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March 28, 2016

Howard Shelanski
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President
725 17th Street, NW
Washington, DC 20503

RE: (CMS-10407) Summary of Benefits and Coverage and Uniform Glossary

Dear Administrator Shelanski:

The undersigned members of the Coalition to Preserve Rehabilitation (CPR), the Independence Through Enhancement of Medicare and Medicaid (ITEM) Coalition, and the Habilitation Benefits (HAB) Coalition, and the Consortium for Citizens with Disabilities (CCD) Health Task Force appreciate the opportunity to comment on the *Summary of Benefits and Coverage and Uniform Glossary* (the Comment Request) published by the Internal Revenue Service at the Department of the Treasury ([IRS](#)), the Employee Benefits Security Administration at the Department of Labor ([EBSA](#)), and the Centers for Medicare & Medicaid Services at the Department of Health and Human Services ([CMS](#)) (collectively, the Departments).

The HAB Coalition is a group of national nonprofit consumer and clinical organizations focused on securing appropriate access to, and coverage of, habilitation benefits within the category known as “rehabilitative and habilitative services and devices” in the EHB package under the Patient Protection and Affordable Care Act (PPACA), Section 1302. CPR is a coalition of national consumer, clinician, and membership organizations that advocate for policies to ensure access to rehabilitative care so that individuals with injuries, illnesses, disabilities and chronic conditions may regain and/or maintain their maximum level of health and independent function. ITEM is a coalition of national organizations dedicated to improving access to and coverage of assistive devices and technologies for people of all

ages with disabilities and chronic conditions. CCD Health Task Force works on all the issues encompassed in the very broad term “health.” Specific emphasis is placed on private health insurance; public programs such as Medicaid and Medicare; managed care, as well as quality assurance and consumer education and protections.

In the Comment Request, the Departments invite comment on the proposed documents associated with the Summary of Benefits and Coverage and Uniform Glossary located on CMS’ [website](#), primarily in connection with private insurance plans pursuant to the Affordable Care Act. We comment on the Uniform Glossary of Coverage and Medical Terms, the Summary of Benefits and Coverage (SBC) template, and other documents, below.

Uniform Glossary of Coverage and Medical Terms

A. Existing Definitions

The proposed uniform glossary of coverage and medical terms (Uniform Glossary)¹ contains definitions of orthotics and prosthetics, durable medical equipment, habilitation services, and rehabilitation services. We understand the intent of the glossary terms as plain language descriptions of services meant to facilitate informed decision-making by consumers as they shop for coverage, and *not* as legally-binding definitions of covered benefits. For that reason, we distinguish between definitions intended as communications to consumers generally, from definitions as they should be understood and used by Qualified Health Plans for purposes of providing essential health benefits (EHB).

For purposes of the uniform glossary of coverage and medical terms, we support the Departments for adopting the National Association of Insurance Commissioners (NAIC) definitions of durable medical equipment, habilitation services, and rehabilitation services. However, in future regulations defining coverage requirements, limitations, and exclusions of coverage benefits, we support the Departments adopting more robust, inclusive definitions for these terms. For purposes of the proposal to separately define the term “orthotics and prosthetics,” we strongly support this development and urge its adoption in the final Uniform Glossary.

Orthotics and Prosthetics (O&P)

We thank the Departments for adopting the proposed definition of orthotics and prosthetics in the Uniform Glossary. This new definition helps beneficiaries understand what constitutes orthotic and prosthetic services and devices and prompts them to compare and contrast the levels of such coverage across competing health plans. It also formally signals separate benefit treatment from durable medical equipment (DME) in private health plans. O&P services are significantly different from DME and should be treated as such in private and publicly supported health plans and programs.

The proposed definition of orthotics and prosthetics is excellent as written except for one exception. We recommend that given the fact that mastectomies that require external breast prostheses can be medically necessary for patients that do not necessarily have breast cancer, *the Departments’ definition for orthotics and prosthetics should, therefore, strike “...resulting from breast cancer” from the proposed definition:*

¹ See <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Uniform-Glossary.pdf>.

