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January 29, 2018

William N. Parham, III, Director,
Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: American Association for Homecare’s (AAHomecare’s) Comments on the Centers for Medicare and Medicaid Service’s (CMS’) Paperwork Reduction Act (PRA) Submission on the Implementation of §5002 of the 21st Century Cures Act of 2016 (Cures Act)¹

Dear Mr. Parham:

We are submitting comments on CMS’ PRA submission to implement §5002 the Cures Act. That provision caps federal financial participation (FFP) for Medicaid spending on durable medical equipment (DME) paid under fee schedules. Beginning in 2018, the cap applies to a Medicaid program’s aggregate spending for DME that exceeds Medicare’s aggregate spending for DME under Part B (including competitive bidding).

AAHomecare is the national association representing DME suppliers and manufacturers. In our view, implementing §5002 before analyzing its effects on Medicaid beneficiaries ignores the statute’s unambiguous instruction. Congress understood the difference in the purpose and scope of these two programs. So to monitor Medicaid beneficiaries’ access to medical equipment, Congress explicitly directed CMS to study the impact of cutting Medicaid program funding for DME to Medicare levels.

¹ 82 Fed. Reg. 56242 (Nov. 28, 2017).

As far as we know, CMS has not taken any steps to comply with this mandate. Reducing Medicaid rates for DME to match those of Medicare, promises a loss of access for beneficiaries as bad as, or possibly worse, than what Medicare beneficiaries are now facing under competitive bidding and adjusted fee schedules. We discuss these issues in more detail below.

1. Implementing FFP caps without understanding their effect on Medicaid beneficiaries ignores a statutory mandate and undermines Congress' responsibility to oversee how CMS implements the statute.

Section 503(a)(1) of the Consolidated Appropriations Act of 2016 imposed a cap on FFP for Medicaid programs' aggregate spending for DME in excess of aggregate spending for DME under Medicare Part B, including spending under competitive bidding. But the statute also directed CMS to study the impact on Medicaid programs of cutting spending for DME to Medicare levels. Section 503(b) instructs the Agency to:

[E]valuate the impact of applying Medicare payment rates with respect to payment for durable medical equipment under the Medicaid program under section 1903(i)(27) of the Social Security Act [...]. The Secretary shall make available to the public the results of such evaluation.

Section 5002 of the Cures Act amended §503(a)(1) by moving up its implementation to 2018. The Cures Act amendment did not, however, change Congress' instruction that CMS perform a study and publish the results. Dispensing with this directive while moving forward to impose FFP caps reduces §503(b) to a meaningless appendage.

Every statutory provision has meaning and should be given effect. This rudimentary canon of statutory construction means CMS cannot read §503, as amended by the Cures Act, to exclude the charge the Agency conduct a study. Doing so renders §503(b) "surplusage"² with no effect, when in fact CMS must assume Congress had a *reason* for ordering the study. In this case, we must presume Congress intended to intervene if beneficiaries' loss of access warranted its action.

To our knowledge, CMS has not taken steps to comply with §503(b). But CMS knew it had to produce a study as far back as December 18, 2015 when the Consolidated Appropriations Act of 2016 passed Congress. Our sense is the Agency could be nearing completion of a report by now had it heeded Congress' direction in 2015. Instead, CMS published a PRA request telling *states* to determine the impact of adopting Medicare rates for *themselves* to relieve them from having to complete §5002 forms under review.³

² *Corley v. U.S.*, 556 U.S. 303 (2009) (every part of a statute must be given full effect).

³ The instructions state, in part:

We suggest that states look at their Medicaid DME payment amounts and claims to determine if setting payment rates at or below the Medicare amount is a reasonable approach for compliance. States doing this will be exempt from this Collection of Information.

CMS PRA submission, available at: <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

Contrary to Congress' mandate under §503(b), the instructions shift the burden of producing an impact study to the states. Again, there is a reason Congress asked the Agency, not 50 individual states, to perform a study. CMS, not states, is tasked with enforcing FFP caps, and CMS answers directly to Congress unlike the states. The statutory mandate shows Congress' intent to oversee CMS administration of the statute and intervene if that becomes necessary.

CMS has not said when or how it will comply with §503(b), so at the very least, the plan to forge ahead implementing §5002 is premature. We recommend CMS perform and publish the impact study before it imposes FFP caps on any states.

