



March 11, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

The Healthcare Leadership Council (HLC) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on CMS' initial guidance for the Medicare Part B and Part D Prescription Drug Inflation Rebate Program as part of the implementation of the Inflation Reduction Act (IRA).

HLC is a coalition of chief executives from all disciplines within American healthcare. It is the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century healthcare system that makes affordable high-quality care accessible to all Americans. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors, post-acute care providers, home care providers, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

Lowering the out-of-pocket costs consumers pay for prescription drugs and ensuring that consumers can manage those costs over the plan year is a priority for HLC members. Now that the IRA has passed into law, implementation by the Department of Health and Human Services (HHS) must happen in a way that includes sufficient safeguards and provides clarity in the implementation process for all stakeholders, especially the patient. These include:

Engaging in Meaningful Stakeholder Input

The development of guidance and rules should continue to be open, transparent, and provide meaningful opportunities for stakeholder input, include safeguards for patients, and create accountability for HHS to ensure the program is achieving the goals of helping patients gain access to the medicines they need. It is particularly important that, at least for the initial years, HHS provide ample time and opportunity for stakeholders, including manufacturers, distributors, providers, pharmacists, plans, and patients, to comply with provisions in the law, and also seek feedback on the implementation of the requirements over time. We also encourage HHS to work in collaboration with Congress in the event technical changes are needed to avoid unintended consequences. Additionally, public education campaigns will be vital for patients to understand how the IRA will benefit them as changes take effect.

Utilizing the Federal Rulemaking Process

The IRA includes monumental changes to drug pricing policy that will require significant overhaul of existing systems, processes, and practices throughout the healthcare system.

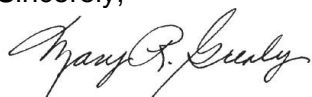
Before HHS formally begins calculating rebates, commences negotiations for drugs offered under Parts B and D, and reforms to the Part D benefit design, formal notice and comment periods should be undertaken to ensure that a broad range of stakeholders can provide input on how best to proceed. This will allow HHS to properly structure these changes and minimize any potential access problems for consumers.

Collaborating with the Private Sector

To improve healthcare quality and reduce costs, HHS must work collaboratively with the private sector to ensure that these new requirements are applied in ways that harness existing market competition instead of creating obstacles to innovation. The process should work to improve patient outcomes, improve access to appropriate medicines and vaccines, and reduce patient cost-sharing, in order to achieve healthcare value and build upon existing mechanisms that drive marketplace competition. The landscape for treatments is regularly and rapidly changing and these changes must be considered in the new administrative framework. Collaboration with the private sector creates confidence in the process and ensures that these significant provisions are implemented in the most efficient way possible. Additionally, HHS must recognize that development of new benefit designs is a multi-year effort and requires extensive investment and planning. We encourage HHS to recognize and account for the complexity of these changes when engaging in future action and collaborate with stakeholders to streamline requirements to ensure successful implementation of the law and to maintain a positive beneficiary experience. Further, the IRA alters the structure of the Part D program. We emphasize that HHS should engage impacted stakeholders and provide a clear timeline, that allows for adequate testing, for when changes will come into effect to ensure a smooth transition for healthcare stakeholders and patients. Additionally, we encourage HHS to provide clear guidance about ambiguous provisions in the IRA so stakeholders can best comply.

HLC looks forward to working with CMS on reducing the cost of prescription drugs without significantly increasing health plan costs or sacrificing access or innovation. Please reach out to Tina Grande ((202) 449-3433 or tgrande@hlc.org) or Debbie Witchey ((202) 449-3435 or dwitchey@hlc.org) with any questions.

Sincerely,



Mary R. Grealy
President