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September 27, 2023

Re: USP DC 2024 Draft is available for Public Comment

The National Health Law Program (NHeLP) is a public interest law firm working to advance access to quality health care and protect the rights of low-income and underserved people. For over fifty years, we have educated, advocated and litigated to advance health equity for all without bias or barriers. Consistent with our mission, we believe that every individual should have access to high quality, affordable, and comprehensive health care and be able to achieve their own highest attainable standard of health.

The following comments on the USP/DC are excerpted from broader comment NHeLP provided to the U.S. Department of Health and Human Services (HHS) in response to a Request for Information (RFI) on Essential Health Benefits (EHB).¹

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We welcome HHS' reconsideration of using the United States Pharmacopeia (USP) Medicare Model Guidelines (MMG) to establish coverage standards for EHB prescription drugs. We have long been concerned that the USP MMG do not adequately reflect the prescription drug needs of the diverse populations who rely on EHB plans.

The USP MMG were designed for the Medicare Part D program and its beneficiaries, and therefore do not adequately classify and categorize drugs for the broader populations who rely on health plans subject to EHB standards. For example, the MMG fall short in covering medications essential for reproductive health, including contraception, and do not include distinct categories for FDA-approved pediatric drugs or formulations. The MMG also do not include medications covered under Medicare Part B.

In the EHB Final Rule from February 2013 (Final Rule 2013), HHS Services (HHS) chose the USP Medicare Model Guidelines (MMG) classification system (version 5.0) as the comparison tool to determine EHB prescription drug coverage.² Per the Final Rule 2013, EHB 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.³

USP Drug Classification

In 2017 USP developed a new list, the USP Drug Classification (USP DC), which purports to assist with formulary support outside of Medicare Part D; however, it uses MMG as the baseline, and then adds additional common outpatient drugs on top of that list. As a result, many of the relics of Part D remain, specifically the exclusion of reproductive and sexual health (RSH) medications and supplies. A significant number of RSH medications are not sufficiently incorporated into the USP DC, particularly medication abortion and contraceptives

USP/DC Development Compared to the MMG

Although annually updated, the USP/DC does not have a separate process in evaluating new market drugs throughout the year. In other words, drugs considered for the upcoming USP DC must be available, and on the market, prior to the release of the Proposed USP DC Draft in the fall. Medications that are not still in the FDA-approval pipeline are not included, resulting in some lag time before new drugs can be included.⁴

¹ U.S. Dept. of Health and Human Svcs., Ctrs. for Medicare & Medicaid Svcs., *Request for Information; Essential Health Benefits*, 87 Fed. Reg. 74097 – 74102 (Dec. 2, 2022), <https://www.govinfo.gov/content/pkg/FR-2022-12-02/pdf/2022-26282.pdf>. See also Héctor Hernández-Delgado & Wayne Turner, Nat'l Health Law Prog., *NHeLP Comments on Essential Health Benefits (EHB) Request for Information (RFI)* (Feb. 2, 2023), <https://healthlaw.org/resource/nhelp-comments-on-essential-health-benefits-ehb-request-for-information-rfi/>.

² See U.S. Dept. of Health and Human Svcs., Ctrs. for Medicare & Medicaid Svcs., *Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule*, 78 Fed. Reg. 12,834, 12,845-46 (Feb. 25, 2013) (codified at 45 C.F.R. pt. 156). For the USP Medicare Model Guidelines version 5.0 see United States Pharmacopeial Convention, *USP Medicare Model Guidelines v6.0 & v5.0*, <https://www.usp.org/health-quality-safety/usp-medicare-model-guidelines/medicare-model-guidelines-v50-v40> (last visited Sept. 25, 2023).

³ 45 C.F.R. § 156.122(a).

⁴ *Id.*

The USP/DC includes 50 categories and 172 classes with 1961 example drugs.⁵ In comparison, MMG’s 2020 version has 47 categories and 156 classes with 1986 example drugs. All of the current MMG classifications have been included in the USP DC.⁶ The three drug categories added to the USP/DC that are not included in the MMG are anti-obesity agency, infertility agents, and sexual disorder agents.⁷

Drugs Essential for Reproductive Health

The USP/DC fails to provide categories specific to abortion or even pregnancy care, even though there are categories for substance use disorder (SUD) treatment, infertility care, sexual disorders, contraceptives, and sexually transmitted infections (STI) treatment. USP/DC has a number of categories and classes that involve hormonal agents, including an “other” class; this is the only place where mifepristone, one of two drugs used for medication abortion, is listed as an example.

Misoprostol, the other drug used for medication abortion, is included on the USP/DC, but completed unrelated to its use in abortion care; misoprostol is listed under the category of gastrointestinal agents as an example of the drugs in the protectant class, as well as under the category of prostaglandins. However, mifepristone and misoprostol are only examples of drugs that could be included under those categories; prescription drug plans would be free to design formularies that exclude medication abortion drugs entirely and still be fully compliant with the proposed EHB standard of one drug per class and category.

USP/DC is not the standard for contraceptive coverage in EHBs; EHBs must cover a broad range of contraceptives, as delineated by the Health Resources Services Administration (HRSA) Women’s Guidelines. Nonetheless, it is worth noting that should USP/DC become the standard for contraceptive coverage, it would be woefully inadequate. The FDA recognizes a minimum of 19 contraceptive methods, ten of which are prescription-only drug products, 3 of which are drug products available over-the-counter, four of which are devices (which may or may not require a prescription), and two of which are medical procedures. The USP DC, on the other hand, has only three drug classes: combination oral contraceptives, progestin-only oral contraceptives, and “other” contraceptives, which is a catchall class that incorporates IUDs, rings, patches, emergency contraception, injectable contraception, and ph modulation gel.

