



February 20, 2012

Steve Larsen, Director
Center for Consumer Information and Insurance Oversight
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Essential Health Benefits Bulletin: “Rehabilitative and Habilitative Devices”

Dear Director Larsen:

The undersigned members of the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition appreciate the opportunity to comment on the Essential Health Benefits (EHB) Bulletins released on December 16, 2011 and the supplementary information released on January 25, 2012 listing the three largest small group plans by enrollment in each State. The ITEM Coalition is a consumer-led coalition of disability-related organizations with the goal of improving access to assistive devices, technologies and related services for individuals with disabilities of all ages.

We are concerned that the proposed benchmark process gives States a tremendous amount of flexibility with little federal oversight. The ITEM Coalition believes the federal government must play a leading role in defining the EHB package by evaluating and approving the establishment of and updates to EHB packages in each state. Specifically, each benefits package must be evaluated for appropriate and affordable coverage of assistive devices and technologies. The Affordable Care Act (ACA) requires coverage of “rehabilitative and habilitative services *and devices*” (emphasis added) as an essential health benefits category. It is likely that many state benchmark options will need substantial revision to ensure that they meet the coverage and nondiscrimination requirements of the ACA, and the federal government should provide oversight of those revisions.

The ITEM Coalition applauds the release of supplemental data on January 25th by HHS. HHS should require FEHBP and small group health plans identified as benchmark options to immediately make available plan details on the Healthcare.gov website, particularly as related to coverage of rehabilitative and habilitative devices. In our review of the plan information on Healthcare.gov, we found that the detail provided by the FEHBP plans on coverage of assistive devices is far more enlightening than the very limited detail currently provided by small group plans. For example, many of the state small group plans cover orthotics and prosthetics, but these plans fail to detail benefits under that category. Without more detail, it is impossible to assess the quality and scope of coverage for these essential devices under the benchmark options.

Define Rehabilitative and Habilitative Devices

For many people with disabilities and chronic conditions, rehabilitative and habilitative services and devices are essential medical interventions—equivalent to the provision of antibiotics to a person with an infection. The definition of rehabilitative and habilitative devices must include:

- At a minimum, durable medical equipment, orthotics and prosthetics and related supplies;
- Certain complex rehabilitation technology not always included in the DMEPOS category, such as augmentative communication devices, hearing aids and related technology, and low vision aids; and
- Devices for use both within the home and in the community so that individuals with disabilities can maintain their independence and live outside institutions.

There is strong legislative history and support for this interpretation of the definition of rehabilitative and habilitative devices. For instance, Congressman George Miller, Chairman of the House Education and Labor Committee when ACA was passed, explained in his House floor statement that the term rehabilitative and habilitative devices “includes durable medical equipment, prosthetics, orthotics, and related supplies.” [Congressional Record, H1882 (March 21, 2010)] See also a similar statement by Congressman Pascrell [Congressional Record, E462 (March 23, 2010)].

Chairman Miller also stated, “I expect that durable medical equipment will not be limited to ‘in-home’ use only.” This statement is important because currently CMS inappropriately limits Medicare coverage for durable medical equipment for use only “in the patient’s home.” Coverage of devices under the EHB packages should include access to devices that allow an individual to live and work independently within their community as well as their homes.

Regulate Criteria for Limitations, Medical Necessity, and Evidence Based Medicine

The ITEM Coalition is concerned that benefit-specific limitations (*e.g.*, dollar or treatment frequency) and condition-based exclusions could be imposed to undermine the restrictions on lifetime and annual limits and to deny individuals appropriate treatment. Different types of illnesses or injuries may require different levels of medical intervention, treatment, or care. Accordingly, it is important that health plans and health insurance issuers not sidestep restrictions on lifetime and annual limits by either imposing dollar caps on costs related to a specific treatment, or by inappropriately limiting treatment frequency. For instance, some private insurance plans limit artificial limb coverage to one prosthesis per lifetime or durable medical equipment to a \$500 annual maximum. Both of these types of restrictions are completely arbitrary, unrealistic, and should be prohibited by the Secretary.

HHS should require that any limits in benefits must be evidence-based and provide for access to a reasonable amount, duration and scope of treatment options to beneficiaries and must comply with the applicable federal laws. The ITEM Coalition also recommends that any benefit-specific limitations or condition-based exclusion of benefits be rigorously reviewed in order to determine whether the exclusion violates the requirements of the ACA. In addition, such limits should not violate the Americans with Disabilities Act of 1990, which prohibits disability-based distinctions in health insurance coverage. Such a finding by the Department or state Insurance Commissioners should render these types of limitations null and void.

