government of providing the special benefits to issuers; however, for 2016 as noted above, we received an exception to this policy because we wish to ensure that the FFEs can support many of the goals of the Affordable Care Act. Because we set the user fee rate below that which is expected to cover full Federal costs (as in 2014 and 2015), we do not see the need at this time to address a situation in which user fee collections exceed costs.

2. Essential Health Benefits Package

a. State Selection of Benchmark (§ 156.100)

We proposed to amend paragraph (c) of § 156.100 to delete the language regarding the default base-benchmark plan in the U.S. Territories of Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands. The change reflects HHS's determination, described in more detail in section III.A.1.b of this final rule, that certain provisions of the PHS Act enacted in title I of the Affordable Care Act that apply to health insurance issuers are appropriately governed by the definition of "State" set forth in that title. Therefore, the rules regarding EHB (section 2707 of the PHS Act) do not apply to health insurance issuers in the U.S. Territories. We also proposed to make a technical change to this section by replacing "defined in § 156.100 of this section" with "described in this section." We note that this has no effect on Medicaid and CHIP programs and that Alternative Benefit Plans will still have to comply with the essential health benefit requirements.

We did not receive any comments regarding this proposal. We are finalizing the provisions as proposed.

b. Provision of EHB (§ 156.115)

(1) Habilitative Services

One of the 10 categories of benefits that must, under section 1302(b)(1)(G) of the Act, be included under the Secretary's definition of EHB is rehabilitative and habilitative services and devices. If a benchmark plan does not include habilitative services, § 156.110(c)(6) of the current EHB regulations requires the issuer to cover habilitative services as specified by the State under § 156.110(f) or, if the State does not specify, then the issuer must cover habilitative services in the manner specified in § 156.115(a)(5). Section 156.115(a)(5) states that a health plan may provide habilitative coverage by covering habilitative services benefits that are similar in scope, amount, and duration to benefits covered for rehabilitative services or otherwise determine which services are covered and report the determination to HHS. In some instances, those options have not resulted in comprehensive coverage for habilitative services. Therefore, we proposed amending § 156.115(a)(5) to establish a uniform definition of habilitative services that may be used by States and issuers. In addition, we proposed to remove § 156.110(c)(6) because that provision gives issuers the option to determine the scope of habilitative services.

We believe that adopting a uniform definition of habilitative services would minimize the variability in benefits and lack of coverage for habilitative services versus rehabilitative services. Defining habilitative services clarifies the difference between habilitative and rehabilitative services. Habilitative services, including devices, are provided for a person to attain, maintain, or prevent deterioration of a skill or function never learned or acquired due to a disabling condition. 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.

We proposed adopting the definition from the Glossary of Health Coverage and Medical Terms[45]: Health care services that help a person keep, learn, or improve skills and functioning for daily living. Examples include therapy for a child who is not 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.

We did not propose any changes to § 156.110(f), which allows States to determine services included in the habilitative services and devices category if the base-benchmark plan does not include coverage. Several States have made such a determination following benchmark selection for the 2014 plan year, and we wish to continue to defer to States on this matter as long as the State definition complies with EHB policies, including non-discrimination. If the State does not supplement missing habilitative services or does not supplement the services in an EHB-compliant manner, issuers should cover habilitative services and devices as defined in § 156.115(a)(5)(i).

We also proposed to revise current § 156.115(a)(5)(ii) to provide that plans required to provide EHB cannot impose limits on coverage of habilitative services that are less favorable than any such limits imposed on coverage of rehabilitative services. Since the statutory category includes both rehabilitative and habilitative services and devices, we interpret the statute to require coverage of each. Therefore, issuers that previously excluded habilitative services, but subsequently added them, would be required under our proposal to impose separate limits on each service rather than retaining the rehabilitative services visit limit and having habilitative services count toward the same visit limit. Because we proposed to establish a uniform definition of habilitative services in new § 156.115(a)(5)(i), we also proposed to delete § 156.110(c)(6), which would remove the option for issuers to determine the scope of the habilitative services. In § 156.110 we proposed to make a technical change to amend the list structure of paragraph (c) by replacing the "and" in (c)(5) with a period and adding an "and" at the end of (c)(4).

