On February 20th, 2015, the Department of Health and Human Services (HHS) issued the Notice of Benefit and Payment Parameters for 2016 final rule (Final Rule 2016), which among changes in other areas, finalized changes to the Essential Health Benefits (EHBs) standard. Introduced by the Affordable Care Act (ACA), EHBs are a set of ten health care service categories that plans must provide to ensure certain items and services are included in the plan. The EHB requirement applies to non-grandfathered health plans offered in the individual and small group markets (both inside and outside the Marketplace.) This fact sheet provides an overview of 1) existing EHB rules, 2) changes or clarifications made to the EHB standard in the Final Rule 2016, and 3) advocacy opportunities available.

**Base-Benchmark Plans**

**Existing rule:**

Each state uses a base-benchmark plan (bbp) as a reference plan to define EHBs in the state. States select their EHB bbp from among ten options:

- the three largest Federal Employees Health Benefits Program plans;
- the three largest state employee plans;
- the three largest small group plans in the state; or

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1 Shyaam Subramanian, a Berkeley Law Public Interest Fellow at the National Health Law Program, contributed to the preparation of this Fact Sheet.


3 The ten EHB statutory categories of benefits are: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services (including chronic disease management); and pediatric services, including oral and vision care.

4 This fact sheet focuses on EHBs as they apply to the private market.
• the HMO plan with the largest commercial, non-Medicaid enrollment in the state.

States not selecting a benchmark plan get the default benchmark, which is the largest small group plan in the state.\(^5\) HHS indicated the benchmark approach and EHB bbp selection made in 2012 would apply for at least the 2014 and 2015 benefit years with HHS revisiting this policy for subsequent years.\(^6\)

**Change/Clarification:**

In the Final Rule 2016, HHS announced it will continue to use the benchmark approach to define EHBs through plan year 2017. But HHS will examine how using the benchmark approach in 2014 (the first EHB plan year) affected enrollees in order to determine what changes, if any, should be made in the future.\(^7\)

For the 2016 plan year, the bbp selected in 2012 will continue to apply. However, HHS will allow states to select a new base-benchmark plan for the 2017 plan year. States will continue to choose from the same ten bbp options listed above, but this time based on 2014 plans. States not selecting a bbp will get the default benchmark. HHS anticipates collecting benchmark plan data for the 2017 plan year during the second quarter of 2015.\(^8\) HHS will publish a list of the selected bbps (or the default benchmark for states that do not select a plan) and will include plan documents collected from the state.\(^9\)

**Advocacy Opportunities:**

**Selection of a new bbp for the 2017 plan year**

- This is an opportunity for advocates to influence the bbp selected by the state. With HHS announcing its intent to collect new bbp data and documents in the second quarter of 2015, this means states may have to make a selection soon.
  - Request that your state set-up a stakeholder process to discuss the state’s options regarding changes to the EHB standard and selection of a new bbp for the 2017 plan year.

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\(^{6}\) Final Rule 2013, *supra* note 5, at 12,841.

\(^{7}\) Final Rule 2016, *supra* note 2, at 10,813.

\(^{8}\) *Id.*

To ensure transparency and the opportunity to provide meaningful input, request copies of the Evidence of Coverage documents for all ten EHB bbp options to compare the benefit package offered by each plan and identify the best choice for your state.

Once your state selects an EHB bbp, make sure it includes items and services in the 10 EHB statutory categories and that any missing categories are supplemented correctly (see supplementing section below.)

Tracking issues with benchmark approach

- HHS indicated it would like to have a more “complete sense” of how the EHB benchmark policy is working before proposing any changes to the benchmark approach.\(^{10}\) Therefore, it will be important to monitor and track how using the benchmark approach has impacted your client community and ensure vulnerable populations can access comprehensive care that consistently meets their needs.

- Let NHeLP know if there are situations where using the benchmark approach has resulted in inadequate coverage of any of the 10 EHB categories.

Supplementing and Substitution

Existing Rule:

**Supplementing**

If an EHB bbp selected by a state does not include items or services in one of the 10 EHB categories, the bbp must be supplemented by adding that particular category in its entirety from any other EHB bbp option. There are some exceptions to this general supplementing rule; for example, pediatric oral and vision care have their own supplementing methodology.

