[Draft]

February 26, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: (CMS–9938–P) Summary of Benefits and Coverage and Uniform Glossary

Dear Acting Administrator Slavitt:

The undersigned members of the Coalition to Preserve Rehabilitation (CPR) appreciate the opportunity to comment on the proposed rule *Summary of Benefits and Coverage and Uniform Glossary* (the Proposed Rule). The 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.

In the Proposed Rule, the Internal Revenue Service at the Department of the Treasury, the Employee Benefits Security Administration at the Department of Labor, and the Centers for Medicare & Medicaid Services at the Department of Health and Human Services (collectively, the Departments) invite comment on the proposed documents associated with the Summary of Benefits and Coverage and Uniform Glossary located at http://www.dol.gov/ebsa/healthreform/regulations/summaryofbenefits.html, primarily in connection with private insurance plans and pursuant to the Affordable Care Act. The CPR comments 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[1] contains definitions of durable medical equipment, habilitation services, and rehabilitation services. We understand the intent of the glossary

[1] See http://www.dol.gov/ebsa/pdf/SBCUniformGlossary.pdf.

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, the CPR supports 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, the CPR supports the Departments adopting more robust, inclusive definitions for these terms.

Durable Medical Equipment (DME)

The CPR supports, for the purposes of the uniform glossary of coverage and medical terms, the definition of Durable Medical Equipment (DME), which reads: "Equipment and supplies ordered by a health care provider for everyday or extended use. Coverage for DME may include: oxygen equipment, wheelchairs, crutches or blood testing strips for diabetics." The CPR does not recommend a change to the uniform glossary of coverage and medical terms definition of DME.

However, for purposes of future regulations defining coverage requirements, limitations, and exclusions, the CPR proposes 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

For the purposes of the uniform glossary of coverage and medical terms, the CPR supports the Departments for their definition of Habilitation Services, which reads: "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." The CPR also supports 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.[2]

[2] https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-03751.pdf, page 227, 450.

The CPR proposes that the Departments' definition for 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 the purposes of future regulations defining coverage requirements, limitations, and exclusions, the CPR also proposes 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

For the purposes of the uniform glossary of coverage and medical terms, the CPR supports the Departments for their definition of Rehabilitation Services, which reads: "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 CPR is supportive of the Department of Health and Human Services (HHS) for including 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."[3]

Patient Protection and Affordable Care Act (PPACA) §1302 states that "rehabilitative services and devices" are essential health benefits. The CPR believes that the uniform glossary of coverage and medical terms should be consistent with that statutory language. This could be achieved by adding the term "and devices" after "Health care services."

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

[3] https://s3.amazonaws.com/public-inspection.federalregister.gov/2015-03751.pdf, page 227.

- 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.

B. Further Detail of Habilitative & Rehabilitative Services

Additional Services
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, 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.

Medically Necessary
The current definition of the term "medically necessary" in the uniform glossary of coverage and medical terms 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." The CPR proposes 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.

C. Proposed Additional Definition

Orthotics and Prosthetics
It is clear from the legislative history of PPACA that durable medical equipment (DME) and orthotics and prosthetics (O&P), were intended to be covered in the essential health benefits package and we, therefore, believe that a separate definition of "orthotics and prosthetics" for purposes of comparing medical benefits across different health plans is appropriate. To define O&P care under the DME benefit would be inappropriate as these are two entirely different benefits and would result in unintended negative consequences for patients that need artificial limbs and orthopedic braces.

While the majority of DME items are largely product or commodity-based, O&P entail a high level of clinical service by educated and trained practitioners who design, fabricate and fit custom orthoses and prostheses. This is the reason why Medicare defines DME separately from O&P and uses the term "DMEPOS," (durable medical equipment, prosthetics, orthotics, and supplies).

The Congressional Record lays the foundation for the Departments to use their discretion to include a separate definition in the list of medical terms for "Orthotics and Prosthetics." House Education and Labor Committee Chairman George Miller, during passage of PPACA, explicitly stated that Congress intended to include prosthetics and orthotics in the new health care law's essential health benefits package under the term "rehabilitation and habilitation services and devices," but also intended to define prosthetics and orthotics separately from DME in the definitions section of the Affordable Care Act. "**It is my expectation 'prosthetics, orthotics, and related supplies' will be defined separately from 'durable medical equipment**,'" Miller stated. (Congressional Record, H-1882, March 21, 2010).

Therefore, the CPR proposes that the Departments adopt the following definition in its uniform glossary of coverage and medical conditions:

- 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.

D. Future Regulatory Definitions

The CPR proposes that the Departments further define the following for purposes of future regulations defining coverage requirements, limitations, and exclusions:

1. Orthotics and Prosthetics: as defined above.

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

3. Prosthetic Devices: Includes but is 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, and implanted breast prostheses incident to mastectomy resulting from breast cancer, 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 physical condition.

