The Honorable Kevin Brady (TX-8)
U.S. House of Representatives
Chair, Ways and Means Committee
Washington, D.C. 20515

The Honorable Richard Neal (MA-1)
U.S. House of Representatives
Ranking Member, Ways and Means Committee
Washington, D.C. 20515

The Honorable Greg Walden (OR-2)
U.S. House of Representatives
Chair, Energy & Commerce Committee
Washington, D.C. 20515

The Honorable Frank Pallone (NJ-6)
U.S. House of Representatives
Ranking Member, Energy & Commerce Committee
Washington, D.C. 20515

November 19, 2018

**Re: Please Pass Legislation to Restore Access to Manual CRT Wheelchair Accessories**

Dear Chairman Brady, Ranking Member Neal, Chairman Walden, and Ranking Member Pallone:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition Steering Committee **urge you to pass H.R. 3730.** This bipartisan legislation from Representatives Lee Zeldin (R-NY) and John Larson (D-CT) permanently exempts manual Complex Rehab Technology (CRT) wheelchair accessories and components for people with disabilities and chronic conditions from Medicare's Competitive Bid Program (CBP). This important legislation will protect Medicare beneficiary access to manual complex rehab technology, as well as essential components known as wheelchair "accessories." This letter is being sent in follow up to our recent September 21st letter to you requesting passage of H.R. 3730. We now urge you to pass this important legislation before the end of the year to ensure Medicare beneficiary access to manual CRT wheelchair accessories, and to capitalize on the significant bipartisan support for the bill in Congress and amongst stakeholders.

Last year, on June 23, 2017, the Centers for Medicare and Medicaid Services (CMS) announced it will not be applying Medicare CBP reimbursement levels to CRT Group 3 *power* wheelchair accessories. This policy change averts significant cuts that were scheduled to go into effect July 1, 2017 and avoids drastic reductions in access to this specialized mobility technology for Medicare beneficiaries with significant disabilities. The ITEM Coalition is grateful to CMS and the Members of Congress that supported this important action.

Unfortunately, CMS did not extend the new rule to CRT *manual* wheelchairs, making a legislative fix necessary to preserve Medicare beneficiary access to CRT accessories and components in manual wheelchairs. Now, we are asking that you pass H.R. 3730, the important final iteration of the effort begun by H.R. 1361.

Congressional action is urgently needed to permanently help Medicare beneficiaries who are manual CRT wheelchair users obtain medically necessary CRT accessories and components. H.R. 3730 has gained widespread bipartisan support, with 119 cosponsors, including a number of Ways and Means and Energy and Commerce Committee members. The decision to not make the same policy change to manual wheelchairs has led to a disparity in access. This disparity adversely impacts Medicare beneficiaries by unfairly penalizing manual wheelchair users by limiting their access to needed wheelchair accessories and components. The impact of this decision is playing out in real time.

Data from a recent survey of over 400 Medicare supplier locations[1] shows that nearly two-thirds of respondents indicated the reimbursement cuts to manual CRT wheelchair accessories have "significantly reduced our ability to provide the right wheelchair accessories to Medicare beneficiaries who require Complex Rehab Manual Wheelchairs." A decrease in access to manual CRT wheelchair accessories would be detrimental to many wheelchair users that rely on Medicare to provide these essential components.

As you know, power and manual CRT wheelchairs and CRT accessories or components are essential for a small segment of wheelchair users, about 10 percent of the Medicare population that requires wheeled mobility. This impacts beneficiaries with significant disabilities such as ALS, cerebral palsy, multiple sclerosis, muscular dystrophy, spinal cord injury and traumatic brain injury. For these wheelchair users, a wheelchair is not complete, usable, or safe without the appropriate complex rehab technology components included.

To ensure that all CRT wheelchair users, both power and manual, have access to the components they need, we urge you to pass H.R. 3730. We are writing to express our strong support for H.R. 3730 and to emphasize the importance of protecting patient access not just to accessories used with complex rehab *power* wheelchairs, but also to those used on complex rehab *manual* wheelchairs. Passage of H.R. 3730 is supported by a wide range of consumer and provider organizations, including over 30 members of the ITEM Coalition.

Regardless of injury, illness, disability, or chronic condition, all Medicare beneficiaries should be eligible for the same access to medically necessary mobility devices, services, and accessories. Anything less can have serious consequences for beneficiaries. **We urge you to pass H.R. 3730 to ensure that access to components and accessories used with CRT manual wheelchairs is protected.**

For more information on H.R. 3730, please contact Sarah Talmage (Sarah.Talmage@mail.house.gov) in Representative Zeldin's office or Sylvia Lee (Sylvia.Lee@mail.house.gov) in Representative Larson's office.

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[1] "New Medicare CRT Supplier Survey Identifies Major Decrease In Access To Critical Components (Accessories) Used With CRT Manual Wheelchairs," The National Coalition for Assistive and Rehab Technology (NCART), September 2018. Available online at http://blog.access2crt.org/congress-needs-to-see-new-data-showing-crt-access-issues/

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.

