3 September, 2014

The Honorable Dr. Sylvia M. Burwell
Secretary of Health and Human Services
200 Independence Ave SW
Washington, DC 20201

RE: Changes to CMS Coverage for Augmentative and Alternative Communication Devices Severely Limit the Utility of these Crucial Devices

Dear Madam Secretary:

I am the Chairman of the Board and co-founder of the Prentke Romich Company (PRC), a small business in Wooster, Ohio. We provide augmentative and alternative communication devices ("AAC") (CMS term is Speech Generating Device, or "SGD") for people with severe disabilities who have limited motor control and cannot speak—those who are among the neediest beneficiaries of CMS. Recent changes in CMS policy have put this population at risk, and we plead for your attention and intercession.

PRC was founded in 1966. A pioneer in the field of assistive technology, PRC originally made devices to help disabled veterans; over time the company's focus moved to serving a very needy disabled population: individuals with multiple disabilities who cannot speak. The founders' engineering background helped them develop an early micro-processor based system that could provide electronic communication. That device operated on a switch, which could be activated by any part of the body a person could control. The statements were 'static communication' e.g., "I'm cold"; "I have to go to the bathroom"; "I'm hungry". Additional leaps in technology, and collaboration with an academic linguist, brought a more sophisticated understanding of language and communication to the company's products. In 1983, PRC produced the first AAC device which allowed individuals with both severe physical and cognitive disabilities to generate spontaneous communication. It was designed to be operated even by individuals who could control only one part of their body, for example by people who could operate only a head switch. [1]

Today, these devices are used by a tiny segment of the population – individuals with multiple severe disabilities.[2] PRC devices can be operated by eye gaze; by the movement of a single eyebrow; or by twitching a toe. Many of our users are in the final stages of diseases like ALS; others have cerebral palsy or other severe birth defects; others have had severe spinal cord injuries. The devices can currently be used to communicate verbally (including making phone calls); to communicate in writing (via email and print); to manipulate the individual's environment (like turning on/off lights). All of these functions permit these severely disabled

[1] The devices are subject to regulation by the FDA as Class II medical devices (21 C.F.R. 870.3910).
[2] There are fewer than 10 companies providing products for this population

Corporate Office: 1022 Heyl Road, Wooster, OH 44691 **Toll Free Service**: 800-262-1990 • **Sales**: 800-262-1933
800-262-1984 • (330) 262-1984 • FAX (330) 263-4829 **Consultant Information**: 800-848-8008
E-mail: info@prentrom.com **Web Site**: www.prentrom.com

individuals to live more independently, allowing many of them to pursue education, to be employed, and to remain in a community setting, with the aid of caregivers, as opposed to being institutionalized.

Funding was a serious barrier to obtaining a PRC device for many users. Caring for a person with disabilities is very expensive, and families are often stretched, and sometimes torn apart under the financial pressure. Few people could afford to buy devices that cost as much as a small used car, so bake sales, service clubs and Easter Seals were often the source of payment. Medicaid began funding PRC devices in the 1980's as States discovered the reduction in health care costs achieved when people in fragile medical condition can report on their needs and effect solutions. Schools began purchasing devices as more children with severe disabilities began to attend public school, and there are many college graduates among PRC users.

In 2001, Medicare began to provide funding for PRC devices (then labeled as Speech Generating Devices, or SGDs), which was of great help in persuading commercial insurance carriers to provide the devices as a covered benefit. The funding requirements are rigorous: a multi-disciplinary team must conduct an evaluation; a speech language pathologist must provide a written recommendation of the appropriate device; a physician must sign a prescription.

In 2013, PRC saw a big change in the reimbursement landscape. CMS announced it was moving SGDs to a capped rental formula in an effort to reduce costs. This is of particular concern to the population with severe disabilities (such as ALS), as the capped rental rules require that an individual return a device (one that has been customized for his or her own needs) if that person is admitted to a hospital or nursing home - a not infrequent circumstance in a population as medically needy as this one. The capped rental rules mean that a user is left without a device during a time when it is most needed - and, if the person is able to return home, the replacement device will not be the customized one the user had prior to his inpatient stay.

The CMS capped rental proposal reported $20,170,612 in payments for SGDs in 2012 at average cost of $7,356. That means that Medicare helped 2,742 people with complex medical needs and no way to communicate with medical professionals to achieve functional communication ability. This represents **.000008** of the United States population.

In March 2014, CMS issued a devastating blow to the community of disabled people who need SGDs with a "Coverage Reminder[3]) which amended the 2001 coverage decision that allowed reimbursement of SGDs, severely limiting the permitted functionality of the devices by stating that non-speech functions could not be added at the user's expense (i.e., 'unlocking'). We believe this is a reaction to CMS's fear that a perfectly healthy person could somehow go through the rigorous funding requirement process and that Medicare would purchase an expensive SGD that would then be used for non-disability needs. This fear is likely based on recent changes in State Medicaid policies allowing the purchase of iPads as SGDs as a less expensive (while often less functional) alternative to the devices of the sort PRC provides. As it happens, PRC agrees that iPads can often be a successful tool for some people, such as some children with diagnoses in the autism spectrum – but iPads and other consumer devices are not durable medical equipment and *do not* provide the functionality necessary to serve the people with severe

[3] https://www.dmepdac.com/resources/articles/2014/03_31_14.html

multiple disabilities who use SGD's such as the PRC device. In fact there is no actual quantitative evidence of the communication efficacy of consumer devices.