4. 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.

5. 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.

6. 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.

Summary of Benefits and Coverage (SBC) Template

The CPR has reviewed the proposed Summary of Benefits and Coverage (SBC) template,[4] and recommends the following revisions:

Clarify how deductibles and out-of-pocket maximums apply in family plans, so that consumers have a more precise understanding of their cost-sharing obligations**.** Annual cost-sharing charges in plans covering more than one individual can be either "embedded" or "aggregate." ***We urge the Departments to update the SBC template so that plans are required to note whether out-of-pocket costs are "embedded" or "aggregate" and why it matters.*** Specifically,

- On page 1, explain if the overall deductible is embedded or aggregate under "Why this matters" for the "What is the overall deductible?" row.
  - If embedded: "If you are enrolled in single/individual coverage, you must meet the individual deductible ($XXXX) before the plan pays claims for covered services. If you are enrolled in family coverage, the plan begins paying claims for an individual family member once he/she meets the individual deductible ($XXXX). Once the family has met the family deductible ($ZZZZ), the plan pays claims for all members of the family for covered services."
  - If aggregate: "If you are enrolled in family coverage, once the family has met the family deductible ($ZZZZ), the plan pays claims for covered services. The individual deductible does not apply in family coverage."
- Explain if the out-of-pocket maximum is embedded or aggregate under "Why this matters" column for the "Is there an out-of-pocket limit on my expenses?" row.
  - If embedded: "If you are enrolled in single/individual coverage, once you meet the individual out-of-pocket maximum ($YYYY), the plan will pay 100% of the cost of covered services. If you are enrolled in family coverage, once an individual family member has met the individual out-of-pocket maximum ($YYYY), the plan will pay 100% of the cost of covered services for that individual. Once the family meets the family out-of-pocket maximum ($WWWW), the plan will pay 100% of the cost of covered services for all members of the family.";

- On page 2, under "Services You May Need" column in the row "If you visit a health care provider's office or clinic," "practitioner" is not defined in the field "other practitioner office visit." The CPR asks that the Departments provide further clarification of what "practitioner" means in the SBC template, and define it in the Glossary of Health Terms and Medical Coverage if it is different than "Primary Care Provider" or "Provider.";

- On page 3, the "Habilitation services" and "Rehabilitation services" items under "Services You May Need" should be renamed "Habilitation services and devices" and "Rehabilitation

[4] See http://www.dol.gov/ebsa/healthreform/regulations/summaryofbenefits.html.

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 our new proposed definitions above;

- **On pages 2-3, and especially for the sections regarding rehabilitation services and devices, habilitation services and devices, durable medical equipment, and orthotics and prosthetics, any quantitative limits for covered services (e.g. number of hours, days, visits covered, device exclusions) should be clearly specified in the SBC in the "Limitations & Exceptions" column;**

- On page 3, rehabilitation services and devices, habilitative services and devices, durable medical equipment, and orthotics and prosthetics that are not covered should be explicitly enumerated in the "Services Your Plan Does NOT Cover" section of the SBC; and

- Covered habilitative and rehabilitative services and devices should be listed somewhere in the SBC with specificity to provide optimal clarity to the public.

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, the CPR proposes 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. The CPR further recommends 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, CPR staff, by emailing them at Peter.Thomas@ppsv.com or Steven.Postal@ppsv.com, respectively, or by calling 202-466-6550.

Sincerely,

CPR Steering Committee Members

Amy Colberg (Brain Injury Association of America) AColberg@biausa.org
Judith Stein (Center for Medicare Advocacy) JStein@medicareadvocacy.org
Maggie Goldberg (Christopher and Dana Reeve Foundation) MGOLDBERG@ChristopherReeve.org
Kim Calder (National Multiple Sclerosis Society) Kim.Calder@nmss.org
Alexandra Bennewith (United Spinal Association) ABennewith@unitedspinal.org

Endorsing Organizations

American Academy of Physical Medicine and Rehabilitation
American Association on Health and Disability
American Congress of Rehabilitation Medicine
American Music Therapy Association
American Speech-Language-Hearing Association
American Therapeutic Recreation Association
Amputee Coalition
The Arc of the United States
Association of Academic Physiatrists
Brain Injury Association of America
Center for Medicare Advocacy
Christopher and Dana Reeve Foundation
Disability Rights Education & Defense Fund
Easter Seals
Epilepsy Foundation
Lakeshore Foundation
National Association of State Head Injury Administrators
National Disability Rights Network
National Multiple Sclerosis Society
Paralyzed Veterans of America
United Spinal Association

Cc: John Koskinen, Commissioner, Internal Revenue Service, Department of the Treasury
Phyllis C. Borzi, Assistant Secretary, Employee Benefits Security Administration, Department of Labor