2. Disabled persons have the right to live in the least restrictive environment suitable to their circumstances.

State Medicaid programs facilitate beneficiaries' ability to receive home and community based care through access to DME that lets them live in their communities.

Congress' desire to understand how FFP cuts will affect Medicaid programs is not surprising considering the fundamental difference between Medicare and Medicaid. Medicare covers DME for elderly and disabled beneficiaries to use primarily in their homes. State Medicaid programs on the other hand must provide DME items that are suitable for any settings "in which normal life takes place."⁴ This is a much broader mandate, consistent with the different demographic Medicaid programs cover.

Medicaid beneficiaries include disabled children and younger adults who can engage with their communities. Some attend school, go to work and socialize in settings outside their homes. Ensuring access to DME that allows them to do this is one goal of the federal/state Medicaid partnership. The Supreme Court decision in *L.C. & E.W. v. Olmstead*⁵ upheld disabled persons' right to live in the least restrictive environment that is appropriate for them. And *Olmstead* confirmed states' role in facilitating beneficiaries' access to community based care.

Following *Olmstead*, CMS recognized Medicaid programs' "critical" role in ensuring disabled persons are integrated into their communities.⁶ Medicaid programs are "the primary agents" to facilitate the transition from institutional to home and community based care, providing access to equipment, especially mobility equipment that makes it possible. It is imperative to know whether cutting FFP for DME impairs beneficiaries' access to this equipment.

Its broader scope also means Medicaid programs might spend more than Medicare for DME items beneficiaries use in their communities. It is a mistake for CMS to suggest, as it does in the PRA request, that states should reduce their rates to match Medicare item-for-item to avoid completing §5002 forms. The instruction seems designed for the Agency's own administrative convenience without regard for the consequences to beneficiaries in states that adopt this approach. Section 5002 notwithstanding, states have the authority to administer their resources according to their own priorities.

⁴ 42 CFR §400.70

⁵ 119 S.Ct. 2176 (1999).

⁶ State Medicaid Directors Letter (SMD), dated January 14, 2000, available at: <https://www.medicaid.gov>.

3. Reducing Medicaid funding for DME to Medicare levels will create access barriers for beneficiaries that are as bad, or worse, than the those Medicare beneficiaries face under competitive bidding and adjusted DME fee schedules.

Medicaid programs are broader in scope than Medicare and have a specific responsibility under *Olmstead* to facilitate beneficiaries' access to community based care. Cutting Medicaid reimbursement for DME to current Medicare levels will create the same – or possibly worse – barriers to access than those Medicare beneficiaries face under competitive bidding and adjusted fee schedules.

Beginning July 1, 2016, Medicare replaced the traditional DME fee schedules with adjusted rates derived from competitive bidding payment amounts. Now Medicare pays for most DME under competitive bidding programs or fee schedules derived from competitive bidding prices. The result is that in a survey conducted last year, 52% of beneficiaries reported having trouble getting DME since July 1, 2016.⁷ And 77% of discharge planners surveyed reported difficulties discharging Medicare beneficiaries who need DME. Overall, referral sources and suppliers reported an astonishing 81.4% increase in the number of complaints from Medicare beneficiaries about access to DME or an increase in their out-of-pocket costs.

The indisputable inference from these data is that Medicare payment for DME is now so low, that beneficiaries, discharge planners and referral sources cannot get equipment they need when they need it. The other glaring inference is that applying Medicare DME rates to Medicaid will prove equally problematic for the nearly 20.5 million Medicaid beneficiaries who receive DME directly from Medicaid programs and the other 54.6 million who get their DME through Medicaid managed care plans that are based on Medicaid fee schedules. The most vulnerable among these are dual eligible beneficiaries like qualified Medicare beneficiaries who already have trouble getting DME, especially mobility equipment, they need.

This outcome is almost certainly unavoidable if Medicare payment rates become prevalent throughout state Medicaid programs. On the strength of the Dobson study alone, we see a crisis looming for Medicaid beneficiaries who need DME. Again, we ask CMS to begin the §503(b) study and publish its results right away.

4. The PRA submission and other materials CMS addressed to State Medicaid Directors contain confusing, incomplete and at times misleading information.

