HIV+HEP
POLICY INSTITUTE

April 14, 2023

Meena Seshamani, MD, PhD
Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Re: Comments on *Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026*

Dear Dr. Seshamani:

The **HIV+Hepatitis Policy Institute** is a leading national HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. Given the importance of medications to the health and well-being of people living with and at risk of HIV, people with hepatitis B & C, and their growing reliance on Medicare for prescription drugs, we are keenly interested in the implementation of the *Medicare Drug Price Negotiation Program* that CMS is setting up as required by the *Inflation Reduction Act* (IRA). While much of the request for comments contained in the *Initial Memorandum* are more appropriate for drug manufacturers to respond to, patient groups such as ours are also keenly interested in the negotiation process and its outcomes.

Patients are looking forward to the implementation of the IRA and its new $2,000 out-of-pocket maximum along with an annual smoothing mechanism. We are also closely monitoring the *Medicare Drug Price Negotiation Program* to ensure that patients will directly benefit from the process in the form of lower out-of-pocket costs and fewer access barriers such as utilization management. We are also concerned about the unintended consequences of the *Negotiation Program.* We want to make sure that as a result of the negotiation process, patient access to the medications they need will not be reduced by more limited formularies and increased utilization management. At the same time, patients should not pay higher out-of-pocket costs for drugs that are not undergoing the negotiation process. Additionally, patients need assurance that the *Negotiation Program* will not impede development of new medications that can help improve the lives and well-being of people not only here in the United States but throughout the world.

Our comments below are not in order of importance but follow the order of the *Initial Memorandum*. The **HIV+Hepatitis Policy Institute** has also reviewed the *Information Collection Request for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act* and will separately provide comments on the proposed data collection elements, but our review of this document has also helped inform the comments below.

Sections 50.1 Manufacturer Specific Data & Section 60.3.4 Consideration of Manufacturer Specific Data

The **HIV+Hepatitis Policy Institute** has witnessed the ups and downs of the drug development process over the years. Drugs to treat HIV have progressed from the first antiretrovirals with serious side-effects and limited effectiveness to more effective multi-drug regimens to highly safe and effective single-tablet antiretroviral regimens which enable people with HIV today, not only in the United States but around the world, to live as long as people who do not have HIV. We now even have drugs that prevent HIV as well as new long-acting medications for the treatment and prevention of HIV, with more in the pipeline. Hepatitis B can be treated with daily drugs and Hepatitis C can be *cured* in as little as 8 to 12 weeks. Drug researchers are currently working on a cure for HIV and hepatitis B and vaccines for HIV and hepatitis C.

While CMS is seeking specific data points for the costs and revenues for specific drugs, the research and development process for drugs does not work on an individual drug by drug process. It is essential to look at research and development costs not just for an individual drug, but in the aggregate, including the vast majority of medications in the R&D pipeline that never make it to market. Again, we would expect drug manufacturers to explain all of this in their comments but given our experience in the significant advances in HIV and hepatitis drug development, we are keenly aware of how these advancements have taken place.

By requesting data on specific drug costs and revenues at the time of the negotiation process, CMS is ignoring many factors including the following:

1) The years of R&D that the drug manufacturer invested and learned from as it researched other drugs that led to the development of the negotiated drug;
2) The failures and costs of those other drugs;
3) Manufacturers may highly profit from the negotiated drug in order to invest in other drugs that fail or may not be as profitable;
4) The investment and costs that may occur for new indications for the negotiated drug, along with future revenue that may arise from it;
5) The investment the manufacturer is making on new drug development that is not associated with the negotiated drug;
6) The amount and costs of free or reduced cost drugs the manufacturer provides globally to low income countries; and
7) The value of the drug to the rest of the world and eradicating illnesses, such as infectious diseases.

Seeking specific data on only the drug that is subject to negotiation does not fully capture the aggregate cost of drug development and will likely curtail future drug development by undervaluing the R&D process.

Section 60.3.3.1 Analysis for Selected Drugs with Therapeutic Alternatives

This seems to be the only section for which the public, including patient groups, will be able to provide comments on the negotiation process. Not only is the scope very limited, but the comment period will only be 30 days, leaving under-resourced patient groups and the general public out of the process. Since we have reviewed the proposed *Information Collection Request* for this section, we also know that CMS will only be collecting comments that are cited in literature. This is not a true public comment period that patients and their providers can participate in.

We would urge CMS to provide more opportunities for public input into the negotiation process so we can offer true comment on the patient experience and our needs. There are many factors that should be addressed that CMS is not seeking public comment on, including how specific drugs promote health equity and reduce racial, ethnic, and other health disparities. These matters are particularly important to people with or at risk of HIV and hepatitis. CMS must also take into account that not every patient is the same and reacts to a particular drug in the same manner. Further, not everything patient communities would want to comment on is cited in literature.

We urge CMS to provide additional opportunities for meaningful public comment as part of the negotiation process and to offer responses to the comments submitted.

Section 110 Part D Formulary Inclusion of Selected Drugs

The proposed guidance offers just one sentence on the topic of formulary inclusion of drugs selected for the *Negotiation Program*, merely restating what is in the law, namely that a negotiated drug must be covered by Medicare plans. We believe that patients need to realize a substantial benefit for any drug that undergoes the negotiation process. Patients should be able to access the drug at the lowest tier and free of any utilization management barriers such as prior authorization and step therapy. Since the IRA will most likely impact the price of similar drugs, patients should also benefit from their reduced costs and should realize those savings free of restrictions.

While plans are required to cover negotiated drugs, we are concerned at the same time that plans may limit the inclusion of non-negotiated drugs. This would be damaging to the health and well-being of Medicare beneficiaries.

We urge CMS, as it implements the drug negotiation process, to monitor benefit plan design to ensure that access and affordability of Medicare drugs are not diminished.

Thank you for this opportunity to comment on this proposal. Should you have any questions or need any additional information, please do not hesitate to reach out via phone at (202) 462-3042 or email at cschmid@hivhep.org.

Sincerely,

Carl E. Schmid II
Executive Director