July 16, 2021

SUBMITTED ELECTRONICALLY via cures2@mail.house.gov

The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Re: ITEM Coalition Recommendations on Cures 2.0 Discussion Draft

Dear Representatives DeGette and Upton:

On behalf of the undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition Steering Committee, we thank you for the opportunity to provide our comments on the recently released discussion draft for the "Cures 2.0" legislative package. We offer several recommendations below to modernize coverage, especially in the Medicare program, and enhance access to life-saving cures and medical products. We appreciate your willingness to consider these comments and engage with the patient perspective on this important bill.

The ITEM Coalition is a national consumer and clinician-led coalition advocating for access to and coverage of assistive devices, technologies, and related services for persons with injuries, illnesses, disabilities, and chronic conditions of all ages. Our members represent individuals with a wide range of disabling conditions, as well as the providers who serve them, including such conditions as multiple sclerosis, spinal cord injuries, brain injuries, stroke, paralysis, limb loss, cerebral palsy, hearing and speech impairments, visual impairments, vision loss, spina bifida, myositis, and other life-altering conditions.

Overview

The ITEM Coalition has long advocated for legislative reforms that expand the ability of patients with disabilities and chronic conditions to access assistive devices and technologies to improve their health and independent function. Many of the provisions in the 21st Century Cures Act were critical in advancing this goal, and we look forward to continuing to work with your offices to help craft a follow-up legislative package to further enhance the health care system for patients and providers.

There are a number of provisions included in the discussion draft that we strongly support, including the Medicare Coverage of Innovative Technology (MCIT) pathway, the incorporation of patient experience data, and the expansion of telehealth past the end of the public health emergency. We offer additional comments on these areas below. Additionally, we raise one additional concept that we recommend for inclusion in this and/or future packages: the creation of a separate benefit category for complex rehabilitation technology and the revision of the "in

the home" restriction for certain Medicare Durable Medical Equipment. We believe that this reform aligns closely with the goals of modernizing Medicare and increasing access to innovative technology, and look forward to advancing this policy in Cures 2.0 or future legislation.

Integrating the Patient Voice into Coverage, Payment, and Cost Containment Decisions in Medicare

We applaud the inclusion of Sec. 204 in the discussion draft mandating the collection and consideration of patient experience data for clinical trials under the auspices of the Food and Drug Administration (FDA). Data collection should support the user, and too often, the patient voice in health care is de-emphasized, dismissed, or omitted entirely.

We strongly encourage that these sections be expanded to apply to evaluations of new items and services under the jurisdiction of the Centers for Medicare and Medicaid Services (CMS) as well. Currently, though there are opportunities for public comment in Medicare National Coverage Determinations and other coverage analysis processes, there is no mandate to consider patient experience data in making evaluations, nor is there a requirement for applicants to submit such data as part of their requests for coverage. Additionally, the Medicare program continues to expand competitive bidding for certain items and services as a cost containment method and does not typically include patient experience data in those deliberations. This represents a significant gap in the decision-making process at CMS.

We recommend that Sec. 204 in this discussion draft be revised to require that CMS integrate patient experience data in all payment, coverage, and cost containment determinations for all drugs, devices, and services fulfilling unmet needs. Additionally, we recommend the inclusion of language that applies the FDA requirements from Sec. 3001 in the 21st Century Cures Act to applications under CMS. This would ensure that CMS report as part of their payment, coverage, and cost containment determinations if patient experience data and related information was submitted and reviewed as part of the review process. These changes would enhance the consideration of the patient perspective across CMS coverage determinations and ensure a more fully patient-centered health care system.

Medicare Coverage of Innovative Technology (MCIT)

The ITEM Coalition has strongly supported the creation of the MCIT pathway to provide immediate, nationwide Medicare coverage of medical devices designated as breakthrough and market-authorized by the Food and Drug Administration (FDA). The ITEM Coalition is dedicated to expanding beneficiary access to critical technology and devices that improve health outcomes and function for people with disabilities, injuries, and chronic conditions. We believe that immediate MCIT coverage of breakthrough devices will provide enhanced access to beneficiaries and allow manufacturers sufficient time and real-world experience with their device(s) to develop the data necessary to support long-term coverage.

While we recognize and appreciate that CMS is carefully considering operational questions related to the MCIT proposed regulation, ***we believe that it is important to move forward with***

instituting this coverage pathway and applaud its inclusion in the Cures 2.0 discussion draft. We have also provided several recommendations for improving the MCIT pathway, some of which are addressed in the proposed legislative language. For example, we appreciate that Sec. 404 in the discussion draft clarifies that the transitional coverage period for MCIT devices lasts for four years from the date that coding and payment is established for these devices, an important consideration given the often-lengthy process to make such determinations. Additionally, we strongly support the requirement for transparency and public notice and comment on the assignment of code(s) for MCIT devices. Finally, the opportunity for an extension of the temporary coverage period for two years to develop additional data or evidence is another area that we had recommended for the initial regulatory proposal.

For further detail on these recommendations, we direct your attention to the ITEM Coalition's previous regulatory comments, on the initial MCIT proposed rule and in response to the first temporary delay of the regulation in April 2021. We continue to support additional opportunities and avenues to expand coverage of new devices, especially those that offer potential health and functional benefits for beneficiaries with disabilities. As such, ***we appreciate the requirement of the HHS report on alternative coverage pathways in Sec. 405 and look forward to the establishment of additional patient-centered coverage policies following such report***.

