Essential Health Benefits Prescription Drug Standard

Issue No. 4 – United States Pharmacopeia Classification System

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Introduced by the Affordable Care Act (ACA), Essential Health Benefits (EHB) are a set of ten health care service categories that plans must cover.[1] The EHB requirement applies to non-grandfathered health plans offered in the individual and small group markets (both inside and outside the Marketplace).[2] One of the ten categories of benefits is prescription drugs.

On February 20, 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 finalized changes to the EHB standard.[3] The Final Rule 2016 significantly modified the EHB prescription drug requirements.

This fact sheet, focusing on the use of the **United States Pharmacopeia Classification System** to establish EHB prescription drug coverage, is the fourth in a series of NHeLP fact sheets describing the EHB prescription drug standard. Additional fact sheets in this series examine formulary transparency, the exceptions process, mail-order pharmacies, and Pharmacy and Therapeutics (P&T) Committees.

Background – United States Pharmacopeia Classification System

The United States Pharmacopeial Convention (USP) is a non-profit organization that sets standards for "the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide."[4] The USP's annual publication, the *United States Pharmacopeia-National Formulary* (*USP-NF*) is the official compendia, or compilation, of drugs marketed in the United States.[5]

In 2003, Congress tasked the Secretary of HHS to request the USP to develop a list of model prescription drug categories and classes for Medicare Part D prescription drug plan formularies.[6] This led to the creation of the USP Medicare Model Guidelines. The

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USP initially updated the Model Guidelines annually but in 2008 began to revise them every three years.

The USP Medicare Model Guidelines classify drugs into categories and classes. A **category** is a broad classification and is designed to include potential therapeutic agents for diseases and conditions of Medicare Part D beneficiaries.[7] A **class** is a more granular or detailed classification within a category, structured around types of Food and Drug Administration (FDA) approved medications and is supposed to reflect current U.S. health care practices and standards of care.[8]

In the Essential Health Benefits Final Rule from February 2013 (Final Rule 2013), HHS chose the USP Medicare Model Guidelines classification system (version 5.0) as the comparison tool to determine EHB prescription drug coverage.[9] Per the Final Rule 2013, health plans must cover at least ***the greater of*** 1) one drug in every 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.[10]

HHS noted that directing health plans to submit their drug lists using the *same* classification system would "facilitate review, analysis, and comparison" of the number of drugs in the health plan's list to the number of drugs in the EHB base-benchmark plan's list.[11] To help with this process, HHS developed a crosswalk tool to count the number of drugs available in each USP category and class.[12]

Figure 1: Example of a category and class (USP Medicare Model Guidelines version 5.0)

USP Category	**USP Class (types of drugs)**	**Examples of Part D Eligible Drugs (provided in USP Medicare Model Guidelines)**
Analgesics (pain relievers)	1) Nonsteroidal Anti-inflammatory drugs (NSAIDs)	Drug list with 19 examples of NSAIDs, including Ibuprofen and Naproxen
	2) Opioid Analgesics, Long-Acting	Drug list with 8 examples, including Morphine
	3) Opioid Analgesics, Short-Acting	Drug list with 11 examples, including Codeine

Using the USP category *Analgesics* (from Figure 1) as an example, under the Essential Health Benefits standard, every plan required to provide EHBs must cover at a minimum one drug in each of the three classes under that category. However, if the

state's EHB base-benchmark plan covers more than one drug in each class, then health plans must cover the greater number of drugs. See Figure 2 below for a state example.

Figure 2: California's EHB base-benchmark coverage of Analgesics (for the 2014-2016 plan years)

USP Category	USP Class (types of drugs)	Submission Count (based on # of drugs covered by CA's EHB-benchmark plan)
Analgesics (pain relievers)	1) Nonsteroidal Anti-inflammatory drugs (NSAIDs)	**10**
	2) Opioid Analgesics, Long-Acting	**3**
	3) Opioid Analgesics, Short-Acting	**8**

Issues with using the USP Medicare Model Guidelines for EHBs

There are several issues with using the USP Medicare Model Guidelines to set the EHB prescription drug standard, including:

- ***Updated Infrequently:*** The USP Medicare Model Guidelines are revised every three years, which creates a gap in formulary coverage of newly approved FDA drugs.
    - USP released a new version of the Medicare Model Guidelines (version 6.0) in February 2014. Many of the prescription drugs added to the Guidelines' drug lists were drugs approved by the FDA since the release of version 5.0 in 2011.[13]
    - For EHB purposes, even though the USP released a new version of the Medicare Model Guidelines, each state's EHB prescription drug benchmark for the 2014 and 2015 plan years was set using the old version of the USP Medicare Model Guidelines. In the Final Rule 2016, HHS announced that the same EHB benchmark will continue to apply for the 2016 plan year, which means the new version of the USP Medicare Model Guidelines will not be incorporated into the EHB prescription drug standard until the 2017 plan year.