- Orthotics and Prosthetics: Leg, arm, back, and neck braces, and artificial legs, arms, and eyes, and external breast prostheses incident to mastectomy ~~resulting from breast cancer~~. These services include: adjustments, repairs, and replacements required because of breakage, wear, loss, or a change in the patient’s physical condition.

Durable Medical Equipment (DME)

For the purposes of the Uniform Glossary, we support the Departments’ definition of Durable Medical Equipment (DME), which reads:

- Durable Medical Equipment: Equipment and supplies ordered by a health care provider for everyday or extended use. DME may include: oxygen equipment, wheelchairs and crutches.²

For purposes of future regulations defining coverage requirements, limitations, and exclusions, we propose that the Departments should include a more expansive definition of durable medical equipment, which would read as follows:

- Durable Medical Equipment: Includes but is not limited to equipment and supplies ordered by a health care professional for everyday or extended use to improve, maintain or prevent the deterioration of an individual’s functional ability. Examples of DME include, but are not limited to, manual and power wheelchairs, oxygen equipment, canes, crutches, walkers, standing system chairs, blood testing supplies for people with diabetes, as well as supplies, equipment, and repairs to support medically necessary devices.

Durable medical equipment, related devices and assistive technologies are critically important to people with injuries, illnesses, disabilities and chronic conditions. These devices and technologies enable these individuals to achieve health improvement, full function, return to work and live independently when possible. An inappropriate benefits package of durable medical equipment benefits in health insurance plans will produce long-term cost-ineffective outcomes for enrollees.

Habilitation Services

We support the definition of Habilitation Services in the Uniform Glossary, which reads:

- Habilitation Services: Health care services that help a person keep, learn or improve skills and functioning for daily living. Examples include therapy for a child who isn’t walking or talking at the expected age. These services may include physical and occupational therapy, speech-language pathology and other services for people with disabilities in a variety of inpatient and/or outpatient settings.

That said, we also applaud the Department of Health and Human Services (HHS) for including the term “and devices” after health care services to its definition of habilitative services in the 2016 Notice of Benefit and Payment Parameters final rule.³ ***Therefore, we propose that the Departments’ definition for habilitation services should also include a reference to devices in the uniform glossary. This could be achieved by adding the term “and devices” after “Health***

² We noticed that “blood testing strips for diabetics” has been removed as part of this definition, but we agree with this omission, as such strips are not traditionally viewed as a form of DME.

³ <http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf>, page 63, 123.

care services.” This would make the definition of these terms consistent with the statutory requirements of the ACA’s essential benefit categories found at Section 1302.

For the purposes of future regulations defining coverage requirements, limitations, and exclusions, we also propose that the Departments should go farther in specifying the scope and breadth of this important benefit, and should include a more expansive definition of habilitative services and devices, which would read as follows:

- Habilitation Services and Devices: Includes but is not limited to health care services *and devices* that are designed to assist individuals in acquiring, improving, or maintaining, partially or fully, skills and functioning for daily living. These services may include, but are not limited to, physical therapy, occupational therapy, speech-language pathology and audiology, and other services and devices for people with disabilities in a variety of inpatient and/or outpatient settings. Plans should use Medicaid coverage as a guide where there is a question of whether to cover specific habilitation benefits.

Habilitative services should be provided based on the individual’s needs, in consultation with a clinician, and based on an assessment by an interdisciplinary team and resulting care plan.

Habilitative devices shall include, but not be limited to, orthotics and prosthetics, prosthetic devices, low-vision aids, Augmentative and Alternative Communication Devices (AACs), and hearing aids and assistive listening devices, as defined elsewhere in this section.

Rehabilitation Services

We support the definition of Rehabilitation Services in the Uniform Glossary, which reads:

- Rehabilitation Services: Health care services that help a person keep, get back or improve skills and functioning for daily living that have been lost or impaired because a person was sick, hurt or disabled. These services may include physical and occupational therapy, speech-language pathology and psychiatric rehabilitation services in a variety of inpatient and/or outpatient settings.