⁵ *Id.*

⁶ United States Pharmacopeial Convention, USP Drug Classification, <https://www.usp.org/health-quality-safety/usp-drug-classification-system> (last visited Jan. 31, 2023).

⁷ United States Pharmacopeial Convention, FAQs: USP Drug Classification System (Feb. 1, 2017), <https://www.usp.org/frequently-asked-questions/usp-drug-classification-system> (last visited Jan. 31, 2023).



Nonoxynol-9, which is the active ingredient in the sponge and spermicide, is completely omitted.

If HHS adopts the USP DC as the EHB prescription drug standard, it must underscore for issuers that contraceptive formularies must be based on statutory requirements, FDA's Orange Book, and HRSA's Women's Guidelines.⁸

Pediatric Prescription Drugs

The USP DC provides no specific classes or categories of drugs for use in children. For example, Nusinersen and Onasemnogene were recently approved to be used on children as young as two months old for Spinal Muscular Atrophy (SMA) and infantile-onset.⁹ These are the only two FDA-approved drugs to manage SMA in children. However, in the USP/DC, both drugs are included in the broad category "Genetic, Enzyme, or Protein Disorder: Replacement, Modifies, Treatment," along with 60 other drugs. This category includes drugs that do not treat SMA or relate to any neurological or spinal disease. Thus, these two drugs will likely not be covered by drug company formularies, preventing children from receiving the necessary drugs to treat SMA.

Moreover, pediatric patients, including newborns and young children, often require alternatives to taking needed medications in pill form. These can include liquid forms, as well as buccal, nasal, transdermal, and rectal routes.¹⁰ The USP/DC does not provide for pediatric formulations of prescription drugs approved for both adults and children.

Drugs covered under Medicare Part B

In 2012, the American Hemophilia Foundation and a coalition of organizations representing people who use plasma-derived and recombinant products raised concerns that the MMG,

⁸ DOL, HHS, Dep't of Treasury, *FAQs About Affordable Care Act Implementation (Part 54)* (July 28, 2022), <https://www.cms.gov/files/document/faqs-part-54.pdf>. See also Liz McCaman Taylor, Nat'l Health Law Prog., *Fact Sheet: State Contraceptive Equity Laws* (Dec. 2021), <https://healthlaw.org/wp-content/uploads/2021/12/CE-Fact-Sheet-12082021-final.pdf>.

⁹ See NIH, Spinal Muscular Atrophy: Treatment, <https://www.ninds.nih.gov/health-information/disorders/spinal-muscular-atrophy#:~:text=The%20U.S.%20Food%20and%20Drug,the%20maintenance%20of%20motor%20neurons> (last visited Jan. 31, 2023).

¹⁰ U.S. Pharmacist, *How Liquids Benefit Adherence for Pediatric Patients* (Nov. 22, 2022), <https://www.uspharmacist.com/article/how-liquids-benefit-adherence-for-pediatric-patients>.

designed for the Medicare Part D program, does not include clotting factors and other blood products which are covered under Medicare Part B.¹¹

The USP/DC includes all clotting factors (and some non-factor products) into one single class (blood products and modifiers) and one single category (blood component deficiency/replacement). The USP/DC system lumps together a wide array of products used to treat (non-interchangeably) at least seven wholly separate conditions: hemophilia A, hemophilia B, von Willebrand disease, etc.

For example, drugs to treat hemophilia A are grouped under “Blood Products and Modifiers” with only five differentiating classes.¹² Under each class, multiple drugs treat Hemophilia A, but there are also drugs that only treat other blood diseases such as hemophilia B and Von Willebrand disease. Thus, drug formularies may choose five different “Blood Products and Modifiers,” however, they may choose drugs that do not treat hemophilia A at all. Further, treatment of hemophilia A may require a combination of drugs with varying ease of use.

Thus, while an incremental improvement over the MMG, the USP/DC still falls significantly short of meeting the needs of a diverse patient population that relies on plasma-derived and recombinant products. Although the USP/DC attempts to classify combinations of drugs, it does not go far enough to account for the complexities of drug prescription and usage.

Conclusion

To date, HHS has not taken regulatory action to address issues raised in the EHB RFI, including whether to update the drug classification system used to establish prescription drug coverage requirements in EHB plans. Still, we urge USP to make improvements in the USP/DC, given the likelihood that it will eventually replace the MMG in EHB prescription drug coverage.

¹¹ Letter from American Plasma Users Coalition (A-PLUS) to Marilyn Tavenner, Acting Administrator CMS, HHS, *Re: Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation (CMS-9980-P)* (Dec. 21, 2012), <https://www.hemophilia.org/sites/default/files/document/files/A-PLUS%2012.21.12.pdf>. See also Nat’l Hemophilia Found., *Re: HHS Notice of Benefit and Payment Parameters for 2022 (CMS-9914-P)* (Dec. 30, 2020), <https://www.hemophilia.org/sites/default/files/document/files/A-PLUS%2012.21.12.pdf>.

¹² Nat’l Hemophilia Found., *supra* note 11.

Thank you for the opportunity to comment on this important issue. Please feel free to contact me at (202) 289-7661 or turner@healthlaw.org if you have questions.

Yours truly,

A handwritten signature in black ink, appearing to read 'W. Turner', followed by a long horizontal flourish.

Wayne Turner
Senior Attorney

