CMS to utilize timely data for relevant policymaking**

RESNA notes that Congress has delegated a great deal of regulatory authority to agencies such as CMS, accompanied by the expectation that regulations be responsive to technological change and flexible to meet patient needs. We are concerned that the proposed rule fails to appreciate Congress's mandate that CMS adapt to advances in assistive technology and service delivery. Hence, we affirm the observation offered by our colleagues from the National Coalition for Assistive and Rehab Technology (NCART) that, "It is counterintuitive that Congress would establish a payment category that effectively had no ability to accommodate new technologies or changes in application."

Furthermore, RESNA expresses dismay that data from 1986-1987 has been referenced to justify the proposed rule. Just as regulatory decisions guiding the provision of care for patients with cancer or cardiac disease would be expected to utilize current data, so should decisions regarding rehabilitation

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technology. Rather than apply *decades*-old data to affirm an outdated methodology and definition for DME, we urge CMS to use this opportunity to consider the relevance of its regulations and update them in a manner that is consistent with the current state-of-the-art in technology and actual practices. The very fact that Congress has recently considered the need to establish a separate benefits category for complex rehabilitation technology (CRT) that distinguishes it from other DME suggests the importance of this issue and the need for more appropriate and responsive policies.

## **II. Rationale for proposed rule and the need to ensure flexibility and options**

RESNA expresses concern regarding the rationale behind the proposed rule to designate the indicated items of DME, many of which include speech generating devices and CRT utilized by people with profound and permanent disabilities, as capped rental. (See addendum for a list and selected comments.) Users of these technologies typically have congenital disorders such as cerebral palsy, neuromuscular diseases such as amyotrophic lateral sclerosis (ALS) or Lou Gehrig's disease, or injuries or traumas, such as spinal cord or head injuries, that result in significant physical or functional needs and capacities. In such cases for these individuals, these disabilities are permanent, as are the users' needs for the enabling technology. However, this does not necessarily mean that their lifespan is so shortened that capped rental is the only viable option for obtaining these necessary technologies. Consider the example of physicist Stephen Hawking who has lived with motor neuron disease for almost 50 years and who has relied upon CRT and a speech generating device for much of this period. For him and other individuals like him, renting individualized equipment designed to meet a lifetime medical need does not make sense for the person and is not fiscally responsible. In short, it would only create a burden of paperwork and ineffective, expensive processes.

When an item is rented over 13 months for an individual with a lifetime or permanent medical need, the Medicare program not only pays 5 percent more than they would when the item is purchased outright, but they also must pay to process a claim 13 times, adding additional cost to administer this proposed change.

Furthermore, research undertaken by colleagues at the University of Pittsburgh in collaboration with wheelchair clinics and selected members of the National Registry of Rehabilitation Technology Suppliers (NRRTS) suggests that wheelchair users served by complex rehabilitation technology professionals tend to have neuromuscular and musculoskeletal conditions. In fact, whereas ALS accounts for 3 percent of these users, a larger proportion of the population includes people with spinal cord injuries (21%), orthopedic diagnoses (13%), cerebral palsy (10%), and multiple sclerosis (9%). For these individuals, who are expected to experience life with a permanent disability over a long-term duration, the proposed rule to reclassify CRT as capped rental is inconsistent with current findings.

RESNA also encourages CMS to consider giving service providers and clinicians the appropriate options to make the best decisions for their patients and to place the financial decision making in the hands of

beneficiaries and their caregivers. For example, linking a purchase option for speech generating devices and CRT to diagnosis, prognosis, and a documented lifetime medical need by the attending physician might be a more judicious method for guiding these decisions. Such a move would also respect the specificity of patient experiences and acknowledge the individual nature of disability and rehabilitation outcomes. RESNA observes that safeguards already exist, including rules by which a patient with impending death is generally covered under hospice and not Medicare.