While not explicitly adding “and devices” to rehabilitative services in the regulatory section of the 2016 Notice of Benefit and Payment Parameters final rule, the Department of Health and Human Services (HHS) did include such an addition in the comments of the rule, by stating: “Rehabilitative services, including devices, on the other hand, are provided to help a person regain, maintain, or prevent deterioration of a skill or function that has been acquired but then lost or impaired due to illness, injury, or disabling condition.”⁴ Further, Patient Protection and Affordable Care Act (PPACA) §1302 states that “rehabilitative services and devices” are essential health benefits. *Therefore, we believe that the uniform glossary of coverage and medical terms should be consistent with that statutory language, and proposes that the Departments’ definition of rehabilitation services—like the definition of habilitation services—should include a reference to devices in the uniform glossary. This could be achieved by adding the term “and devices” after “Health care services.”*

For purposes of future regulations defining coverage requirements, limitations, and exclusions, we also propose that the Departments go farther in specifying the scope and breadth of this important benefit,

⁴ *Id.*, at 63.

and should include a more expansive definition of rehabilitative services and devices, which would read as follows:

- Rehabilitation Services and Devices: Includes but is not limited to health care services *and devices* that are designed to assist individuals in improving or maintaining, partially or fully, skills and functioning for daily living. These services include, but are not limited to, physical therapy, occupational therapy, speech-language pathology and audiology, cognitive rehabilitation, and psychiatric rehabilitation services in a variety of inpatient and/or outpatient settings.

Rehabilitative devices shall include, but not be limited to, orthotics and prosthetics, prosthetic devices, low-vision aids, Augmentative and Alternative Communication Devices (AACs), and hearing aids and assistive listening devices, as defined elsewhere in this section. Rehabilitative services should be provided based on the individual's needs, in consultation with a clinician, and based on an assessment by an interdisciplinary team and resulting care plan.

Medical Necessity

The current definition of the term “medically necessary” in the Uniform Glossary reads “Health care services or supplies needed to prevent, diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine.” We propose that the words “health care services” be replaced with “physical and mental health care services” to ensure that the public understands the breadth of health care services provided.

B. Future Regulatory Definitions

Optimally, future regulations would include references to the variety of services and devices typically provided to meet a wide range of patient needs. For instance, we encourage future regulations to include broader definitions of what many of the terms mentioned above typically include, such as the following.

1. Prosthetic Devices: Separate from the definition of “orthotics and prosthetics,” we encourage federal regulations to adopt a definition of “prosthetic devices.”

“Prosthetic Devices” should be defined as follows: Prosthetic devices include but are not limited to devices that replace all or part of an internal body organ or all or part of the function of a permanently inoperative or malfunctioning internal body organ. Examples of prosthetic devices include, but are not limited to, joint replacements, colostomy care, cochlear implants, and osseointegrated implants to replace middle ear or cochlear function. Covered services include maintenance, adjustments, repairs, and replacements required because of breakage, wear, loss, or a change in the patient’s size or physical condition.

2. Habilitative Services and Devices and Rehabilitative Services and Devices: as defined above.

In addition to those services listed in our recommended definitions of habilitative and rehabilitative services and devices, future regulations defining coverage requirements, limitations, and exclusions, should include many other types of services that are typically provided under these benefits, including rehabilitation medicine (i.e., physician services), behavioral health services, recreational therapy, developmental pediatrics, cardiac and pulmonary rehabilitation, cognitive and psychiatric

rehabilitation, and psycho-social services provided in a variety of inpatient and/or outpatient settings. These services should be provided based on the individual's needs, prescribed in consultation with a clinician, and based on the assessment of an interdisciplinary team and resulting care plan.

3. Low-vision Aids: Includes but is not limited to devices that help correct for the partial loss of eyesight, making it possible for an individual with impaired vision to accomplish everyday tasks, including reading, writing, driving a car or recognizing faces. Examples of low vision aids include, but are not limited to, devices which magnify, reduce glare, add light or enlarge objects as to make them more visible.

4. Augmentative and Alternative Communication Devices (AACs): Includes but is not limited to specialized devices ordered by a health care professional which assist individuals with severe speech or language problems to supplement existing speech or replace speech that is not functional. Examples of AAC devices include, but are not limited to, picture and symbol communication boards and electronic devices.