**Pediatric Oral Care**

Supplement with:

- the Federal Employees Dental and Vision Program (FEDVIP) dental plan with the largest enrollment, or
- dental benefits available under the state’s separate Children’s Health Insurance Program (CHIP) plan.

**Pediatric Vision Services**

Supplement with:

- the FEDVIP vision plan with the largest national enrollment, or
- vision benefits available under the state’s separate CHIP plan.

**Substitution**

Unless prohibited by state law, issuers offering EHB may substitute benefits that are 1) actuarially equivalent to benefits replaced and 2) within the same EHB category. Therefore, covering EHBs means the health plan provides benefits “substantially equal”

\(^{10}\) Final Rule 2016, *supra* note 2, at 10,813.
to the EHB bbp. This can lead to problems because issuers can substitute services that certain populations may need (e.g. individuals with chronic conditions) and replace them with actuarially equivalent services, which may be less costly and more likely to attract healthier populations. States have the option to adopt more stringent standards that limit or prohibit this type of substitution. In states not prohibiting substitution, consumers may find it difficult to compare health coverage options, which can make plan selection challenging.

**Change/Clarification:**

None.

**Advocacy opportunities:**

**Supplementing**

- Since states will have the option to select new bbps for the 2017 plan year (or get the default benchmark), ensure the bbp covers all ten EHB categories, and gets supplemented correctly.
- As mentioned above, it will be important to request copies of the Evidence of Coverage documents for all ten EHB bbp options to ensure the state supplements any missing benefit categories with the best possible plan option to fill the gaps.
- For pediatric oral care and vision services, the supplementing options are FEDVIP and CHIP (as mentioned above.) Evaluate whether the FEDVIP or CHIP selection made by your state in 2012 continues to be the right option for your state. Assess whether there were any coverage issues related to pediatric oral care or vision services in the first EHB plan year (2014), which could be resolved by selecting the alternative option.

**Substitution**

- Advocate for your state to prohibit substitution of benefits by issuers, if it does not already do so.

**Habilitative Services**

**Existing Rule:**

HHS did not define habilitative services for 2014 and 2015 and instead gave states and issuers flexibility in determining how to cover this service. Through 2015, states can provide habilitative services as covered by the EHB bbp. If the bbp does not include coverage of habilitative services (most do not), the state may determine which services to include. If the state does not make the determination, then issuers may include

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11 45 C.F.R. § 156.115(a)(1); see also Final Rule 2013, *supra* note 5, at 12,844 (explaining that the benefit substitution policy does not apply to prescription drugs and is subject to non-discrimination requirements).
habilitative services that meet one of the following requirements: 1) parity with rehabilitative services, or 2) as defined by the issuer and reported to HHS.

**Change/Clarification:**

HHS established a uniform definition of habilitative services, which will be used beginning with the 2016 plan year in order to minimize 1) variability in how the benefit is covered, and 2) lack of coverage of habilitative services versus rehabilitative services.

*Uniform Definition:*

*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.*

If the EHB bp selected does not provide coverage of habilitative services or provides inadequate coverage, states continue to have the option to define the benefit. States will compare the EHB bp's definition of habilitative services to the uniform definition to determine if the bp coverage of habilitative services is adequate. If it is not adequate, the state may define the benefit but must use the uniform definition as a minimum standard. If the state does not define the benefit, issuers will cover habilitative services and devices as defined in the uniform definition. HHS *removed* the issuer flexibility to define this benefit.¹²

In addition, issuers required to provide EHB cannot 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.¹³ Beginning plan years on or after January 1, 2017, issuers will be required to impose separate limits on habilitative and rehabilitative services.

HHS also indicated that state laws enacted in order to define habilitative services will not be considered mandates in addition to the EHB, and therefore the state will not have to defray the cost for those state benefit mandates related to habilitative services.¹⁴

**Advocacy opportunities:**

- Request that your state set-up a stakeholder process for advocates to provide input on state decisions regarding the EHB standard, including whether to define habilitative services.

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¹³ This change is effective April 28, 2015, which is the date the Final Rule 2016 goes into effect, with the exception of sections that specify a different implementation date. *Id.* at 10,750.

