VIA ELECTRONIC SUBMISSION

January 8, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Re: Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program (CMS-9895-P)

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Dear Administrator Brooks-LaSure,

On behalf of the United States Pharmacopeia (USP), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) in response to the proposed rule "Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program." USP is governed by more than 400 organizations, including scientific, healthcare practitioner, consumer, and industry communities, as well as dozens of government agencies, who together comprise the USP Convention. A core pillar of USP's mission is to help strengthen the global supply chain so that the medicines are available when needed and meet quality standards as expected and required. As part of this work, USP provides prescription drug classification resources for use in drug formulary development and review.

The Federal Food, Drug, and Cosmetic Act of 1938 created the statutory requirement that medicines sold in the United States generally must adhere to USP's public quality standards to help ensure the quality of medicines and the safety of patients. USP standards are developed through an open, transparent, science based, expert-led process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep up with evolving science and technology. The process utilizes the work of scientific and healthcare experts who volunteer their time on USP's standard-setting committees.[1]

USP appreciates the opportunity to provide information to CMS concerning the prescription drug classification standard used for defining the essential health benefit (EHB) prescription drug category and to provide additional information pertinent to CMS's request for comments to help inform a potential future policy proposal to transition from the USP Medicare Model Guidelines (MMG) to the USP Drug Classification (USP DC) for prescription drugs covered under § 156.122(a)(1).

[1] USP standards are developed by Expert Bodies comprised of more than 750 scientific experts. These experts collaborate to develop USP standards through an open, transparent process, offering the ability to adjust standards to confront public health emergencies, adapt to new industry practices, and keep up with evolving science and technology.

Below, we provide comments that address specific issue areas identified by CMS in the proposed rule, particularly as they pertain to a potential transition from MMG to USP DC. USP supports the MMG as a long-standing tool that helps to ensure Medicare beneficiaries have access to medicines and believes it is beneficial to continue to build on this foundation in addressing stakeholder needs in prescription drug classification, including in defining the EHB prescription drug category. However, USP acknowledges the MMG is intended to address prescription drug covered under Medicare Part D, and as such they may not be fully inclusive of outpatient drugs used by patients of all ages. USP sees value and utility in both the MMG and USP DC and will continue to work with CMS to ensure an appropriate drug classification system for prescription drugs required to be covered under EHB.

USP Medicare Model Guidelines (MMG)

USP is recognized in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 which stipulates that the Secretary shall request the United States Pharmacopeia to develop, in consultation with pharmaceutical benefit managers (PBMs) and other interested parties, a list of categories and classes that may be used by prescription drug plans to revise such classification from time to time to reflect changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs. In revising MMG, USP follows a science-based, expert-led, transparent process that relies on stakeholder input through public comment periods. The most recent version of the MMG, USP MMG V9.0 was published in September 2023.

USP Drug Classification (USP DC)

Based on stakeholder feedback in 2016, the USP Drug Classification (USP DC) was created in 2017 by an Expert Panel under USP's Healthcare Quality & Safety Expert Committee (HQS EC). USP DC is an independent drug classification system for non-acute and outpatient care settings and includes prescription medications used in community pharmacies, specialty pharmacies, skilled nursing facilities, and infusion centers. USP DC includes categories and classes of common outpatient drugs that are relevant for the broader population of patients enrolled in plans subject to EHB requirements including categories such as anti-obesity agents and contraceptives, as well as additional classes in categories such as cardiovascular and ophthalmic categories.

USP DC is a fit-for-use tool updated annually with formatting already familiar to key stakeholders – including health plans, PBMs, and States – with a category, class, and example drug to provide formulary support outside of Medicare Part D. It is not only composed of categories and classes, but also includes pharmacotherapeutic grouping, an additional informational tier level.

The USP DC is a classification system separate from the MMG and is not funded by CMS. The most recent update to USP DC, USP DC 2024, was published in December 2023, with 50 categories and 174 classes of drugs, 1991 example drugs and 129 pharmacotherapeutic groups. Also in December 2023, USP launched the USP Drug Classification PLUS (USP DC PLUS), a subscription service which has added interactive features and data access such as access to RxNorm Concept

Unique Identifiers (RxCUIs) and National Drug Codes for another layer of clinical categorization. The USP DC remains readily accessible on the USP.org website.