5. Hearing Aids and Assistive Listening Devices: Includes but is not limited to medical devices which amplify sound and/or counter the negative effects of environmental acoustics and background noise to assist individuals who have been diagnosed with a hearing loss by a physician and/or hearing health professional.

Proposed SBC Sample Completed Template

We have reviewed the proposed Summary of Benefits and Coverage (SBC) template.⁵ While we commend the Departments for several of their recommendations, we further recommend the following changes:

- On page 3, the “Habilitation services” and “Rehabilitation services” items under “Services You May Need” should be renamed “Habilitation services and devices” and “Rehabilitation services and devices,” respectively, to be consistent with our new proposed definitions above;
- On page 3, “Services You May Need” under “If you need help recovering or have other special health needs” should include “Orthotics and prosthetics” right below “Durable medical equipment,” to be consistent with the proposed Uniform Glossary, and our new proposed definitions above. “Limits, Exceptions, & Other Important Information” should be listed for orthotics and prosthetics as well.
- On page 3, there appears to be a joint limitation of rehabilitation and habilitation services listed under “Limits, Exceptions, & Other Important Information.” Under the February 2015 final rule *Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016*, every state’s EHB plan must not impose combined limits on habilitative and rehabilitative services and devices for plan years beginning on or after January 1, 2017.⁶ We request that the Departments modify the template to have separate limitations for rehabilitation and habilitation services.

⁵ See <https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/SBC-Sample-Completed.pdf>.

⁶ Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016, 80 Fed. Reg. 10750, 10871 (February 27, 2015).

Proposed Instructions for Completing the SBC - Group Health Plan Coverage & Individual Health Insurance Coverage Documents

To be consistent with the recommendations proposed to the revised SBC template, we propose that all references to “habilitation services” be changed to “habilitation services and devices.”

We greatly appreciate your attention to our concerns and your interest in our participation in this process. We further recommend that the Departments coordinate consumer testing and broader consultation on the Summary of Benefits and Coverage and Uniform Glossary, as well as associated documents, with the consumer representatives of the National Association of Insurance Commissioners (NAIC) as well as other stakeholders.

Should you have further questions regarding this information, please contact Peter Thomas or Steven Postal, HAB/CPR/ITEM/CCD Coalition staff, by emailing them at Peter.Thomas@ppsv.com or Steven.Postal@ppsv.com, respectively, or by calling 202-466-6550.

Sincerely,

Endorsing Organizations

Academy of Spinal Cord Injury Professionals
ACCSES
American Academy of Physical Medicine and Rehabilitation
American Association on Health and Disability
American Cochlear Implant Alliance
American Congress of Rehabilitation Medicine
American Medical Rehabilitation Providers Association
American Music Therapy Association
American Network of Community Options and Resources
American Occupational Therapy Association
American Physical Therapy Association
American Speech-Language-Hearing Association
American Therapeutic Recreation Association
Amputee Coalition
The Arc of the United States
Association for Education and Rehabilitation of the Blind and Visually Impaired
Association of Academic Physiatrists
Association of Assistive Technology Act Programs
Association of University Centers on Disabilities
Autism Speaks
Bazelon Center for Mental Health Law
Brain Injury Association of America
Caregiver Action Network
Center for Medicare Advocacy
Child Neurology Foundation
Christopher & Dana Reeve Foundation
Clinician Task Force
Disability Rights Education and Defense Fund
Easter Seals
Epilepsy Foundation
Family Voices
Hearing Loss Association of America
Institute for Matching Person & Technology
Lakeshore Foundation
National Association for Home Care & Hospice
National Association for the Advancement of Orthotics and Prosthetics
National Association of County Behavioral Health and Developmental Disability Directors
National Association of State Head Injury Administrators
National Disability Rights Network
National Multiple Sclerosis Society
National Stroke Association
Paralyzed Veterans of America
Parkinson's Action Network
United Cerebral Palsy
United Spinal Association

cc: CMS Desk Officer; Desk Officer for Treasury; OMB Desk Officer for DOL–EBSA