- ***Created for the Medicare population*:** The USP Medicare Model Guidelines were created for use by prescription drug plans for the Medicare Part D

population and not designed with the health needs of the EHB population in mind. The EHB population includes those receiving coverage through the Marketplace, such as women of reproductive age and children whose health needs are significantly different than those of Medicare Part D beneficiaries.

- ***Lacks Medicare Part D consumer protections*:** The use of the USP categories and classes in the EHB context does not incorporate important Medicare Part D consumer protections.
    - The EHB prescription drug standard does not include "protected classes" of drugs. In Medicare Part D there are six "protected classes" of drugs, and every Part D plan must cover all or substantially all of the drugs in these classes.[14] These classes include anti-cancer drugs, anti-psychotics, anti-convulsants, anti-depressants, immune suppressants, and HIV/AIDS drugs.[15]
    - For EHB purposes, health plans are only required to provide at least one drug in every USP category and class or the number of drugs covered by the state's EHB base-benchmark plan (whichever is greater).[16] This differs from the Medicare standard where Medicare Part D plans must cover *two* chemically distinct drugs in each USP category and class in their formularies.[17] The EHB minimum requirement means that in some categories and classes only one drug will be covered, which limits the prescription drug options available to enrollees and their providers.

Updating the EHB Prescription Drug Minimum Standard

In response to concerns raised by advocates and stakeholders regarding the continued use of the USP classification system to set the EHB prescription drug standard, HHS suggested several alternative options in the Notice of Benefit and Payment Parameters for 2016 proposed rule (Proposed Rule 2016). HHS proposed 1) the adoption of P&T Committees in place of or in combination with a classification system to ensure drug formularies cover a sufficient number and type of prescription drugs; 2) replacing the USP standard with one based on the American Hospital Formulary Service (AHFS) classification system or any other classification system either in conjunction with P&T Committees or on its own; or 3) continuing to use the USP classification system as a drug count standard.[18]

In comments to the Proposed Rule 2016, NHeLP and other advocates expressed concerns regarding the continued use of the USP standard (for the reasons discussed above) and also raised the following concerns and recommendations to HHS' proposed changes:

- HHS should require health plans to use a combination of P&T Committees and a recognized, comprehensive standard classification system when designing and updating their prescription drug formularies.[19]
    - Using a classification system alone to set a drug count without the involvement of P&T Committees means health plans are only required to meet a target number of drugs within a specific category and class without regard to which drugs are covered within each category and class.
    - The best way to ensure that enrollees have access to comprehensive prescription drug coverage is through a common organization and classification tool, as well as a committee process to review and update formularies based upon the most current standard of care and clinical practice guidelines.[20]
    - Advocates urged HHS to implement these changes in 2016 and not wait until the 2017 plan year.
- HHS should develop its own prescription drug classification standards and publications rather than relying on those developed and published by private companies.
    - AHFS is difficult to access and charges considerable fees for its drug classification system. Advocates urged HHS to use a classification system that consumers and other stakeholders can access free of charge.[21]
    - Many advocates and stakeholders lacked sufficient information to specifically endorse the adoption of the AHFS classification system as an improvement over the USP Medicare Model Guidelines for EHB purposes.
    - Advocates urged HHS to move towards a categorization system designed by HHS based on the needs of the EHB population, and specifically designed for use as a standard for drug counts in the EHBs.[22]

Change/Clarification

The Final Rule 2016 adopts an approach that combines:

- the use of a P&T committee and
- the existing USP standard.

This change will go into effect beginning with plan years on or after January 1, 2017. HHS stated that the use of P&T Committees in conjunction with other standards will help ensure health plan's formulary drug lists cover a broad array of prescription drugs.[23] HHS noted that a combination of a qualitative and quantitative approach will best ensure a robust formulary design because the two standards complement each other.[24] (For more information about P&T Committees see Issue No. 5 of NHeLP's EHB Prescription Drug Standard Series.)

HHS decided to continue using the USP Medicare Model Guidelines classification system for EHB purposes because "stakeholders are now familiar with it after using it in 2014 and 2015" and to reduce the "administrative burden and cost to the states and issuers in implementing a combined P&T committee process with a drug count standard."[25] Starting with the 2017 plan year, HHS intends to use the most up-to-date

version of the USP Medicare Model Guidelines classification system available at the time that HHS builds its formulary review tools each year.[26]

Advocacy Opportunities

- Ensure that health plans are covering the ***greater*** of one drug in every USP category and class ***or*** the same number of drugs in each category and class as the EHB base-benchmark plan.
- Encourage coverage of new FDA-approved drugs not yet included in the EHB base-benchmark.
    - HHS indicated that plans are permitted to extend coverage beyond the number of drugs offered by the benchmark without exceeding EHB, so advocacy for the inclusion of new drugs will be important.[27]
- Document gaps in coverage and monitor whether using the new version of the USP Medicare Model Guidelines along with P&T Committees addresses the coverage gaps once these changes go into effect in 2017.
- Remind your state and health plans that coverage for contraceptives is required under the preventive services mandate and separate from the USP categories and classes.
    - The EHB prescription drug benefit standard and section 2713 preventive health services are separate legal requirements, and plans must meet *both* requirements to fulfill their obligations under the ACA. Section 2713 requirements include covering all FDA-approved contraceptive methods without cost-sharing.
- Let NHeLP know if you see issues with the implementation of the new EHB prescription drug requirements or any other prescription drug access issues.