Preserve State Mandates

The ITEM Coalition applauds HHS for allowing states to incorporate their mandates into one of the benchmark options. The Coalition strongly believes that HHS should offer additional avenues for states to incorporate their mandates into the essential health benefits. State mandated benefit laws exist because the private insurance market has failed to cover health benefits that duly-elected legislators and Governors subsequently deem worthy of coverage. For individuals with disabilities who need access to assistive devices, mandated benefit laws can remedy coverage determinations that reflect bad health policy. Arbitrary determinations of medical necessity, denials based on artificial distinctions between habilitation and rehabilitation, exclusions in benefits based on flimsy evidence, and faulty judgments that specific treatments are experimental or investigational in nature, can entirely shut out vulnerable populations from access to needed devices.

The ITEM Coalition also supports the federal subsidy for inclusion of state mandates in the EHB. This financial support helps States to maintain their mandates rather than repealing them due to financial constraints, and we support continuing that subsidy beyond two years. The Bulletin also states that HHS will evaluate the benchmark approach in 2016 and may exclude some State mandates from the EHB package at that time. If this is the case, the ITEM Coalition requests that HHS release in advance a defined process the agency will use to determine this exclusion and allow public input on this process.

Ensure an Appropriate Balance Among the Ten Essential Benefits Categories

Under the ACA, the category rehabilitative and habilitative services and devices must be covered, and many private insurance plans typically either do not cover or place significant and arbitrary limitations on coverage. The fact that these categories of benefits must be included in the essential benefits package helps ensure an appropriate balance of benefits under private plans. It is essential that healthcare plans cover rehabilitative and habilitative devices that help a person acquire, maintain, restore or improve a person's ability to function inside and outside the home.

Additionally, HHS requested feedback on allowing substitutions both within and between EHB categories of care. Allowing substitutions between categories undermines the non-discrimination standards set forth in the ACA and could result in inadequate coverage of one of the categories of care. HHS needs to incorporate enforceable safeguards to ensure the benchmark plan selection, as well as any allowable substitutions between and within categories, results in benefit packages meeting the needs of people with disabilities and respects the letter and spirit of the ACA. People with disabilities and chronic conditions who need rehabilitative and habilitative devices should not encounter unreasonably restrictive coverage policies in their ability to access appropriate devices.

Develop Process to Ensure Appropriate Benefit Packages

The Secretary should create and utilize a Federal Advisory Board to advise the Secretary on the review and approval of each state's essential health benefits package. The board would also serve as a regular and integral resource to provide input to design considerations, obtain feedback on benefit packages, and share information with consumers, including people with disabilities. The board should include individuals with disabilities that need assistive devices and technologies, their family members and

caregivers, and providers. The Advisory Group should have real ability to influence the decisions of the HHS Secretary on an ongoing basis. The Secretary should also meet with members of state organizations, non-profit associations, advocates, providers and other important stakeholders who are devoted to furthering the rights of those populations in order to inform the process and ensure that the plans are meeting the high standards for access, nondiscrimination, comprehensiveness and quality that the ACA establishes.

Transparent and Public Process for Updating Essential Benefits

In order to ensure that beneficiaries have access to the most effective and appropriate devices, the Secretary of HHS should establish a transparent, unbiased, public process for the regular review and update of the essential benefits package. The Secretary should establish a formal process to appeal to HHS to add, modify, or delete coverage of a particular device to the essential benefits package. The benefits packages should be evaluated annually to identify patterns in order to encourage parity and compliance.

To assess the challenges of beneficiaries in accessing devices and related services, it will be necessary to implement a system of data collection to document the healthcare benefits experience faced by patients, including patients with disabilities and chronic conditions, particularly around difficulty accessing needed benefits. Coverage criteria must keep pace with advances in technologies that deliver improved beneficiary outcomes. To demonstrate efficacy, all forms of medical evidence should be considered and weighted appropriately, so that devices without the benefit of double-blinded, randomized controlled studies, are not automatically excluded from consideration.

We greatly appreciate your attention to our concerns and your interest in our participation in this process. Should you have further questions regarding this information, please contact Peter Thomas or Theresa Morgan, ITEM Coalition staff, at 202-466-6550.

Sincerely,

American Foundation for the Blind
American Music Therapy Association
American Speech-Language-Hearing Association
American Therapeutic Recreation Association
Association of Assistive Technology Act Programs
Blinded Veterans Association
Christopher & Dana Reeve Foundation
Disability Rights Education and Defense Fund
Easter Seals
National Coalition for Assistive and Rehab Technology
National Family Caregivers Association
National Multiple Sclerosis Society
Paralyzed Veterans of America
United Spinal Association
Rehabilitation Engineering and Assistive Technology Society of North America