Risks and Benefits of Potential Transition from MMG to USP DC

In the proposed rule, CMS generally summarizes comments received from the Request for Information; Essential Health Benefits (EHB RFI) published on December 2, 2022, which sought input on whether CMS should consider using an alternative prescription drug classification standard for defining the EHB prescription drug category, such as USP DC or others. USP submitted comments to CMS on the EHB RFI defining the function and scope of MMG and USP DC.

CMS notes in the proposed rule that most commenters to the EHB RFI supported the transition from MMG as currently used for EHB purposes and for Medicare Part D, to USP DC as the standard for defining the EHB prescription drug category. Some commenters to the EHB RFI recommended retaining the MMG, expressing concern about the potential for administrative burden, among other concerns, and CMS seeks feedback on possible disruptive impacts to issuer operations and systems related to transitioning from MMG to USP DC. Throughout the USP 2023 stakeholder engagement processes, we have received feedback regarding the structure, frequency, and transparency associated with the MMG and USP DC.

Tiered Classification Format of MMG and USP DC

While MMG and USP DC are different classification systems, they maintain similar formulary tier structure, review, and decision-making processes. They are both developed with USP expert volunteers comprised of academicians, practitioners, formulary experts, patient advocates, and clinicians that utilize the similar guiding principle for establishing categories and classes to strike a balance of assuring patient access to the drugs that patients need with the flexibility that health plans require in offering an affordable and effective benefit. When creating the categories and classes, the experts offer careful consideration to minimize the creation of categories or classes with less than three drug examples and through the lens of equity and diversity, when appropriate, consider issues such as genomic status, medical conditions, race, ethnicity, disability, sexual orientation, or gender identity in drug classification.

Frequency of MMG and USP DC Updates

The MMG is updated every three years, whereas USP DC is updated annually. CMS notes in the proposed rule that some commenters encouraged CMS to consider implementing an annual review and update process that includes input from consumers and other interested parties.

Opportunity for public comment is a key component of the process for MMG and USP DC. Throughout the public comment period, USP has also received feedback from stakeholders for a more frequent classification of newly approved FDA drugs. The requests have been from monthly to bi-annually. USP remains willing to work with CMS to increase the frequency of MMG and is working to increase the frequency of the USP DC in the near future to meet stakeholder needs.

Stakeholder Input for MMG and USP DC

The MMG and USP DC rely on stakeholder input during public comment periods as part of the updating process. Public comment periods are announced and interested parties have 30 days to provide comments prior to final publication. For USP DC, stakeholders have three ways of communicating – via written comments, public comment form, or through one-on-one meetings with USP staff. This feedback is evaluated and considered for incorporation by the USP DC Subcommittee, which is comprised of academics, practitioners, formulary experts, patient advocates, and clinicians, prior to final approval by the HQS EC.

Stakeholder engagement and public input in updating the MMG and USP DC is essential to ensuring that these tools can evolve and meet patient and public health needs. More frequent updates in subsequent years will further bolster public input and help in remaining current with the prescription drug landscape.

Potential Consequences of Transition from MMG to USP DC

In the proposed rule, CMS summarizes that a few commenters noted the potential risk of negative consequences as payers could shift costs associated with covering high-cost drugs with low clinical value to patients, potentially increasing premiums and total cost of care. While there is limited line of sight into the potential cost burden on patients or payers, when creating categories and classes in USP DC, care is taken to minimize the creation of categories or classes with less than three drug examples. USP recommends further exploration of this issue through ongoing engagement with stakeholders, including patients and payers, to understand how proposed changes could potentially impact patients and health plans.

USP has collaborated with CMS on the Medicare Model Guidelines for over 19 years and has institutional interest to continue to strike a balance of assuring beneficiary access to the safe and effective drugs that they need with the flexibility that Part D sponsors need to offer an affordable and effective benefit. USP experts remain committed to maintaining these timely classification systems to assure beneficiary access to both Part D medications through MMG and to medications outside of Part D through USP DC.

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USP welcomes the opportunity to discuss and/or convene around the best utilization of and future roles for the USP Medicare Model Guidelines and the USP Drug Classification. For more information, please contact Nakia Eldridge, Director, Healthcare Patient Safety Information, at (301) 692-3486 or nakia.eldridge@usp.org.

Sincerely yours,

Anthony Lakavage, J.D.
Senior Vice President, Global External Affairs
Secretary, USP Convention and Board of Trustees