March 2, 2015

SUBMITTED ELECTRONICALLY

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 Independence Through Enhancement of Medicare and Medicaid ("ITEM") Coalition appreciate the opportunity to comment on the proposed rule Summary of Benefits and Coverage and Uniform Glossary (the Proposed Rule). ITEM Coalition is a national consumer and clinician-led coalition advocating for access to and coverage of assistive devices and technologies 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, paralysis, hearing and speech impairments, cerebral palsy, visual impairments, spinal cord injuries, brain injury, stroke, spina bifida, myositis, limb loss, Osteogenesis Imperfecta ("OI"), and other life-altering conditions.

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. ITEM 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 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, ITEM supports the Departments' adoption of 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, ITEM supports the Departments' adoption of more robust, inclusive definitions for these terms.

Durable Medical Equipment (DME)
For the purposes of the uniform glossary of coverage and medical terms, ITEM supports 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."

ITEM 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, ITEM 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.

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

Habilitation Services

For the purposes of the uniform glossary of coverage and medical terms, ITEM 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." ITEM also commends 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]

ITEM 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" and would make the two regulations consistent.

For the purposes of future regulations defining coverage requirements, limitations, and exclusions, ITEM 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 devices should 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 below.

Habilitative services and devices 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.

Rehabilitation Services

For the purposes of the uniform glossary of coverage and medical terms, ITEM 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 HHS did not explicitly add "and devices" to rehabilitative services in the regulatory section of the 2016 Notice of Benefit and Payment Parameters final rule, ITEM is supportive of

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

HHS' inclusion of the following statement in the comment section of the final rule: "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. ITEM believes that the uniform glossary of coverage and medical terms should be consistent with that statutory language. This could be achieved by simply adding the term "and devices" after "Health care services."

For the purposes of future regulations defining coverage requirements, limitations, and exclusions, ITEM 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:

- 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. 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).

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

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, ITEM 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.

C. Future Regulatory Definitions

ITEM 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

ITEM 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 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 our new proposed definitions above;

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

- 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, orthotics and prosthetics and other assistive devices and technologies 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, ITEM proposes that all references to "habilitation services" be changed to "habilitation services and devices."

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We greatly appreciate your attention to our concerns and your interest in our participation in this process. ITEM 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 the information contained in our letter, please contact the ITEM Coalition Steering Committee, listed below, or Peter Thomas, ITEM Coalition staff, via email at Peter.Thomas@ppsv.com or by calling 202-466-6550.

Sincerely,

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