We are finalizing our policy as proposed, adopting the definition of habilitative services from the Uniform Glossary in its entirety, to be effective beginning with the 2016 plan year and requiring separate limits on habilitative and rehabilitative services beginning with the 2017 plan year. We are codifying this final policy in revised § 156.115(a)(5) and removing § 156.110(c)(6).

*Comment:* Several commenters requested more State flexibility, even in cases where the benchmark plan includes habilitative services; they sought assurance that a Federal definition will not supersede a State law, and that State-required benefits that could be considered habilitative services would be treated as EHB.

*Response:* States are required to supplement the benchmark plan if the base benchmark plan does not include coverage of habilitative services as defined in this final rule. We are codifying the definition of habilitative services as a minimum for States to use when determining whether plans cover habilitative services. State laws regarding habilitative services are not pre-empted so long as they do not prevent the application of the Federal definition. State laws enacted in order to comply with § 156.110(f) are not considered benefits in addition to the EHB; such laws ensure compliance with § 156.110(a) which requires coverage of all EHB categories. Therefore, there is

[45] *http://www.cms.gov/CCIIO/Resources/Files/Downloads/uniform-glossary-final.pdf.*

no obligation to defray the cost of such State-required benefits.

*Comment:* Several commenters objected to imposing separate limits on rehabilitative and habilitative services and devices, claiming issuers do not have operational capacity to differentiate between habilitative and rehabilitative services and devices based on enrollee diagnosis or whether the enrollee is seeking to maintain or achieve function.

*Response:* We are finalizing the requirement to ensure coverage of each with separate limits, but the requirement will not become effective until 2017. This delay is intended to provide issuers with the opportunity to resolve operational issues with their claims systems.

*Comment:* Several commenters asked that "devices" be included in the definition of habilitative services.

*Response:* We originally omitted devices because the term is already included in the statutory description of this category of EHB. In response to comments, however, we have added "devices" to our regulatory definition. We remind issuers that the statute requires coverage of devices for both rehabilitative and habilitative services.

*Comment:* Several commenters requested that we require issuers to have an exceptions process similar to the process required by OPM for multi-State plans, in case a patient needs treatment that exceeds the visit limits allowed by the plan.

*Response:* Enrollees wishing to appeal an adverse benefit determination, including denial of habilitative services, should follow the process established in § 147.136, which implements section 2719 of the PHS Act for internal claims and appeals and external review processes.

*Comment:* Commenters offered many suggestions for specific services and devices, such as orthotics and prosthetics, which they stated should be required to be covered as habilitative services and devices by all issuers.

*Response:* We are not codifying such a list at this time, as we continue to allow States to maintain their traditional role in defining the scope of insurance benefits, but we encourage issuers to cover additional services and devices beyond those covered by the benchmark plan.

(2) Pediatric Services

In the preamble of the EHB Rule, we stated that pediatric services should be provided until at least age 19 (78 FR 12843). States, issuers, and stakeholders requested clarification on this standard. To provide this clarification, we proposed amending § 156.115(a) to add paragraph (6), specifying that EHB coverage for pediatric services should continue until the end of the plan year in which the enrollee turns 19 years of age. This was proposed as a minimum requirement.

This age limit is consistent with section 1201 of the Affordable Care Act,[46] which phased in the prohibition on preexisting conditions exclusions by first prohibiting them for children under age 19, as well as the age limit for eligibility to enroll in CHIP. In addition, as noted in the EHB Rule, this proposed policy aligns with Medicaid rules (78 FR 12843), which require States to cover children up to age 19 with family incomes up to 100 percent of the FPL as a mandatory eligibility category.

*Comment:* Many commenters requested that pediatric services continue only until the end of the *month* in which the enrollee turns 19, stating that this is the industry standard.