Permanent Expansion of Telehealth Services

We appreciate and support the inclusion of policies to extend the availability of telehealth for Medicare, Medicaid, and CHIP beneficiaries after the expiration of the Department's temporary authorities once the public health emergency (PHE) ends. During the pandemic, telehealth has emerged as a particularly useful modality for individuals with disabilities, who often face significant barriers to accessing in-person care. The ITEM Coalition appreciates that the rapid expansion of telehealth has allowed many Medicare beneficiaries to safely access medically necessary health care while protecting themselves from the threat of infection, as well as avoiding additional complications associated with planning, transportation, and accessibility of in-person visits. In particular, individuals with mobility impairments face burdens on their physical access to in-person visits that can be eased through the use of telehealth; similarly, individuals with cognitive impairments have often found that virtual services are more accessible and, in some cases, more effective, ensuring more stable, continuing access to needed care.

In the realm of assistive technology specifically, telehealth has been particularly effective for enabling more efficient and accessible technology evaluations, allowing individuals to maintain their systems and devices without the need for travel to in-person visits. We encourage Congress to work with CMS to ensure that telehealth remains available post-PHE. However, ***we must also ensure that the expansion and proliferation of telehealth does not become a barrier to accessing in-person care; this modality should be utilized as a supplement, not a replacement, for in-person care***. There are many situations, especially for those with disabilities and chronic conditions, where a thorough physical exam is needed and where in-person care is critical to appropriately assess and treat patient needs.

Modernizing Payment and Reimbursement Policies for Americans with Disabilities

In keeping with the overarching goal of modernizing the Medicare program, we recommend that the eventual Cures 2.0 package include specific language addressing the "in the home" requirement for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) in Medicare. One of the five "prongs" defining the DMEPOS benefit is a requirement that an item be "appropriate for use in the home." For decades, the ITEM Coalition and other stakeholders have identified this as a significant barrier to coverage of and access to some DMEPOS, especially mobility assistive equipment. While we question whether the current interpretation of this requirement should be modified for the entire DMEPOS benefit, ***we particularly recommend that Cures 2.0 include language similar to the Ensuring Access to Quality Complex Rehabilitation Technology Act of 2019 (H.R. 2408 in the 116th Congress) to enhance access specifically to critical complex and individually configured medical equipment, items, and technologies used by beneficiaries with significant disabilities***.

The Medicare statute defining the DMEPOS benefit states that DMEPOS includes "iron lungs, oxygen tents, hospital beds, and wheelchairs… *used in the patient's home*" (emphasis added). The associated regulations further define the "five prongs" of the DMEPOS benefit, one of which is that the equipment "is appropriate for use in the home." The ITEM Coalition has long held that the clear congressional intent in enacting the "in the home" requirement was to distinguish the DMEPOS benefit from equipment used in the hospital and, therefore, separately reimbursable under Medicare Part A.

However, CMS has traditionally interpreted this requirement as restricting Medicare coverage of DMEPOS to only items and services that are medically necessary within the four walls of the beneficiary's home, excluding any broader needs of the beneficiary, such as participation in employment, education, or community activities. This interpretation restricts access to a wide range of critical equipment that is not used exclusively within the home, presenting a particular barrier in the realm of mobility equipment. CMS has restricted access to such equipment for beneficiaries with mobility impairments that would allow users to perform important everyday activities such as participating in employment and in the community.

Enacting the *Ensuring Access to Quality Complex Rehabilitation Technology Act* would specifically address this and other limitations of the DMEPOS benefit by creating a separate Medicare benefit category for complex rehabilitation technology (CRT). CRT includes a range of highly configurable wheelchairs, complex power wheelchairs, and associated specialized equipment that is prescribed and individually configured to meet the specific medical and functional needs of individuals with disabilities and chronic conditions, representing approximately 10% of the Medicare mobility-impaired population. These highly specialized medical devices and related services are unique and significantly different from standard DMEPOS items, but currently subject to the same blanket restrictions, including the "in the home" restriction. CRT's current inclusion in Medicare's outdated DMEPOS coverage and classification system leads to threatened and diminished access for individuals who need CRT.

A separate benefit category for CRT should be established within the Medicare program to protect individual access to these critical technologies for people with disabilities and chronic conditions. A separate CRT category will lift the "in the home" requirement for these items and allow for needed improvements in other coverage policies, coding, and quality standards to better serve the needs of CRT users and maximize their health, function, and independence while maintain existing and appropriate standards for the provision of more standardized DMEPOS items. Since CRT is already covered by the Medicare program, we do not believe this legislation will cost significantly more than Medicare already spends with respect to the DMEPOS benefit. ***We urge you to consider including the Ensuring Access to Quality Complex Rehabilitation Technology Act in the Cures 2.0 package to ensure that Medicare beneficiaries with long-term or permanent mobility impairments have access to the high-quality rehabilitation technology they need to live a more healthy, independent, and functional life.***

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We appreciate your leadership in developing the Cures 2.0 package and look forward to working with your offices during this process. Should you have any further questions regarding the information contained in this letter, please contact the ITEM Coalition coordinators by email at Peter.Thomas@PowersLaw.com and Joseph.Nahra@PowersLaw.com or call 202-466-6550.

Sincerely,

The ITEM Coalition Steering Committee

ALS Association
Amputee Coalition
Christopher & Dana Reeve Foundation
Spina Bifida Association
United Spinal Association