The CMS Coverage Reminder limited functionality of SGDs to speech output only. This means that a person who has been able to use the device to control the environment (turning lights on and off, adjusting the television, adjusting the bed) can no longer do so. With functionality limited to speech output only, the user can no longer use the device to send email or to connect to a computer for even basic tasks. Indeed, the functional limitation means that the user can no longer use the device to communicate by telephone, including calls to medical professionals, family and friends. The CMS Coverage Decision has taken SGDs back to the functionality they had in 1979 – denying this medically needy population of over 35 years of medical and technological advances, many of which were the result of United States government initiatives

CMS's Coverage Reminder on SGDs represents a terrible milestone in the history of assistive technology in this country. For the previous half a century, the federal government, universities, and private companies have collaborated to develop devices that clearly and tangibly improved the lives of people with disabilities through assistive technology. Our company's mission is to improve the quality of life for our users; for the first time ever, and as a direct result of the Coverage Reminder, we must affirmatively limit the ability of disabled users to communicate and actively take away functions that aided the autonomy and self-determination of this medically needy and multiply disabled population.

Until today, a device user with even limited control over only one portion of the body—the eyes; a finger, an eyebrow, a toe—has been able to use the telephone to schedule appointments with the doctor or talk to the nurse; to go online to check EOBs, pay bills, order prescription refills and groceries and even Skype with the speech language therapist or an out of state specialist; to turn the lights on and off, adjust the thermostat, and change the channel on the television.

Until today, because those functions were in their devices, our users have been able to move from long term skilled facilities into semi-independent living—to home! Inpatient hospital stays and visits to the ER have been reduced. The mental health problems resulting from isolation and frustration, such as depression and bleeding ulcers, have been greatly ameliorated.

Some may say that these devices are no different than the inexpensive tablets and smart phones teenagers use for texting and games. That is not true. PRC devices are Class II devices that meet all durable medical equipment rules and are specifically designed for people with severe, multiple disabilities. For the 5000 people we serve every year, across all funding sources, most of whom will be impacted by the CMS Coverage Reminder and a concurrent change in HCPCs coding, this is a step back toward isolation, increased dependence, reduced potential for higher education and employment, and higher risk of medical issues. We find this morally reprehensible. As a country, we are better than this.

If we assume that CMS's Coverage Decision was, in fact, motivated by a concern that people would claim reimbursement for iPads and other consumer devices, as if they were SGDs, these concerns could be addressed in a more efficient manner that has a less draconian impact on those with serious disabilities. It is our thought that a device recommendation should be based less on specific technology, which changes quickly, but more on an analysis of the functional

needs of the individual. CMS could also require that SGDs be entitled to reimbursement only if they comply with FDA regulations for Class II medical devices.

We ask that you review the Coverage Reminder and (1) clarify it to allow SGDs that are Class II Medical Devices or otherwise are ordered by a physician's prescription to have multiple functions (and not be limited to speech generation only) or (2) develop new guidelines that focus on the needs of your beneficiaries and do not inhibit advances in technology. Please contact me if you would like any additional information on this topic. We appreciate your kind attention.

Sincerely yours,

Barry A. Romich, P.E.

The Prentke Romich Company
1022 Heyl Road
Wooster, Ohio 44691

Tel: 800-262-1984, ext. 211
Email: BAR@prentrom.com

cc:

Marilyn B. Tavenner, Centers for Medicare & Medicaid Services Administrator
Richard Kronick, Ph.D, Agency for Healthcare Research and Quality Director
Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies
Senate Finance Subcommittee on Health Care
House Appropriations Subcommittee on Labor, Health and Human Services, and Education and Related Agencies
House Ways & Means Subcommittee on Health
Katya Hill, AAC Institute
Barbara Newhouse, ALS Association
Arlene Pietranton, ASHA
Catherine M. Rydell, American Academy of Neurology
Mark Perriello, American Association of People with Disabilities
Katherine O'Neil, American Bar Association Commission on Disability Rights
Andrew Imparato, Association of University Centers on Disabilities
Susan H. Connors, Brain Injury Association of America
Kathleen Holt, Center for Medicare Advocacy
Alexander Graham, Council for Exceptional Children
Katy Neas, Consortium for Citizens with Disabilities
Garry Augustine, Disabled American Veterans
Curtis Decker, National Disability Rights Network
Barb Trader, TASH
Peter Berns, The ARC
Stephen Bennett, United Cerebral Palsy
Joseph Gaskins, United Spinal Association
Valerie Jarrett, Taryn MacKenzie Williams, The White House
Rep. Jim Renacci
Senator Sherrod Brown
Senator Rob Portman