COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

April 14, 2023

Meena Seshamani, M.D., Ph.D.
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Center for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

RE: Medicare Drug Price Negotiation Program Guidance

Submitted electronically to IRARebateandNegotiation@cms.hhs.gov

Dear Dr. Seshamani:

Thank you for the opportunity to provide comments on the March 15,2023 memorandum entitled "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments."

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: bringing down the cost of health care for all Americans. Our members include employers, medical providers, patient groups, insurers, agents and brokers, technology companies, pharmaceutical manufacturers, and pharmacy benefit managers who collectively represent tens of millions of lives in the private market.

We are submitting comments on two aspects of the Initial Memorandum:

1. The process CMS is using to implement the program is opaque and lacks critical stakeholder input to ensure the principles of good government are followed. This must be improved.

2. The provisions related to Orphan products must be modified to ensure implementation of the Medicare negotiation program does not harm our most vulnerable patients.

Process

While most businesses are seeking to provide more transparency and accountability for their constituents, the Administration's implementation of the Inflation Reduction Act (IRA) moves in the opposite direction. Under Section 1198 of the Inflation Reduction Act, Congress instructed HHS to implement the negotiation law by "program instruction or other forms of program guidance" for 2026, 2027 and 2028. Congress also limited administrative and judicial review.

This is not the regular process established by Congress to encourage citizen participation in a transparent government for the people.

Enacted in 1946, the Administrative Procedures Act ensures citizens have a right to be heard by government, that government responds to their concerns, and that parties harmed by government have access to recourse. The law includes requirements for informing the public of rules and providing for public participation in the rule making process by publishing notices of proposed and final rulemaking in the Federal Register and the opportunity for the public to comment on notices of proposed rulemaking.

While CMS must produce the program guidance as instructed, CMS was not instructed by Congress on the process for seeking out and responding to stakeholder input. We are disappointed that CMS has solicited feedback in limited venues, on limited sections of the law, from a discrete panel of stakeholders who already support the program. A law of this magnitude and complexity should have robust stakeholder feedback, including diverse views from every party impacted. We are concerned to learn that some stakeholders have been told their comments may not even be read, much less responded to.

Additionally, the inclusion of language that bars manufacturers from being transparent about government activities during the negotiation process is an egregious overreach of government censorship. CMS proposes a sweeping policy that would restrain manufacturer speech by placing limits on what a manufacturer can use or disclose from CMS offers, requires a "certificate of data destruction" of any and all material related to the negotiation process- including the manufacturer's own written notes or emails, and prevents manufacturers from audio or video recording any oral conversations between CMS and the manufacturer. This proposal seriously undermines transparency and the ability to validate information if a conflict arises. The need to shield CMS decision-making process from scrutiny will erode public confidence in the price-setting process and should be removed.

Recommendation: We encourage CMS to open the process up to sunshine by:

- Making your meetings transparent (with recorded minutes and records of attendees) with any stakeholder willing to participate.

- Provide responses to stakeholder questions through the program guidance process. Congress provided $3 billion in funding to implement the program. We suggest spending some of this money on outreach and response to legitimate concerns and questions. CMS is undermining its credibility by failing to respond to stakeholders.

- Work with Congress to change the law to require the program be implemented through the regular rulemaking process. While the guidance route may be expeditious for CMS employees, it undermines citizen trust in the program and the Agency itself. There is little reason to continue using program guidance rather than the normal rulemaking process in the program's second or third year.

- Remove the gag clause on manufacturers to destroy all information related to the negotiation process.

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.

Orphan Products

More than 10,000 rare diseases impact more than 30 million people (about the population of Texas) in the United States. Fewer than 5% of these diseases have any FDA-approved therapies. Half of those afflicted with a rare disease are children and thirty percent of them will die before their fifth birthday due to the lack of available treatments. For most of the 1 in 10 Americans with a rare disease, surgeries or other medical procedures will not help – they need prescription drugs to either keep their disease from progressing, to get better, or hopefully with new advancements in drug development, be cured. The rare disease ecosystem is extremely sensitive to changes in policy and incentives that drive investment in these patient populations which are high risk and have unmet needs.

Under the IRA, if a chemical drug has been FDA-approved for at least seven years (at least 11 years for a biological product) it may be eligible for price "negotiation." There are exceptions. For example, drugs with a generic or a biosimilar substitute are exempt from price limits.

The law states that CMS must exclude from price controls a drug "…for only one rare disease or condition and for which the only approved indication (or indications) is for such disease or condition" (Section 1191(e)(3)(A)).

The intent behind this language was to continue to incentivize drug development for rare diseases, carving out products that treat rare diseases from the damage that price controls will cause to access and innovation where it is needed most. However, drug developers often continue research on approved products for other indications and conditions. Particularly in the rare disease community, where studying potential new uses of repurposed products can lead to faster access and less expensive therapies for diseases in need of treatments, this is especially important. More than 60 percent of oncology medications approved more than a decade ago, for example, received additional approvals to treat new indications in later years. Yet under the IRA, if a product indicated to treat one rare disease was studied and approved for the treatment of another rare disease, the product could be subject to price limits, thereby eliminating the incentive to study approved products on additional patient populations and disease groups.

The IRA makes clear that companies developing orphan drugs are now at increased risk of market failure – the opposite of what the Orphan Drug Act sought to address through tax, market exclusivity, and other incentives. Companies are unlikely to invest in products that could be subject to price limits because they are unlikely to see a return on their investment. Stack that negative incentive on top of others that already make this a difficult landscape for drug development – fewer patients (many of them pediatric), high cost of clinical trials, difficulty designing trials that meet the FDA's demands and regulatory uncertainty – and it makes the market for orphan products very unfavorable. Faced with this uncertainty, investors and manufacturers are unlikely to develop follow-on treatments for the more than 30 million Americans (and their caregivers) who all share the same desire: to have treatments developed for their diseases.

We are concerned that the March 15th guidance language on the single rare disease or condition indication is even more restrictive than what was intended by Congress and will undoubtedly have a damaging impact on development of rare disease drugs. Resolving the problems created by the orphan drug language in the IRA must be done quickly and transparently.

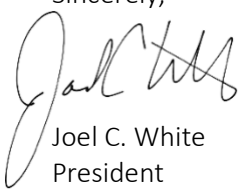
Recommendation: In the program guidance, CMS states the Agency is considering whether there are additional actions it can take to best support orphan drug development. CMS has sufficient flexibility through program guidance in implementing the law to immediately help. Given the limited nature of the exclusion for orphan drugs in the MDPNP, CMS should delay the start of the price negotiation clock for when an excluded orphan product loses its exemption from price controls due to FDA approval of an additional indication until it is proven that the changes do not threaten patient access or innovation. This will help incentivize new research and the discovery of therapies to treat rare diseases. It is pro science and does not conflict with the goal of the law – namely, to reduce prices for products without generic or biosimilar competition.

Conclusion

CAHC encourages CMS to rework the rule to ensure that scientific discovery, product development and patient access are unharmed, and to work with Congress to promote transparency and accountability in rulemaking that will ensure people trust a program of this size and scope is implemented appropriately. 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.

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

Sincerely,



Joel C. White
President
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