April 14, 2023

Meena Seshamani, MD, PhD
CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Drug Price Negotiation Program Guidance

Dear Deputy Administrator Seshamani:

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 Drug Price Negotiation Program for Price Applicability Year 2026.

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, all while not sacrificing appropriate patient access to life-saving therapies, is a top priority for HLC members. We appreciate CMS laying out the requirements and parameters of the Negotiation Program included under Sections 11001 and 11002 of the Inflation Reduction Act (IRA). In response, HLC offers the following comments on what we identify as problematic provisions within the IRA, as well as the initial guidance which undermines biopharmaceutical innovation and patient access to next generation therapies.

Transparency

HLC encourages CMS to develop guidance and rules that are open and transparent, and provide meaningful opportunities for stakeholder input. The IRA includes vague standards for government price settings and gives CMS wide latitude to implement those provisions. In particular, the law sets tight deadlines for implementation, far shorter than other major healthcare legislation. It also allows CMS to implement policy changes through program instruction or guidance, rather than traditional rulemaking that gives stakeholders adequate time to digest and respond thoughtfully to any major proposed policy changes. We urge CMS to work more collaboratively with all of the impacted stakeholders, including patients, and all parts of the healthcare community to ensure the proposals are as workable as possible.

Patient Access and Part D Redesign

HLC believes government price controls will have a negative impact on the Medicare Part D program which reaches beyond the specific number of drugs selected for price setting and results in patients losing access to their medicines. We were disappointed that CMS did not proactively address patient access concerns in the proposed guidance. Specifically, we believe price setting one selected drug could impact other therapeutic competitors in the same class of medicines. In addition, we are concerned that the downstream effects of price setting will reduce consumers' choice of plans and formularies in Part D, greatly impacting access to medicines. Today, beneficiaries enjoy a broad array of plan choices in Part D, including different formulary options.[1] As more prescription drugs are subject to Maximum Fair Pricing (MFP), the ability of plans to differentiate from one another will decrease and lead to fewer choices in plans or formulary distinctions for consumers. It is critical for CMS to ensure that access to both negotiated and non-negotiated drugs is not impacted by the negotiation or Part D Redesign elements of the Inflation Reduction Act. Furthermore, with fewer plan choices, we are concerned that premiums will continue to increase.

Reference Pricing Standards

CMS proposes to base its decision making on standards of therapeutic "reference pricing," which is controversial and often results in judgments that are clinically inappropriate and disregard the needs of patient subgroups. The requirement of a therapeutic alternative that is similar to the selected drug often overlooks significant differences in the needs of patients, as many alternative therapies do not fit within broad judgments of clinical similarity. We believe this metric which is relied upon by the Department of Veterans Affairs is not appropriate for care delivered in a broader community setting compared to special populations who receive care in closed healthcare delivery systems.

We are also concerned the proposed definition of "unmet needs" is too narrow. The definition proposes to restrict these unmet needs only for diseases for which there are limited or no treatment options available. Such a narrow definition devalues medicines that help address patient needs and could result in worse health outcomes for individuals who don't meet this definition precisely but have few treatment options. CMS must ensure they incorporate appropriate stakeholder feedback and encompassing the full value of a medicine on patients, caregivers, and society at-large.

Innovation

HLC strongly supports policies that are transparent and incentivize innovations that enable all Americans to live longer, healthier lives. We have already seen several biopharmaceutical companies withdraw medicines from clinical trials because of the expectation that IRA's price controls would keep them from recouping their investment. We believe this initial guidance will further compound the IRA's negative effects on continued innovation by setting rules that explicitly devalue existing patents or exclusivities for selected drugs.

Within the guidance, CMS states they intend to consider the length of available patents and exclusivities and may consider adjusting the preliminary price downward if the patents and exclusivities will last for several years. We believe this policy penalizes companies that have secured patent rights even prior to approval by the Food and Drug Administration, particularly for small molecules. Devaluing existing patents and exclusivities will also be damaging for post-approval research and development which many manufacturers invest in for patient safety, as

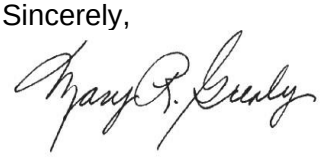
[1] Medicare Part D: A First Look at Medicare Drug Plans in 2023, Kaiser Family Foundation https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-drug-plans-in-2023/

well as finding further indications for their medicines that will aid more patients.[2] CMS also does not consider any special circumstances in which medicines should be priced at the ceiling price or close to the ceiling price, such as when there is a risk of imperiled patient access.

We urge CMS to continuously review their proposals, particularly in the initial price applicability years, to ensure the agency minimizes the detrimental impacts to patients and innovation. To do this, CMS should develop a meaningful process for 1) patients and other stakeholders to provide consistent feedback, and 2) CMS to report the outcomes of policy decisions made for the initial year of negotiation and incorporate necessary changes quickly for future years..

Thank you for the opportunity to provide comments on the initial guidance for the Medicare Drug Price Negotiation Program. HLC looks forward to engaging with the administration as the regulatory process proceeds. If you have any questions, please do not hesitate to contact Debbie Witchey at (202) 449-3435 or dwitchey@hlc.org.

Sincerely,



Mary R. Grealy
President

[2] PhRMA. "WTAS: Inflation Reduction Act already impacting R&D decisions," January 17, 2023.