Conclusion

Although the Final Rule 2016 did not fully address all of the concerns raised by advocates, the changes to the EHB prescription drug standard resulted in significant steps forward. Moreover, the new requirement for health plans to use a combination of P&T Committees and the USP Medicare Model Guidelines classification system to ensure adequate coverage of prescription drugs demonstrates the importance of advocacy efforts and lays the groundwork for future improvements in EHB prescription drug standards.

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[1] 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.

[2] *See* 42 U.S.C. § 300gg–6(a); 45 C.F.R. § 147.150. *See also* 29 C.F.R.§ 2590.715-1251(c)(1). This fact sheet focuses on EHBs as they apply to the private market.
[3] HHS Notice of Benefit and Payment Parameters for 2016, Final Rule, 80 Fed. Reg. 10,750 (Feb. 27, 2015) (to be codified at 45 C.F.R. pts. 144, 147, 153, 154, 155, 156, and 158), *available at* http://www.gpo.gov/fdsys/pkg/FR-2015-02-27/pdf/2015-03751.pdf [hereinafter Final Rule 2016].
[4] *See* United States Pharmacopeial Convention, *About U.S.P.* (2015), http://www.usp.org/about-usp.
[5] *See* U.S. Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 321(g)(1), (j).
[6] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, 42 U.S.C. § 1395w-104(b)(3)(C)(ii).
[7] United States Pharmacopeial Convention, *USP Medicare Model Guidelines v6.0: Development of the USP Medicare Model Guidelines v6.0* (2015), http://www.usp.org/usp-healthcare-professionals/usp-medicare-model-guidelines/medicare-model-guidelines-v60.
[8] *Id.*
[9] *See* Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, 78 Fed. Reg. 12,834, 12,845-46 (Feb. 25, 2013) (to be codified at 45 C.F.R. pt. 156). For the USP Medicare Model Guidelines version 5.0 *see* http://www.usp.org/usp-healthcare-professionals/usp-medicare-model-guidelines/medicare-model-guidelines-v50-v40#Guidelines5.
[10] *See id.* at 12,867.
[11] *Id*.
[12] *See id.* at 12,846. *See* HHS' EHB Prescription Drug Crosswalk Methodology, *available at* https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/ehb-rx-crosswalk.pdf, and 2016 updated crosswalk *available at* https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/2016EHBRxCrosswalkMethodology-031815.pdf.
[13] *See* United States Pharmacopeial Convention, *USP Medicare Model Guidelines v6.0* (2014), *available at* http://www.usp.org/sites/default/files/usp_pdf/EN/uspmmg_v6_0_markedchangesrev140415.pdf.
[14] *See* Medicare Prescription Drug Benefit Manual, ch. 6 § 30.2.5.
[15] *See id.*
[16] 78 Fed. Reg. at 12,867.
[17] *See* Medicare Prescription Drug Benefit Manual, *supra* note 14, at § 30.2.1.
[18] *See* HHS Notice of Benefit and Payment Parameters for 2016 Notice of Proposed Rulemaking, 79 Fed. Reg. 70,674, 70,718-20 (proposed Nov. 26, 2014) (to be codified at 45 C.F.R. pt. 156), *available at* http://www.gpo.gov/fdsys/pkg/FR-2014-11-26/pdf/2014-27858.pdf.
[19] *See* NHeLP, RE: CMS-9944-P at 20 (Dec. 22, 2014), *available at* http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0276.
[20] *Id*.
[21] *See* NHeLP, *supra* note 19, at 20; *see also* Raising Women's Voices for the Health Care We Need, RE: CMS-9944-P at 9 (Dec. 22, 2014), *available at* http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0205; *see also* National Women's Law Center, RE: CMS-9944-P at 7 (Dec. 22, 2014), *available at* http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0163.
[22] *See* Raising Women's Voices for the Health Care We Need, *supra* note 21, at 10; *see also* National Women's Law Center, *supra* note 21 at 8.
[23] Final Rule 2016, *supra* note 3, at 10,813.
[24] *Id.* at 10,815.
[25] *Id.*
[26] *Id*.
[27] *See* 78 Fed. Reg. at 12,845.