### **III. Potential effects of rule on industry and provision of device and service delivery**

RESNA expresses grave concern about how CMS's proposed rules might upend a very delicate industry. Unlike standard DME currently covered by Medicare, speech generating devices and CRT are distinguished by a reliance on customization and specialization. As a result, there are fewer suppliers for this equipment, as well as a reliance on specialized expertise for its assessment, manufacture, and provision.

In addition to a service and delivery model that is substantially different from standard DME, speech generating devices and CRT rely heavily upon processes of adapting the equipment to meet the precise needs of its individual users. CRT products require a physical evaluation, a technology assessment, measuring, fitting, simulations and trials, a mixing and matching of products from different manufacturers, significant training and education, and refitting and ongoing additional modifications.

There also is the matter of specialized staff and standards that sets specialized equipment, such as speech generating devices and CRT, apart from DME. These devices require an evaluation by a licensed clinician to be considered for payment. The Medicare program also requires that CRT companies employ specialized and credentialed staff to analyze the needs of individuals with disabilities and assist in the selection of the appropriate equipment. These credentialed personnel, called Assistive Technology Professionals (ATP), are certified by the RESNA, and they specialize in the assessment, selection, and provision of CRT products. Furthermore, the Medicare program has established quality standards that all DME companies must meet to qualify for the Medicare program. CMS has included additional and more rigorous quality standards with which CRT companies must comply.

If implemented, the proposed rule to reclassify speech generating devices and CRT items as capped rental could very well threaten the provision of these technologies altogether by disrupting the very delicate markets that make them available in the first place. We urge CMS to take seriously these potential ramifications of its proposed rulemaking.

There also must be concern for the broader implications of such a rulemaking on other health care provision. Many other payers follow CMS rules. These proposed changes may adversely affect many individuals who are not currently Medicare recipients, especially in pediatrics. CMS sets an example for pertinent payers, and policies that ensure children can receive correct equipment makes

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them more likely to be able to be higher functioning and potential job holders who pay taxes and contribute to the system as adults rather than simply becoming Medicare recipients as soon as they reach adulthood.

We recognize that these types of policy decisions are often needed for purposes of cost savings. We also know that most polices are set today with minimal evidence of outcomes, as there will never be sufficient CRT evidence available, given their high cost of execution. To assist in better future decision-making RESNA would like to take this opportunity to encourage CMS to continue supporting the collection of better comprehensive case-based evidence. RESNA believes that equipment should be provided only when needed and better case-based indicators and outcomes data are needed to assist in the development of cost efficient policy. The proposed rule, *Section IV. Clarification of the Definition of Routinely Purchased Durable Medical Equipment (DME)*, however, is not based on current evidence.

In conclusion, RESNA urges CMS to consider the three major issues in its comments—regulatory authority and responsiveness to current needs; rationale for the rulemaking and the need for flexibility and options; and market impact. We believe that, if enacted, the proposed rule to reclassify these CRTs and speech generating devices as capped rental would have a negative impact. Thank you for your consideration.

Respectfully submitted,



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Nathan W. Moon, Ph.D.  
Chair, RESNA Government Affairs Committee

**Addendum: Indicated DME Categories and Codes with Specific Comments**

<b>Group Category</b>	<b>HCPCS</b>	<b>Descriptor</b>	<b>Comment</b>
Speech Generating Devices	E2500	SGD digitized pre-rec <=8min	These items need to be removed from this proposal as they are individually configured for individuals with permanent disabilities and a lifetime medical need.
	E2502	SGD prerec msg >8min <=20min	
	E2504	SGD prerec msg>20min <=40min	
	E2506	SGD prerec msg > 40 min	
	E2508	SGD spelling phys contact	
	E2510	SGD w multi methods messg/access	
Wheelchairs Manual	E1161	Manual adult wc w tiltinspac	This code is CRT by policy and need to remain IR, like K0005
	E1232	Folding ped wc tilt-in-space	Medicare is not the primary payor for these items as utilization is less than 400 units annually for all 7 codes combined. Moving these HCPCS codes from IR to CR could adversely affect access with other payors with no positive impact on Medicare. In addition, these items are the same as other identified CRT items coded E1161 and K0005. The only difference is that their seat width is less than 15".
	E1233	Rig ped wc tltnspc w/o seat	
	E1234	Fld ped wc tltnspc w/o seat	
	E1235	Rigid ped wc adjustable	
	E1236	Folding ped wc adjustable	
	E1237	Rgd ped wc adjstabl w/o seat	
	E1238	Fld ped wc adjstabl w/o seat	