With respect to the current PRA, CMS tells states they can reduce the burden of responding to the information collection by setting payment rates for DME “at or below” Medicare rates for the items. Section 5002 applies to states' aggregate fee schedule spending for DME over aggregate Medicare spending for the items. But it *does not* require that states match their reimbursement to Medicare item-for-item. States can set payment amounts according to their priorities, subject to FFP limits, §5002 notwithstanding.

Encouraging this approach as a way to minimize collection of information burdens is also somewhat misleading. Inevitably, states will end up amending their state plan each time Medicare rates change under competitive bidding. This reduces the initial convenience of taking this approach and interjects uncertainty and procedural complexity depending on a state's process for amending the state plan.

⁷ Dobson DaVanzo & Associates (2017) (Dobson study).

Importantly, adopting Medicare fee schedules does not guarantee a state's spending for DME will be less than under Part B because rates for some items will increase. Even assuming they make across the board cuts to match Medicare spending, states may still spend more than Medicare for items with higher Medicaid utilization that are not included in the 255 HCPCS codes identified by the CMS as affected by the CURES amendment.

We also think the instructions are confusing and incomplete. First, they lack information states need to complete the forms. Medicare and Medicaid cover and pay for DME differently. Medicaid allows lump-sum sales for many items that Medicare first rents for 13 months. And Medicare reimbursement for DME often depends on claim modifiers states might not use. These are only two of many conflicting rules that can determine a state's aggregate spending on medical equipment. But the instructions and supporting statement do not explain how to reconcile these discrepant billing rules.

Nearly a month after making this request, CMS published an SMD elaborating on §5002 requirements.⁸ Then CMS published appendices telling states how to arrive at their aggregate spending for DME. The appendices contain detailed instructions for cross-walking a lump-sum DME purchase price to the corresponding 13-month rental rate and for resolving other conflicts between the two programs' rules. In comparison, the forms under review are so general they would be difficult to complete without consulting the appendices. Notably, CMS did not submit the appendices for PRA review. This flaw makes the forms, instructions and supporting statement incomplete. AAHomecare recommends CMS revise all of them to include instructions from the appendices.

Next, without the material in the appendices, this is a seemingly straightforward PRA request for forms that will be equally straightforward to complete. But a review of the appendices suggests they are more complicated and will be more time consuming to complete than CMS predicts. Looking at the amount of information states must produce, for example, states must use the competitive bidding price for each item in each competitive bidding area in the state, and the level of detail CMS requests, aggregate spending for items depends on their utilization, makes us question the Agency's time and cost burden estimates. It *could* take only eight hours to *fill-in* the forms, but the amount of time and work for collecting and analyzing data they solicit is likely more. We recommend CMS revise the time burden estimate to account for collecting and analyzing data to complete the forms.

Third, the instructions are confusing. In some places, they direct states to adopt the entire DME fee schedules, including over 1000 HCPCS codes. In others, they say the §5002 analysis applies only to the roughly 255 HCPCS codes that both programs cover. Overall, they encourage states to adopt Medicare rates so they can avoid FFP caps (and having to complete the forms). Again, §5002 does not require Medicaid DME rates to correspond one-to-one with Medicare rates for DME. States still can set reimbursement according to their own priorities, subject to FFP caps.

CMS must be completely transparent with the state and DME providers in findings on any reconciliation data including breakdown by procedure code for aggregate spend. This information will be important for the state Medicaid programs and industry stakeholders to partner together to ensure access to care for Medicaid beneficiaries.

⁸ SMD dated December 27, 2017, available at [Medicaid.gov](https://www.medicare.gov).

Conversations with multiple state Medicaid programs have shown that the 8 hours estimated by CMS for data collection by the states has been grossly underestimated. One state Medicaid program stated “We have already spent more than 8 hours at this point and have not begun to analyze the data. This will cost states millions of dollars in programming efforts and will take more than a year to complete.”

It is a concern that the ongoing accuracy of the CMS Data Tool that was developed will be updated as changes in pricing and regulatory requirements occur.

Most Medicaid MCO plans follow Medicaid fee schedules or a discount off of Medicaid fee schedules. This directive is impacting not only the 20.5 million beneficiaries covered by primary Medicaid Fee for Service but also indirectly impacting the 55 million beneficiaries covered by Medicaid MCO plans. Implementation of this legislation will impact access to care for up to 75 million beneficiaries across the country. This includes 36 million pediatric beneficiaries.

