February 13, 2023

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

**Re: CMS-4201-P**

Dear Administrator Brooks-LaSure:

The Healthcare Leadership Council (HLC) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments in response to the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications proposed rule.

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.

HLC appreciates CMS' efforts through the payment and policy proposals to lower out-of-pocket Medicare Part D prescription drug costs and increase consumer protections, reduce disparities, and improve health equity in MA and Part D. MA continues to grow in popularity and today serves more than 28 million Medicare beneficiaries (46% of the total Medicare population); the program appeals to new beneficiaries whose previous employer-sponsored health coverage resembles MA.[1] HLC encourages CMS to finalize proposals that support the continued growth and success of MA and Part D, and consider our recommendations provided below.

[1] Medicare Advantage in 2021: Enrollment Update and Key Trends, Kaiser Family Foundation (March 2022) Medicare Advantage in 2021: Enrollment Update and Key Trends | KFF

## Enhancements to Medicare Advantage and Part D Prescription Drugs

Protecting Beneficiaries: Marketing Requirements

HLC believes all MA and Part D marketing entities must meet standards to ensure beneficiaries are able to make the best healthcare choices that meet their needs. We support CMS' focus on closing marketing loopholes and targeting bad actors that mislead beneficiaries, cause abrasion, and reduce trust in the Medicare program. As bad actors may not have contracts with health plans or plan sponsors, CMS should have the appropriate regulatory authority and staffing to directly regulate those entities. HLC recommends CMS work with stakeholders and Congress to ensure the right framework exists to regulate third parties, which could include requiring all individuals and entities marketing MA and Part D to register with CMS and be subject to fines for not being registered.

We also recommend CMS take the following additional steps to mitigate non-compliant marketing by third parties:

- Preserve federal Medicare preemption to ensure consistency in addressing misleading marketing materials across the country,
- Create a consolidated document containing all marketing requirements with examples for stakeholders to reference,
- Revise the process for third party marketing organization (TPMO) material,
- Establish a compliance resolution process for reports of potentially non-compliant marketing materials or tactics, and
- Perform trainings targeted at TPMOs and downstream entities.

Strengthening Quality: Star Ratings Program

HLC supports CMS' goal to ensure beneficiaries have continuous access to quality healthcare. The Star Rating system continues to increase the quality of health plans available, and the care provided to MA and Part D beneficiaries. Research has shown that MA delivers significantly better care, leading to improved outcomes and lower costs compared to traditional Medicare.[2] [3] We are concerned CMS' proposal to remove the hold harmless provision for the Star Rating improvement measures would harm beneficiaries by limiting the availability of high-quality plans, increased benefits and lower cost sharing that are critical to address social determinants of health (SDOH). By removing the hold harmless provision, health plans that achieve a 4-4.5-Star Rating would see their quality improvement score drop, despite being a high-quality plan. This change would significantly decrease the number of contracts obtaining 4 or more Stars, increase the volatility of Star Ratings, and reduce the incentive for quality improvement. In addition, the elimination of the hold harmless provision for 4-4.5 Star plans would result in over $19 billion in cuts in beneficiaries' benefits over the next 10 years. A significant portion of these cuts would come from supplemental benefits which help improve whole-person health and address social issues that impact health outcomes. As such, we urge CMS to withdraw this proposal as it will have a negative impact on the Administration's health equity goals.

## Advancing Health Equity

HLC supports CMS' commitment to enhance health equity and further identify and reduce health disparities for all Medicare enrollees. We encourage policies and practices that will address SDOH and improve health equity, including eliminating variations in care delivery,

[2] DuGoff E, Tabak R, Diduch T, Garth V: Quality, Health, and Spending in Medicare Advantage and Traditional Medicare. The American Journal of Managed Care (September 2021): https://www.ajmc.com/view/quality-health-and-spending-in-medicare-advantage-and-traditional-medicare

[3] Timbie JW, Bogart A, Damberg CL, Elliott MN, Haas A, Gaillot SJ, et al.: Medicare Advantage and Fee-for-Service Performance on Clinical Quality and Patient Experience Measures: Comparisons from Three Large States. Health Services Research (December 2017): https://pubmed.ncbi.nlm.nih.gov/29130269/

addressing diversity challenges in the workforce and clinical trials, investing in data infrastructure to assess disparities, and enhancing interoperability standards.

HLC encourages CMS to focus its efforts on standardizing SDOH data capture and measurement, leveraging resources currently available to providers, and reducing administrative burden across programs. Despite the numerous initiatives to address SDOH in patient care, providers still struggle to incorporate addressing SDOH into care because they lack the necessary data capabilities to uniformly assess and identify potential social risk factors among all patients. Standardization will also foster the development and sharing of best practices within clinical settings, health systems, and delivery designs.

To further CMS' health equity goals, we recommend the agency consider ways to leverage interoperability and health information technology to foster data flow on social risk. To truly address social needs and reduce healthcare disparities, we need national data and exchange standards that permit stakeholders from across the healthcare industry to report and exchange information. Such information should ideally be available in real-time and at the point of care, not only when a claim is submitted.

C-SNP Chronic Conditions

HLC supports CMS' proposal to expand the list of chronic conditions C-SNP plans can target. Including additional condition categories and diseases within existing C-SNP categories will help improve health outcomes for beneficiaries. In particular, this expansion will help beneficiaries with chronic diseases such as kidney disease better manage their health, and delay or even avoid further progression to End-Stage Renal Disease. We urge CMS to finalize this proposal.

Telehealth and Digital Health Literacy

We appreciate CMS for their continued support for coverage of telehealth services. Telehealth continues to be widely used by patients. In 2020, over 52 million Medicare beneficiaries had an appointment with a physician through a virtual platform.[4] We appreciate CMS working with Congress to extend the public health emergency (PHE) telehealth waivers an additional two years and we encourage you to work with stakeholders to ensure that telehealth coverage does not lapse as you update coverage decisions to comply with the two-year extension. HLC supports CMS' proposal to require MA organizations to develop and maintain procedures to offer digital health education to beneficiaries with low digital health literacy to assist them with accessing medically necessary covered telehealth benefits. Digital access is a key SDOH and addressing it can help reduce health disparities. Further, it is important to ensure beneficiaries have the right tools to make the best healthcare decisions by making health information easier to understand and act upon.

We encourage CMS to provide clarification on which definition the agency is using to measure digital health literacy and provide flexibility as health plans innovate to expand access to telehealth, digital access, and digital literacy in the Medicare population. We also encourage CMS to do annual assessments of digital health literacy across the Medicare population to help inform best practices and lessons learned.

**Implementation of Certain Provisions of the Consolidated Appropriations Act, and the Inflation Reduction Act (IRA)**

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

[4] HHS reports 52.7 million Medicare telehealth visits during pandemic, American Hospital Association (December 6, 2021), https://www.aha.org/news/headline/2021-12-06-hhs-reports-527-million-medicare-telehealth-visits-during-pandemic.

the IRA has passed into law, implementation of the law by the U.S. 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

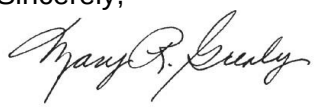
The development of guidance and rules should be open, transparent, and provide meaningful opportunities for stakeholder input, include safeguards for patients, and create accountability for HHS to ensure the program is achieving the goals of helping patients gain access to the medicines they need. It 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 affect 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, starts negotiations for drugs offered under Parts B and D, and instituting 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.

Thank you for your commitment to the MA and Part D programs. HLC looks forward to working with you on our shared priorities. 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