¹⁴ *Id.* at 10,811-12.
➢ Ensure the state is following the proper process for defining habilitative services and advocate for a comprehensive definition.
➢ States do not have to defray the cost for new state benefit mandates enacted in order to define habilitative services. So if your state was considering a mandate related to habilitative services, but was hesitant to enact a new mandate because of the cost, inform your state of HHS’ clarification that states will not have to defray the cost for new mandates that help define habilitative services.
➢ On an ongoing basis, monitor and track how habilitative services are covered to ensure the services are clearly defined and that the coverage is meeting enrollees’ needs. Let NHeLP know if you are noticing any issues.

**Pediatric Services**

**Existing Rule:**

Pediatric services must be provided to individuals under 19 years old, but states have the option to increase the maximum age in defining pediatric services.\(^{15}\)

**Change/Clarification:**

HHS clarified the age limit for pediatric services by stating that, for plan years beginning on or after January 1, 2016, pediatric services must be provided until at least the end of the month in which the enrollee turns 19 years of age.\(^{16}\)

**Advocacy opportunity:**

➢ Advocate for your state to take the state option to raise the age limit for pediatric services. Encourage your state to at least raise the age limit to age 21, which aligns with existing standards for Medicaid and will ensure that children continue to receive pediatric services, including oral and vision care until age 21.

**State mandates**

**Existing rule:**

State benefit mandates enacted on or before December 31, 2011 (even if not effective until a later date) are considered part of the EHBs, therefore states do not have to defray the cost of covering those benefits.\(^{17}\) The Marketplace (Exchange) identifies which state-required benefits are not part of the EHB, and have an additional cost associated with them. Each Qualified Health Plan (QHP) issuer quantifies the cost attributable to state-required benefits in excess of the EHB based on “an analysis

\(^{15}\) Final Rule 2013, *supra* note 5, at 12,842.
\(^{17}\) 45 C.F.R. § 155.170.
performed in accordance with generally accepted actuarial principles and methodologies; conducted by a member of the American Academy of Actuaries; and reported to the Exchange.”\textsuperscript{18} Since the state, and not the issuer, is responsible for the cost of state mandates which are beyond the EHB requirements, payment for those additional benefits is: 1) made by the state directly to an enrollee or 2) directly to the QHP issuer on behalf of the individual.\textsuperscript{19} In 2013, HHS indicated this state benefit mandates policy would apply for at least the 2014 and 2015 plan years.\textsuperscript{20}

**Change/Clarification:**

HHS did not propose any changes to its EHB state benefit mandate policy in the Final Rule 2016, but rather confirmed that the current policy continues to apply. This means that state benefit mandates enacted on or prior to December 31, 2011 are included as EHBs, and thus states do not have to defray cost associated with them.\textsuperscript{21} Yet, states are expected to continue to defray the cost of state benefit mandates enacted on or after January 1, 2012 unless those mandates were required in order to comply with new federal requirements.\textsuperscript{22}

One of those new federal requirements is the uniform definition of habilitative services. HHS clarified that state mandates enacted in order to define habilitative services are part of the EHB, and therefore the state does not have to defray the cost for those state benefit mandates.\textsuperscript{23}

**Advocacy opportunities:**

- Track the impact that HHS’ policy on state benefit mandates is having on your state’s ability to enact new mandates that address coverage gaps and/or help meet the health goals of the state.
  - Has this policy meant a freeze on mandates that apply to issuers required to provide EHBs? If so, are consumers not getting important new benefits?
  - Let NHeLP know if you notice any coverage issues arising in your state as a result of HHS’ state benefit mandates policy.

- Ensure your state is aware of HHS’ clarification that states will not have to defray the cost for state mandates enacted in order to define habilitative services (see habilitative services section above) and that your state considers enacting new mandates related to habilitative services that are needed in order to fill-in coverage gaps.

\textsuperscript{18} Id. § 155.170(c)(2)(i)-(iii).
\textsuperscript{19} Id. § 155.170(b).
\textsuperscript{20} Final Rule 2013, supra note 5, at 12,838.
\textsuperscript{21} Final Rule 2016, supra note 2, at 10,813.
\textsuperscript{22} Id.
\textsuperscript{23} Id. at 10,811-12.
Non-Discrimination

Existing rule:

An issuer does not provide EHBs if “its benefit design, or the implementation of its benefit design, discriminates based on an individual’s age, expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions.”