Wheelchairs Options/Accessories	E0986	Man w/c push-rim pow assist	Per coverage criteria this item falls under the PMD policy, is CRT and effectively turns a beneficiary owned CRT MWC into a power driven w/c.
	E1002 ^	Pwr seat tilt	All of these items can be provided at initial issue OR could be provided after the initial issue of the CR CRT PWC due to a repair/replacement or change in medical need. These items need to be removed from this proposal as they are individually configured for individuals with permanent disabilities and a lifetime medical need.
	E1003 ^	Pwr seat recline	
	E1004 ^	Pwr seat recline mech	
	E1005 ^	Pwr seat recline pwr	
	E1006 ^	Pwr seat combo w/o shear	
	E1007 ^	Pwr seat combo w/shear	
	E1008 ^	Pwr seat combo pwr shear	
	E1010 ^	Add pwr leg elevation	
	E1030 ^	W/c vent tray gimbaled	
	E2310 ^	Electro connect btw control	
	E2311 ^	Electro connect btw 2 sys	
	E2312 ^	Mini-prop remote joystick	
	E2313 ^	PWC harness, expand control	
	E2321 ^	Hand interface joystick	
E2322 ^	Mult mech switches		
E2325 ^	Sip and puff interface		

Wheelchairs Options/Accessories	E2326 ^	Breath tube kit	
	E2327 ^	Head control interface mech	
	E2328 ^	Head/extremity control interface	
	E2329 ^	Head control interface nonproportional	
	E2330 ^	Head control proximity switch	
	E2351 ^	Electronic SGD interface	
	E2374 ^	Hand/chin ctrl std joystick	
	E2377 ^	Expandable controller, initial	
	E2373	Hand/chin ctrl spec joystick	Should be included in the CR list and follow the rules developed for CRT.
	E1014	Reclining back add ped w/c	All of these items are separately billable at initial issue and have the option to be rented (RR), rather than purchased (NU) under the IR category. Logistically it would be easier to keep them in the IR category and require they be billed with the RR modifier at initial issue when provided with a base that is in the CR category and does not have a purchase option, such as standard power wheelchairs and capped rental manual wheelchairs, but allow billing with the NU modifier when provided at initial issue with a CRT base (E1161, E1232-E1238, K0005 or K0835 – K0064) where the purchase option is exercised or with a beneficiary owned base.
	E1020 *	Residual limb support system	
	E1028 *	W/c manual swingaway	
	E1029	W/c vent tray fixed	
E2227	Gear reduction drive wheel		
E2228 *	Mwc acc, wheelchair brake		
E2376 ^	Expandable controller, replace	This HCPCS code is identified as CRT but cannot be billed at initial issue. It must be able to be billed with the NU modifier when used to repair/replace E2377.	

Wheelchairs Options/Accessories	E2368 *	Pwr wc drivewheel motor replace	These items should be removed from the list as they can ONLY be provided and billed to the Medicare program in conjunction with a beneficiary owned device.
	E2369 *	Pwr wc drivewheel gear box replace	
	E2370 *	Pwr wc dr wh motor/gear comb	
	E2375 *	Non-expandable controller	
	E2378	Pw actuator replacement	
	K0015 *	Detach non-adjus hght armrst	
	K0070 *	Rear whl complete pneum tire	
Wheelchairs Seating	E0955 *	Cushioned headrest	In the IR category this item can be provided as a purchase (NU) or rented (RR) item when billed with the appropriate modifier. It would be far more effective to require a headrest provided with a capped rental item to be rented (RR) but if it is provided with a beneficiary owned device, or with a device where the purchase option is exercised, it should be allowed to be purchased (NU).