*Response:* Although we proposed to require pediatric services until the end of the plan year in which the enrollee turns 19, we recognize these commenters' concerns. Accordingly, we are finalizing a policy in § 156.115(a)(6), under which issuers must provide coverage for pediatric services until at least the end of the month in which the enrollee turns 19. We encourage issuers to cover services under the pediatric services EHB category beyond the 19th birthday month if non-coverage of those services after that time would negatively affect care.

c. Collection of Data To Define Essential Health Benefits (§ 156.120)

In the Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans final rule (EHB Data Collection Rule),[47] we required issuers in each State to submit certain data regarding the three largest health insurance products by enrollment (as of March 31, 2012) to HHS by September 4, 2012. These data, gathered from 2012 plans, were used to determine, for each State, the benefits and limitations of the three largest small group products by enrollment, which were used to establish potential benchmark plans. The EHB Rule unintentionally deleted § 156.120, which included the data submission requirement.

We proposed to allow each State to select a new base-benchmark plan for the 2017 plan year, allowing States to choose a 2014 plan that meets the requirements of § 156.110 as the new EHB-benchmark plan, so that issuers can design substantially equal EHB-compliant products for the 2017 plan year. We believe that this would ultimately create efficiencies for issuers in designing plans. As stated in § 156.115(a), provision of EHB means that a health plan provides benefits that are substantially equal to the EHB-benchmark plan. Therefore, health plans offering EHB in the 2017 plan year will be required to provide benefits substantially equal to the benefit amounts, duration and scope of benefits covered by the 2014 EHB-benchmark plan (supplemented as necessary).

If a category of base-benchmark plans under § 156.100(a)(1)–(4) does not include a plan that meets the requirements of § 156.110, we considered permitting the State to select a base-benchmark plan that does not meet the requirements of § 156.110 in that category and supplement its base-benchmark plan as provided in § 156.110(b) to ensure that all 10 categories of benefits are covered in a benchmark plan.

We proposed re-codifying part of § 156.120, in a manner similar to that which appeared in our regulations prior to the effective date of the EHB Rule. We proposed to require a State that chooses a new benchmark plan in the State or, if a State does not choose a new benchmark plan, the issuer of the default benchmark plan, to provide benchmark plan data as of a date specified by HHS. We anticipate collection of new benchmark plan data for the 2017 plan year and the data discussed in § 156.120(b), including administrative data and descriptive information pertaining to all health benefits in the plan, treatment limitations, drug coverage, and exclusions. We believe that this information is already included in the issuer's form filing that the issuer submitted to the State regulator. The definitions previously adopted in § 156.120(a) for the terms health benefits, health plan, State, and treatment limitations are still applicable and would be codified as previously defined. However, we are not finalizing the definitions for "health insurance market" or "small group market" in

[46] Section 1201 of the Affordable Care Act added section 2704 of the PHS Act, which prohibited preexisting condition exclusions. Section 1255 of the Affordable Care Act states that the provisions of section 2704 of the PHS Act, as they apply to enrollees who are under 19 years of age, shall become effective for plan years beginning on after September 23, 2010.

[47] Patient Protection and Affordable Care Act; Data Collection to Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans, 77 FR 42658 (July 20, 2013) (codified at part 156).

## PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 37. The authority citation for part 156 continues to read as follows:

**Authority:** Title I of the Affordable Care Act, sections 1301–1304, 1311–1313, 1321–1322, 1324, 1334, 1342–1343, 1401–1402, Pub. L. 111–148, 124 Stat. 119 (42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, 26 U.S.C. 36B, and 31 U.S.C. 9701).

■ 38. Section 156.20 is amended by adding a definition of "Plan" in alphabetical order to read as follows:

**§ 156.20 Definitions.**

* * * * *

*Plan* has the meaning given the term in § 144.103 of this subchapter.

* * * * *

■ 39. Section 156.100 is amended by revising paragraph (c) to read as follows:

**§ 156.100 State selection of benchmark.**

* * * * *

(c) *Default base-benchmark plan.* If a State does not make a selection using the process described in this section, the default base-benchmark plan will be the largest plan by enrollment in the largest product by enrollment in the State's small group market.