We would be happy to meet to discuss this issue further and are available for any questions you may have. To contact the ITEM Coalition, please contact the ITEM Coalition coordinators, Peter Thomas, at Peter.Thomas@powerslaw.com or Leif Brierley at Leif.Brierley@powerslaw.com, or by calling 202-466-6550.

Sincerely,

**ITEM Coalition Steering Committee Members**
Amputee Coalition
Christopher and Dana Reeve Foundation
National Multiple Sclerosis Society
Paralyzed Veterans of America
United Spinal Association

November 28, 2018

The Honorable Orrin Hatch
U.S. Senate
Chair, Finance Committee
Washington, D.C. 20510

The Honorable Ron Wyden
U.S. Senate
Ranking Member, Finance Committee
Washington, D.C. 20510

The Honorable Kevin Brady
U.S. House of Representatives
Chair, Ways and Means Committee
Washington, D.C. 20515

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The Honorable Frank Pallone
U.S. House of Representatives
Ranking Member, Energy & Commerce Committee
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**Re: <u>Disability Community Supports Passage of Off-the-Shelf Orthotics Legislation; H.R. 4772 (a.k.a. Section 7 of S. 1191 and H.R. 2599, the Medicare Orthotic and Prosthetic Improvement Act)</u>**

Dear Senators Hatch and Wyden and Representatives Brady, Neal, Walden, and Pallone:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition Steering Committee respectfully request that you pass H.R. 4772 before the 115th Congress adjourns. This bipartisan legislation will clarify Congressional intent regarding the definition of the term, "minimal self-adjustment," which defines off-the-shelf orthotics for purposes of competitive bidding. This provision would help ensure that Medicare beneficiaries have access to the clinical services necessary to properly fit certain orthoses that have been inappropriately defined by the Centers for Medicare and Medicaid Services (CMS) as off-the-shelf when, in fact, they require significant clinical services to be functional for beneficiaries and achieve their therapeutic purpose.

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 limb loss, multiple sclerosis, spinal cord injuries, brain injuries, stroke, paralysis, cerebral palsy, hearing and speech impairments, visual impairments, vision loss, spina bifida, myositis, and other life-altering conditions.

When Congress enacted the Medicare competitive bidding program for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), it exempted all custom fit and fabricated orthotic braces and artificial limbs. To this day, only "off-the-shelf" or "OTS"

orthoses are eligible for competitive bidding because these devices require only "minimal *self*-adjustment," as the statute states. 42 U.S.C. § 1395w-3(a)(2)(C). However, CMS regulated this provision and essentially wrote the word "self" out of the term "minimal self-adjustment." 42 C.F.R. § 414.402. The regulation widely expanded the definition of "minimal self-adjustment" to include a wide range of orthoses that require clinical services and customization required by trained orthotists and other health care professionals. *See id.*

Time to pass this bill is running out. To date, CMS has not implemented competitive bidding of OTS orthotics, but a proposal to do so is currently pending at CMS. If CMS pursues competitive bidding for this wider range of orthoses, the clinical services associated with custom fit orthoses will be lost. Orthotic manufacturers will simply drop-ship orthoses to patients' homes and rely on beneficiaries—or their caregivers—to fit them the best they can. This places patients at potential risk and will lead to Medicare waste and abuse. In fact, almost one in five Medicare beneficiaries who receive an OTS orthoses must later be provided with a custom fit or fabricated orthosis to properly treat their condition. *See* John R. Fisk et al., *Suggested Guidelines for the Prescription of Orthotic Services, Device Delivery, Education, and Follow-up Care: A Multidisciplinary White Pape*, 181:2 MILITARY MEDICINE 11, 15 (2016), <*https://academic.oup.com/milmed/article-pdf/181/suppl_2/.../milmed-d-15-00542.pdf* >.

H.R. 4772 is sponsored by Congressmen Mike Bishop (R-MI), Mike Thompson (D-CA), and Glenn Thompson (R-PA). (An earlier version of the bill is Section 7 of the Medicare Orthotic and Prosthetic Improvement Act, H.R. 2599, and S. 1191, introduced by Senators Grassley (R-IA) and Warner (D-VA). H.R. 4772 would reestablish Congressional intent by restoring the plain-language meaning of the term "minimal *self*-adjustment" to help define OTS orthotics. This would limit competitive bidding to OTS orthotics only, devices that do not need the clinical services or customization that orthotists and other health care professionals provide. Contrary to OTS orthotics, custom fit and custom fabricated orthoses require significant clinical and technical services to be functional and serve the therapeutic needs of the patient. They should not be exposed to competitive bidding, which is consistent with Congressional intent.

We appreciate that the bill's sponsors are working with Committee leaders and the Congressional Budget Office (CBO) to minimize any potential cost associated with enactment of H.R. 4772 and we support any and all efforts to keep this bipartisan legislation budget neutral.

Thank you for your consideration of this important issue. If you have any questions, please contact Peter Thomas, ITEM Coalition Coordinator, at Peter.Thomas@PowersLaw.com or 202-466-6550, Leif Brierley, ITEM Coalition Staff, at Leif.Brierley@PowersLaw.com or 202-466-6550.