Finally, we were surprised by how long it took the Agency to publish these materials and the piecemeal way it released them. We could only guess at CMS’ approach to the statute before the Agency published the SMD and appendices in December. AAHomecare members who serve Medicaid beneficiaries could not plan for 2018 without guidance from Medicaid programs that, in turn, were waiting for guidance from CMS. As we noted, §5002 amended §503 of the Consolidated Appropriations Act of 2016 which Congress passed December 18, 2015. CMS knew then it had to create a framework to comply with the statute so a two year delay in releasing basic information is hard for us to understand.

Once again, Medicaid beneficiaries risk losing access if DME payment rates are too low. Congress addressed this concern by ordering an impact study under §503(b), and we urge CMS to complete and publish the study before it begins enforcing §5002.

5. Medicaid beneficiaries must have mobility equipment, especially complex rehab technology (CRT), so they can receive home and community based care.

Cutting Medicaid spending for mobility and CRT threatens beneficiaries’ access to these technologies.

The lack of a clear understanding and recognition of the specialized nature of CRT within regulations and policies are the biggest challenge to preserving adequate access. The following are important CRT facts that CMS needs to be aware of:

Complex Rehab Technology products and services are significantly different than standard Durable Medical Equipment. The DME benefit was created over fifty years ago to address the medical equipment needs of elderly individuals. Over the years CRT products have been developed for the unique needs of people with disabilities offering more features, function, and durability. Increasingly CMS has grouped these products into single HCPCS codes with vague descriptors. As a result, CRT items with a broad array of features/functions/durability and standard DME items are grouped into a single HCPCS code with only one level of reimbursement.

These specialized products are used by a small population of children and adults who have significant disabilities and medical conditions- Individuals who require CRT have a complex disability or medical condition such as, but not limited to, Cerebral Palsy, Muscular Dystrophy, Multiple Sclerosis, Spinal Cord

Injury, Amyotrophic Lateral Sclerosis, Spina Bifida, or Traumatic Brain Injury. CRT enables these individuals to deal with their daily physical, functional, and cognitive challenges. It plays a critical role in addressing the complex medical needs of these children and adults and in keeping them active and functional within their homes and communities. CRT also keeps health care costs down by reducing medical complications, clinical interventions, hospitalizations, institutionalizations, and caregiver needs.

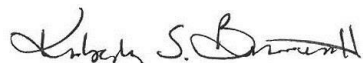
The process of providing CRT products is done through a clinical model and is service-intensive (like the provision of custom Orthotics and Prosthetics). The provision of CRT is typically done through an interdisciplinary team consisting of, at a minimum, a Physician, an independent Physical Therapist or Occupational Therapist, and a credentialed Assistive Technology Professional (ATP). The ATP is employed at a company accredited as a CRT provider by a CMS approved accreditation organization. The team collectively provides clinical services and technology-related services designed to meet the specific and unique medical and functional needs of the individual. The activities of the provider are labor-intensive and include evaluating, recommending, securing funding, purchasing, assembling, delivering, fitting, adjusting, and training. The provider is also responsible for ongoing modifications and repairs.

Due to significant operating costs and low profit margins there are only a small number of qualified providers that supply these specialized products and services- This is a difficult business as companies providing CRT products must maintain the required trained and credentialed staff, supporting systems and facilities, and related company accreditations to perform the necessary activities. It is important to note that the evaluation and delivery process is service-intensive, and providers do not receive any separate payment to cover these costs. Supplying CRT comes with significant operating challenges and costs, along with low profit margins. As a result, there are a very limited number of companies that provide CRT and that number is decreasing across the country. An analysis of Medicare CRT providers from 2011 to 2014 showed a 40% decline.

Congress and CMS have recognized the specialized nature of CRT and it has been excluded from the Medicare Competitive Bid Program since its commencement in 2008. Given the unique nature of individually configured CRT products, these items have been specifically excluded from inclusion in Medicare's Competitive Bid program. Accordingly, for certain DME wheelchair accessory codes the Medicare fee schedule has a different payment rate when an item is provided on a CRT wheelchair through the use of a "KU" modifier.

Thank you for considering our comments above. Please do not hesitate to contact me if you have any questions.

Sincerely,



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VP Regulatory Affairs