Congress of the United States
Washington, DC 20515

September 11, 2014

Honorable Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Administrator Tavenner:

We are writing today with questions regarding recent changes to CMS' policy and Durable Medical Equipment Medicare Administrative Contractor (DME MAC) actions regarding speech generating devices (SGDs) and SGD-related accessories. We have heard from many constituents about these issues including patients living with serious conditions that require the use of SGDs such as cerebral palsy, amyotrophic lateral sclerosis (ALS), Rett Syndrome, muscular dystrophy, multiple sclerosis, Parkinson's disease, brain stem stroke, locked-in syndrome, and traumatic brain injury.

Recently, DME MACs have issued a significant policy change through a "Coverage Reminder" stating that if patients wish to expand the functionality of the device after Medicare coverage and that device can in fact be "unlocked" that the device will not be covered at all by Medicare. This change would also dictate patients' choices regarding functionality of the devices even after ownership of the device has transferred to the patient.

In addition, several DME MACs have started to issue routine denials for eye tracking technology even with required professional documentation showing the technology is medically necessary. For patients, like those living with ALS, who have lost the ability to control most if not all of their bodies with the exception of their eyes, eye tracking or eye gaze technology is their only means of utilizing an SGD.

Finally, CMS recently reclassified SGDs as a "Capped Rental." One of the implications of the "Capped Rental" designation is that Medicare will cease making rental payments for the device if the patient requires a hospital, hospice, or other facility admission forcing these patients who would otherwise be eligible for coverage to pay out of pocket.

It is our understanding that after outreach by stakeholders, CMS has declined to modify the aforementioned policies, in some instances suggesting that statute

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prevents changes. With that in mind, we respectfully request your responses to the following questions regarding these changes:

1) Sec. 1834(a)(19) of the Social Security Act already provides the Secretary with the authority to create a process for patients to be able to upgrade their DME items and caps Medicare spending at the rate of the base covered item. Why has this not been utilized for patients who need to utilize SGDs to communicate and want to be able to expand the functionalities of these devices?

2) Why is Medicare pursuing a policy of preventing unlocking of devices, which will restrict patients' ability to expand the functionality of these devices when Medicare is not being asked to cover or pay for those expanded functionalities?

    a. Has Medicare contemplated the patient impact of dictating the patient's ability to upgrade a device even after the patient then owns the device?
    b. How much does Medicare expect to save by restricting the unlocking of devices?
    c. How much did Medicare spend in FY 2013 for the unlocking of these devices? How much did Medicare spend on maintenance costs that specifically related to the unlocking of the device in FY 2013? If data for FY 2013 is not available, please provide information from the most recent claims data CMS has available.

3) When eye tracking technology is the only option for patients with paralysis to use their device and all DME MAC Local Coverage Determinations (LCDs) state that SGD accessories that meet criteria of reasonableness and necessity are covered, why are CMS and the DME MACs denying claims for the technology and viewing it as not medically necessary or not covered when the required healthcare professional documentation has been provided?
    a. How much did Medicare spend in FY 2013 on eye-tracking additions that were deemed medically necessary? If data for FY 2013 is not available, please provide information from the most recent claims data CMS has available.

4) While inappropriate denials can often be addressed as part of the Medicare appeals process, the appeals process is experiencing a backlog of *multiple years*. How does CMS plan to quickly address appeals of inappropriate denials of eye tracking given this technology is the only way for these patients to communicate?

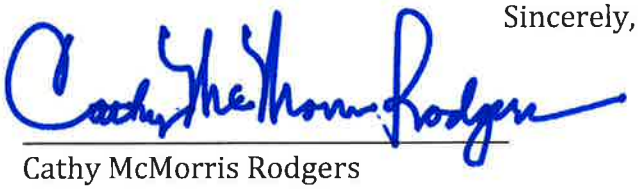
5) Section 1834[a][4] allows for the purchase of items that are "uniquely constructed or substantially modified to meet the specific needs of an individual patient ... " Because SGDs are programmed specifically for each individual and modified to meet their unique needs, why has CMS determined that they do not meet this qualification and instead decided to implement the capped rental policy for SGDs?

6) Given that patients who require SGDs regularly require inpatient, nursing facility care, or hospice stays, does CMS plan to enforce that facilities must provide the patient with a device, especially one that involves the customization and training required to provide the correct SGD, while the beneficiary is admitted ?

The patients who are in need of SGDs are some of Medicare's most vulnerable beneficiaries. As we mentioned, SGDs provide often the only means of communication for patients living with cerebral palsy, amyotrophic lateral sclerosis (ALS), Rett Syndrome, muscular dystrophy, multiple sclerosis, Parkinson's disease, brain stem stroke, locked-in syndrome, and traumatic brain injury. It is imperative that Medicare policy and DME MACs take in account the ability of these patients to communicate with their family, caregivers, and health care providers.

Because the timing of these policies is already impacting patients, we thank you for your attention to this critical matter and look forward to your response before October 1, 2014.

Sincerely,



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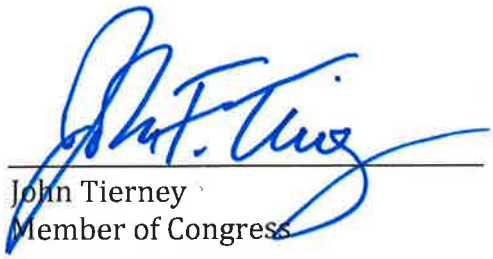

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