Sincerely,

**ITEM Coalition Steering Committee Members**
Amputee Coalition (Dan Ignaszewski: dan@amputee-coalition.org)
United Spinal Association (Alexandra Bennewith ABennewith@unitedspinal.org)
Christopher and Dana Reeve Foundation (Kim Beer kbeer@christopherreeve.org)
National Multiple Sclerosis Society (Kim Calder kim.calder@nmss.org)
Paralyzed Veterans of America (Lee Page LeeP@pva.org)

November 19, 2018

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U.S. Senate
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The Honorable Frank Pallone
U.S. House of Representatives
Ranking Member, Energy & Commerce Committee
Washington, D.C. 20515

**Re: Access to Titanium Wheelchairs**

Dear Senators Hatch and Wyden and Representatives Brady, Neal, Walden, and Pallone:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition Steering Committee respectfully request that you pass legislation that will allow Medicare beneficiaries access to titanium wheelchair frames. A recent decision by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) currently inhibits Medicare beneficiary access to titanium wheelchairs. The DME MACs issued a joint publication indicating that titanium wheelchair frames and patient weight capacity upgrades are no longer separately billable to Medicare, a decision that will preclude patients from accessing this important technology. The Centers for Medicare and Medicaid Services (CMS) have refused to make changes to this DME MAC policy, leaving only legislative options available. Therefore, the ITEM Coalition asks Congress to pass legislation to restore access to titanium wheelchairs for Medicare beneficiaries with mobility impairments.

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.

Titanium wheelchairs are extremely strong and lightweight and are appropriate for a subset of Medicare beneficiaries with long term mobility impairments. Lighter than a standard manual wheelchair, titanium wheelchairs allow beneficiaries improved mobility and decreased risk to secondary injury to the upper body as a result of long term wheelchair use. Beneficiaries with a history of certain upper-extremity issues including pain or dysfunction, can benefit from the use of a lighter wheelchair frame such as titanium. For some beneficiaries, titanium and other ultralight wheelchairs are medically necessary and clinically appropriate, especially in cases where the beneficiary may have a compromised cardiopulmonary system, upper-extremity weakness, a decrease in upper-extremity range of motion, decreased endurance for propulsion, spasticity, pain with propulsion, and orthopedic conditions.

Beneficiaries with such clinical conditions often see improvements in their abilities to perform mobility-related activities of daily living (MRADLs)—which is the standard for Medicare coverage—including toileting, bathing, feeding, dressing, and grooming, as they may become more able to be mobile in the home through the use of a lighter-weight wheelchair.

On December 15, 2016, the four DME MACs issued a joint publication that no longer allows suppliers to bill separate codes or use an advanced beneficiary notice of noncoverage (ABNs) to provide patients with titanium or titanium-alloy wheelchairs. The joint publication announced that all manual wheelchair codes, including the ultra-lightweight manual wheelchairs (HCPCS code K0005 – Ultralightweight Wheelchair), are inclusive of: (1) all materials (specifically, titanium) and (2) patient weight capacities in excess of 250 pounds. The DME MACs claim that a recent review of the K0108 (Wheelchair Component or Accessory, not Otherwise Specified) HCPCS code identified increased billing for titanium components in wheelchairs. The DME MACs said in their joint publication that the HCPCS codes for manual wheelchairs, including the K0005 code for Ultralightweight Wheelchairs, created in 1993, covers titanium wheelchairs, and that suppliers may no longer additionally charge CMS using the K0108 code to account for the cost of the titanium materials used in the wheelchair.

As a result, Medicare beneficiaries cannot obtain access to lightweight, titanium wheelchairs because the added expense of the titanium upgrade is not covered by the K0005 HCPCS code. Additionally, due to the DME MACs' decision, beneficiaries can no longer opt to pay out of pocket, utilizing an ABN, to cover the cost of the titanium upgrade, which had been standard practice for suppliers who had their K0108 codes denied by Medicare. CMS has since refused to change its policy, stating that it lacks the statutory authority to do so. By changing the coding practices surrounding titanium wheelchairs, CMS has effectively removed beneficiaries' choice to acquire a titanium wheelchair through the Medicare program.

Medicare coverage policy for titanium wheelchairs must be clarified. The ITEM Coalition therefore urges Congress to pass legislation that reinstates Medicare beneficiary access to titanium wheelchairs. Such policy changes are necessary to account for the additional manufacturing costs of titanium wheelchairs, and to allow suppliers to properly bill for titanium and titanium-alloy wheelchairs. Such an action would help reinstate beneficiary access to these important assistive technology devices. CMS, through its DME MACs, should not penalize patients for the advances in technology that have allowed for titanium wheelchairs to become more prevalent and useful for beneficiaries.

Thank you for your consideration of these issues and we look forward to discussing our requests with you further. If you have any questions, please contact Peter Thomas, ITEM Coalition Coordinator, at Peter.Thomas@PowersLaw.com or 202-466-6550, Leif Brierley, ITEM Coalition Staff, at Leif.Brierley@PowersLaw.com or 202-466-6550.

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