■ 40. Section 156.110 is amended by revising paragraphs (c)(4) and (5) and removing paragraph (c)(6) to read as follows:

**§ 156.110 EHB-benchmark plan standards.**

* * * * *

(c) * * *

(4) The plan described in paragraph (b)(2)(i) of this section for pediatric oral care benefits; and

(5) The plan described in paragraph (b)(3)(i) of this section for pediatric vision care benefits.

* * * * *

■ 41. Section 156.115 is amended by revising paragraphs (a)(5)(i) and (ii) and adding paragraphs (a)(5)(iii) and (a)(6) to read as follows:

**§ 156.115 Provision of EHB.**

(a) * * *

(5) With respect to habilitative services and devices—

(i) Cover health care services and devices that help a person keep, learn, or improve skills and functioning for daily living (habilitative services). Examples include therapy for a child who is not 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;

(ii) Do not impose limits on coverage of habilitative services and devices that are less favorable than any such limits imposed on coverage of rehabilitative services and devices; and

(iii) For plan years beginning on or after January 1, 2017, do not impose combined limits on habilitative and rehabilitative services and devices.

(6) For plan years beginning on or after January 1, 2016, for pediatric services that are required under § 156.110(a)(10), provide coverage for enrollees until at least the end of the month in which the enrollee turns 19 years of age.

* * * * *

■ 42. Section 156.120 is added to read as follows:

**§ 156.120 Collection of data to define essential health benefits.**

(a) *Definitions.* The following definitions apply to this section, unless the context indicates otherwise:

*Health benefits* means benefits for medical care, as defined at § 144.103 of this subchapter, which may be delivered through the purchase of insurance or otherwise.

*Health plan* has the meaning given to the term "Portal Plan" in § 159.110 of this subchapter.

*State* has the meaning given to that term in § 155.20 of this subchapter.

*Treatment limitations* include limits on benefits based on the frequency of treatment, number of visits, days of coverage, or other similar limits on the scope or duration of treatment. Treatment limitations include only quantitative treatment limitations. A permanent exclusion of all benefits for a particular condition or disorder is not a treatment limitation.

(b) *Reporting requirement.* A State that selects a base-benchmark plan or an issuer that offers a default base-benchmark plan in accordance with § 156.100 must submit to HHS the following information in a form and manner, and by a date, determined by HHS:

(1) Administrative data necessary to identify the health plan;

(2) Data and descriptive information for each plan on the following items:

(i) All health benefits in the plan;

(ii) Treatment limitations;

(iii) Drug coverage; and

(iv) Exclusions.

■ 43. Section 156.122 is amended by revising paragraphs (a)(1), (a)(2), and (c) and adding paragraphs (a)(3), (d), and (e) to read as follows:

**§ 156.122 Prescription drug benefits.**

(a) * * *

(1) Subject to the exception in paragraph (b) of this section, covers at least the greater of:

(i) One drug in every United States Pharmacopeia (USP) category and class; or

(ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan;

(2) Submits its formulary drug list to the Exchange, the State or OPM; and

(3) For plans years beginning on or after January 1, 2017, uses a pharmacy and therapeutics (P&T) committee that meets the following standards.

(i) *Membership standards.* The P&T committee must:

(A) Have members that represent a sufficient number of clinical specialties to adequately meet the needs of enrollees.

(B) Consist of a majority of individuals who are practicing physicians, practicing pharmacists and other practicing health care professionals who are licensed to prescribe drugs.

(C) Prohibit any member with a conflict of interest with respect to the issuer or a pharmaceutical manufacturer from voting on any matters for which the conflict exists.

(D) Require at least 20 percent of its membership to have no conflict of interest with respect to the issuer and any pharmaceutical manufacturer.

(ii) *Meeting standards.* The P&T committee must:

(A) Meet at least quarterly.

(B) Maintain written documentation of the rationale for all decisions regarding formulary drug list development or revision.

(iii) *Formulary drug list establishment and management.* The P&T committee must:

(A) Develop and document procedures to ensure appropriate drug review and inclusion.

(B) Base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other such information as it determines appropriate.

(C) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.

(D) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.