Change/Clarification:

In the preamble of the Final Rule 2016, HHS listed three examples of potential discriminatory practices by issuers:

“(1) attempts to circumvent coverage of medically necessary benefits by labeling the benefit as ‘pediatric service,’ thereby excluding adults; (2) refusal to cover a single-tablet drug regimen or extended-release product that is customarily prescribed and is just as effective as a multi-tablet regimen, absent an appropriate reason for such refusal; and (3) placing most or all drugs that treat a specific condition on the highest cost tiers.”

HHS stated that these practices are potentially discriminatory especially if there is no appropriate non-discriminatory justification for the plan design. In the preamble to the Final Rule 2016, HHS reminded issuers that discriminatory benefit design is prohibited, yet HHS did not prohibit these specific discriminatory practices in the regulatory text. HHS indicated that states, or the Centers for Medicare and Medicaid Services in states not enforcing market-wide standards, are responsible for enforcing EHB standards, including these non-discrimination standards.

Advocacy opportunities:

- Monitor compliance with non-discrimination provisions and make sure issuers are not discriminating against individuals, particularly those with serious and chronic conditions.
- If there are discriminatory practices by an issuer, including those practices listed by HHS in the preamble to the Final Rule 2016, contact NHeLP and consider filing a discrimination complaint with HHS’ Office for Civil Rights.

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24 45 C.F.R. § 156.125.
25 Final Rule 2016, supra note 2, at 10,822-23.
27 Final Rule 2016, supra note 2, at 10,823.
**Prescription Drugs**

In terms of the changes to the EHB standard, the prescription drug section is the one with the most modifications. NHeLP is conducting further analysis of these changes and their implications, and will release a separate fact sheet focusing on the new EHB prescription drug standard and advocacy opportunities available. Below are highlights of the changes made to the EHB prescription drug standard in the Final Rule 2016.

**I. Benefits**

Existing Rule:

Health plans must cover at least the greater of 1) one drug in every United States Pharmacopeia (USP) therapeutic category and class, or 2) the same number of drugs in each USP category and class as the state's EHB base-benchmark plan.

Change/Clarification:

The final rule adopts an approach that combines:

- the use of a pharmacy and therapeutics (P&T) committee, and
- the existing USP standard.

**P&T Committee**

The P&T committee standards are (for the most part) modeled on Medicare Part D P&T committee standards, with some exceptions. HHS stated that the use of P&T committees in conjunction with other standards will help ensure the health plan’s formulary drug lists cover a broad array of prescription drugs. The Final Rule 2016 includes standards on P&T membership (including conflicts of interest), meetings, and establishment and development of formulary drug lists.

**USP Classification System**

HHS intends to use the most up-to-date version of the USP system available at the time that HHS builds its formulary review tools each year, starting with the 2017 plan year.

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28 In the Final Rule 2016 HHS finalized P&T conflict of interest requirements, which are not the same as the Medicare Part D standards. HHS indicated it modified these standards to better address the private health plan population and needs of plans required to cover EHBs. See Id. at 10,815-16.

29 Id. at 10,813.

30 See EHB Prescription Drug Crosswalk Methodology that HHS uses to count the number of drugs available in each USP category and class available at: https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/ehb-rx-crosswalk.pdf.
II. Exceptions Process

Existing Rule:

Health plans providing EHBs must have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan.\(^{31}\) Such procedures include an *expedited exception* request process for exigent circumstances where an enrollee is suffering from a health condition that may seriously jeopardize his/her life, health, or ability to regain maximum function or when an enrollee is undergoing a current course of treatment using a non-formulary drug.\(^{32}\) Enrollees requesting an *expedited exception* must be notified of the coverage determination no later than 24 hours following receipt of the request. Health plans granting an exception based on exigent circumstances must provide coverage for the duration of the exigency.\(^{33}\)

Change/Clarification:

HHS revised the exceptions process for prescription drugs in order to establish a more uniform process across plans and issuers. HHS clarified that this exceptions process is different from the internal claims and appeals process for enrollees receiving an adverse benefit determination for a drug that is included in the plan’s formulary drug list.\(^{34}\) The *expedited exception* process (described above) continues to apply. In addition HHS adopted a *standard exception* process for situations other than “exigent circumstances.” For the *standard exception* process, health plans must make the coverage determination and notify enrollees no later than 72 hours following receipt of the request, and if approved, the non-formulary drugs must be covered for the duration of the prescription, including refills.

