COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

July 2, 2024

Meena Seshamani, M.D., Ph.D.
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Medicare & Medicaid Services
7500 Security Blvd.
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RE: Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191-1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027

Submitted electronically to IRARebateandNegotiation@cms.hhs.gov

Dear Dr. Seshamani:

Thank you for the opportunity to provide comments on the May 3, 2024, memorandum entitled "Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027."

The Council for Affordable Health Coverage (CAHC) has long supported reduced drug costs, greater access to drug therapies, and fostering innovation to help treat and cure disease. CAHC (www.cahc.net) is a broad-based alliance with a primary focus: ensuring all Americans have access to affordable coverage. Our members include employers, medical providers, patient groups, insurers, agents and brokers, technology companies, pharmaceutical manufacturers, and pharmacy benefit managers.

We are submitting comments on three aspects of the Draft Guidance:

1. 30.1 Identification of Qualifying Since Source Drugs for Initial Price Applicability Year 2027
2. 40.4 Providing Access to the MFP in 2026 and 2027
3. 60.4 Negotiation Process

30.1 Identification of Qualifying Single Source Drugs for Initial Price Applicability Year 2027

CAHC is concerned that CMS has adopted an overly broad definition for drugs subject to the Inflation Reduction Act's (IRA) Maximum Fair Price (MFP), grouping together multiple drug products that should be considered separately. CMS' policy will negatively impact patients with chronic and rare diseases by disincentivizing post-approval research and likely violates Section 1192(d)(3)(B) of the law. That Section envisions CMS using data aggregated across dosage forms and strengths of the drug, including new formulations of the drug. CMS has interpreted the section to add another requirement that aggregates data for all products with the same active moiety or ingredient across products with different NDAs or

BLAs. While CMS treats these products the same for pricing, these are different products entirely used to treat different conditions or populations, and with different approvals by FDA. The IRA approach for the drug selection process did not envision this, and its absence does not mean CMS has authority to add this requirement.

In terms of impact, this decision will negatively impact patients with serious chronic or life-threatening conditions. CMS' policy to combine all indications, dosage forms and strengths together as one drug will result in CMS negotiating one MFP for multiple products that share an active ingredient immediately upon launch even if such treatments have not been on the market for 7 years, as required by the law. This means a new drug could face a price set by CMS on the first day of market approval, even if that drug treats an entirely different disease via meaningful clinical advancements, addresses an unmet need, or treats additional patient populations. As a result, manufacturers will have significantly reduced incentives to continue clinical programs after FDA approval of the initial use.

This flawed policy is anti-patient, anti-innovation, and violates the letter and intent of the law, and should be revised to apply separately to each NDA or BLA.

40.4 Providing Access to the MFP in 2026 and 2027

This guidance states that "any Primary Manufacturer of a selected drug that continues to participate in the Negotiation Program and reaches agreement upon an MFP must provide access to the MFP to MFP-eligible individuals and to pharmacies, mail order services, and other dispensing entities…[thereby ensuring] that Part D MFP-eligible individuals will have access to the MFP at the point-of-sale."[1] CMS defines a 14-day prompt MFP payment window for manufacturers to ensure the dispensing entity receives the correct amount of reimbursement based on the MFP. CMS also details options for how a Medicare Transaction Facilitator (MTF) should facilitate the exchange of data and payment between manufacturers and other pharmaceutical supply chain entities but questions remain as to the entire role of the MTF.

CAHC has significant concerns related to the manufacturer effectuation of the MFP, notably the 14-day prompt MFP payment window and how to operationalize the MFP discounts in a system where there are daily payments on thousands of claims to thousands of pharmacies. The pharmaceutical industry and supply chain are not currently set-up in a way that ensures this data and money exchange could be seamlessly implemented within the defined time frames. CMS is not prepared for this and needs to take a strong role in building and implementing the Medicare Transaction Facilitator (MTF).

In order to avoid failure in effectuating the MFP, CMS should direct- with precision- a facilitator built off workable transaction standards currently adopted in the market with adequate data to adjudicate claims within a reasonable time frame.

CMS recognizes that the market does not currently include a direct relationship between manufacturers and pharmacies/dispensing entities. As such, CMS outlines two payment facilitation options for the MFP: (1) Transmittal of banking information only; or (2) pass-through of MFP refunds. CAHC supports option 2, the "pass-through of MFP refunds", as the only viable solution for a functional marketplace. CAHC also

[1] Medicare Drug Price Negotiation Program: Draft Guidance.

suggests CMS consider providing some degree of a government-funded float by bearing the costs of operationalization of this MTF function so pharmacies are not financially overburdened.

Recommendation: CMS needs to provide stability by leveraging systems that already exist, such as the coverage gap discount. Providing a government float to dispensing entities to allow them the flexibility to ensure MFP payments are being made appropriately and promptly in the 14-day window is essential for the operation of the system.

60.4 Negotiation Process

While we appreciate CMS making revisions in this draft guidance based on the lessons learned from implementing the program thus far, including extending the comment period from 30- to 60 days, there is still much room for improvement, especially in the area of stakeholder engagement and public feedback.

CMS states they will "host patient-focused events to seek verbal input from patients and other interested parties" and "intends to improve upon the design [from the previous guidance]."

The patient-focused events need to be more accessible than those in the past, allow those participating enough time to share their feedback, and demonstrate how CMS will use what they learn from those sessions in practice. Listen-only discussion formats are not the best option as they limit the opportunities for engagement and further clarifying questions. CAHC agrees with CMS' suggestion that these events should promote discussion as opposed to being listen-only. A law of this magnitude and complexity should have robust stakeholder feedback, including diverse views from every party impacted.

Additionally, in our comments from last year, we highlighted how the inclusion of language that bars manufacturers from being transparent about government activities during the negotiation process is an egregious overreach of government censorship. The need to shield the CMS decision-making process from scrutiny will erode public confidence in the price-setting process and should be removed. Now a year later, we know more about the negotiation process, however, there is still little public information of how drugs were selected and why, zero public release of regulatory impact or Office of the Assistant Secretary for Planning and Evaluation (ASPE) analysis of CMS' decisions, or even what was done with the information CMS collected during last Fall's stakeholder listening sessions, including who was asked to speak and why. This darkness shrouding the program hides behind Section 1198's requirement that HHS implement the program through guidance and ignore long-established practices to deal transparently with the public and release pertinent information on what government is doing and why. While Congress required CMS to protect proprietary information, it did not require CMS to operate in secret about its processes and analysis. CMS should release all materials to the public that will help the public understand the operations and thinking of the agency while creating meaningful venues for input that mirror the long-established practices ensconced in the Administrative Procedure Act.

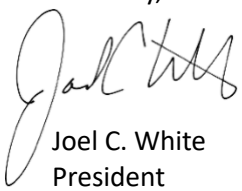
There is nothing in law that precludes CMS from having a more transparent, accountable process. We encourage you to open up the process and commit to the responsible implementation of the law.

Conclusion

While we share your goal of lowering the cost of healthcare, achieving this goal must be approached systemically and not in a way that creates a slew of unintended consequences, namely harming our most vulnerable patients. We encourage you to revisit the policy and procedures outlined in the draft guidance.

If you have questions about these comments, please do not hesitate to contact me.

Sincerely,



Joel C. White
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