In addition, HHS adopted standards for a secondary external review process (by an independent review organization) for circumstances where the first exception request is denied by the plan.\(^{35}\) Again, this is separate from the external review process which exists for drugs on a plan’s formulary drug list. The external review process applies whether the enrollee originally requested an expedited or standard exception request for a prescription drug not included in the plan’s formulary. The same timing that applies to the initial process applies to the external review; therefore a determination must be made within 24 hours following receipt of the *expedited exception* request and within 72 hours following receipt of the *standard exception* request.\(^{36}\) If the request is approved at the external review level, the health plan must provide coverage of the non-formulary

\(^{31}\) 45 C.F.R. § 156.122(c).
\(^{32}\) Id. § 156.122(c)(1)(i).
\(^{33}\) Id. § 156.122(c)(1)(iii).
\(^{34}\) Final Rule 2016, supra note 2, at 10,818; see also 45 C.F.R. § 147.136 (describing the internal claims and appeals and external review process which applies to drugs on a plan’s formulary drug list).
\(^{35}\) Final Rule 2016, supra note 2, at 10,818.
\(^{36}\) Id.
drug for the duration of the prescription (including refills) for a standard exception, and for the duration of the exigency for an expedited exception.\textsuperscript{37}

HHS clarified that health plans must treat drugs covered through the exceptions process as EHBs, and count any cost-sharing towards a plan’s annual limitation on cost-sharing and when calculating the plan’s actuarial value.\textsuperscript{38}

\textbf{NOTE:} All of the new exception process requirements are effective for plan years beginning on or after January 1, 2016.

\section*{III. Formularies Online}

\textbf{Existing rule:}

None (this is a new proposal).

\textbf{Change/Clarification:}

Health plans must publish an up-to-date, accurate and complete list of all covered drugs on its formulary drug list, which includes the tiering structure adopted and any restrictions on how to obtain the drug.\textsuperscript{39} The information must be easily accessible to plan enrollees, prospective enrollees, the state, Marketplace, the Office of Personnel Management and the general public.\textsuperscript{40}

This requirement does not address the issue of health plans changing formularies during the plan year and/or advertising one formulary during open enrollment but offering a different formulary once the plan year begins. HHS is monitoring this issue and will consider whether further standards are needed.\textsuperscript{41} If you are seeing issues with prescription drug access due to changes in formularies please let NHeLP know.

\section*{IV. Retail Pharmacies}

\textbf{Existing:} None

\textbf{Change/Clarification:}

Beginning with the 2017 plan year, plans must have procedures that allow enrollees to access prescription drug benefits at in-network retail pharmacies, subject to certain

\textsuperscript{37} Final Rule 2016, \textit{supra} note 2, at 10,818-19.
\textsuperscript{38} \textit{Id.} at 10,817-18.
\textsuperscript{39} \textit{Id.} at 10,819.
\textsuperscript{40} \textit{Id.}
\textsuperscript{41} \textit{Id.} at 10,822.
exceptions. Health plans can charge a different cost-sharing amount when an enrollee obtains a drug through an in-network retail pharmacy rather than through a mail-order pharmacy. Yet, if a plan charges enrollees a higher cost-sharing amount for obtaining a covered drug at a retail pharmacy, the higher cost-sharing will count towards the plan’s annual limitation on cost-sharing and must be accounted for in the plan’s actuarial value. These changes do not supersede state laws that may apply other cost-sharing standards to mail-order pharmacies.

For certain drugs, health plans may restrict access to mail order, particularly when: “1) the drug is subject to restricted distribution by the U.S. Food and Drug Administration; or 2) the drug requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy.”

Prescription Drug Advocacy Opportunities:

- Monitor compliance with the new EHB prescription drug standards.
- Let NHeLP know if you are seeing prescription drug access issues.
- Look for NHeLP’s fact sheet focusing on the changes to the EHB prescription drug standard and advocacy opportunities available, which will be released soon.

Conclusion

Significant changes to the EHB standard were made in the Final Rule 2016. This is a key time for advocates to influence and shape the next phase of EHBs in their states. NHeLP will release additional fact sheets on EHBs, so please visit our website regularly for more information.

42 Final Rule 2016, supra note 2, at 10,820.
43 Id. at 10,821.
44 Id.
45 Id. at 10,872.