October 15, 2023

The Honorable Michael C. Burgess, MD
Chair
Health Care Task Force
House Budget Committee
Washington, D.C. 20515

Dear Chair Burgess and Task Force members:

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments on solutions to modernize the nation's healthcare system to both improve patient outcomes and reduce spending.

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, homecare providers, group purchasing organizations, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

HLC offers the following solutions to build on and improve innovative programs and to better understand budgetary impacts investing in preventive care:

Transition to Patient-Centered, Value-Based Care

HLC believes Congress should further explore value-based care as a long-term way to improve patient outcomes while reducing costs by using dollars more efficiently. A value-based care system will improve healthcare quality and outcomes for patients. The shift to value-based care will require numerous changes in the way our healthcare system is structured and operates. This shift will enable consistent and efficient data collection, as well as communication among healthcare providers which will allow for better utilization of the healthcare workforce.

We urge Congress to enact H.R. 5013, the "Value in Health Care Act," bipartisan legislation that makes several important reforms to build on the successes of alternative payment models (APMs) and improve health equity and access to care. The bill extends the five percent advanced APM incentives scheduled to expire at the end of the year under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and gives the Centers for Medicare & Medicaid Services (CMS) authority to adjust APM qualifying thresholds so that the current one-size-fits-all approach does not serve as a disincentive to including rural, underserved, primary care or specialty practices in APMs. To allow more clinicians to continue the transition to value, the bill establishes a voluntary track for accountable care organizations (ACOs) in the Medicare

Shared Savings Program to take on higher levels of risk and provides technical assistance for clinicians new to APMs. The bill also removes revenue-based distinctions that disadvantage rural and safety net providers and improves financial benchmarks so that APM participants are not penalized for their own success.

Make CMMI More Effective

After over a decade of projecting that the models initiated by the Center for Medicare and Medicaid Innovation (CMMI) would reduce Medicare spending, the Congressional Budget Office (CBO) issued a recent report estimating that in its first decade of operation, CMMI's efforts had actually elevated federal spending by $5.4 billion between 2011 and 2020. CBO initially estimated that the agency's work would result in a net spending decrease of nearly $3 billion over the 2011 through 2020 budget window. Over the 2021 through 2030 budget window, CBO had previously projected that CMMI models would reduce federal spending by $77.5 billion. CBO's revised estimates now project that CMMI models will increase federal spending by $1.3 billion from 2021 through 2030. There are a couple of important takeaways from this report that can enhance CMMI's work and lead to more successes moving forward.

First, we've already witnessed that CMMI can have its greatest impact in helping to transition the healthcare system from its traditional fee-for-service orientation to a value-based framework. Continuing this progress will lead to greater cost-efficiency within the system, while attaining positive patient outcomes, enhancing equity, and without undermining healthcare quality. In the years to come, this is where CMMI should focus the lion's share of its work, developing sustainable models that will achieve meaningful savings through patient-centered coordinated care and that have bipartisan support.

And, second, it is critical to get health provider participation in innovative payment and delivery models. CBO also notes that CMMI "might achieve larger net budgetary savings in its second decade by drawing on the lessons from past models when designing new ones." We must ensure that providers' incentives to participate in the models are not outweighed by burdens of operating under the model. When new models create onerous burdens on those organizations that might otherwise want to engage, the result is lack of participation. As CBO pointed out in its report, there have been instances in which CMMI models have created inconsistent and even contradictory mandates for providers to follow, creating unnecessary paperwork and expense. Listening to health providers, being responsive to their concerns and ideas, and incentivizing them to participate in new demonstration projects is critical in CMMI's second decade. Mandatory participation models may seem appealing (although MedPac has noted some of the limitations and lack of evidence), but it would be better if we are to see savings to create models that are appealing to providers and their patients.

Providers with more value-based care arrangements fared better during the pandemic than those relying on fee-for-service volume-based arrangements. Legislation that helps focus CMMI's mission on driving toward value-based care should be considered as a way to improve CMMI's success as opposed to tying it's hands.

Make Telehealth and Acute Hospital Care at Home Waivers Permanent

Over the past several years we have seen the value of telehealth in healthcare delivery, especially for vulnerable populations. HLC commends Congress for extending telehealth waivers through the end of 2024 and recommends building upon this foundation by removing the existing prohibitions under Section 1834(m) of the Social Security Act that prevents patients from receiving telehealth services where they are located. Limiting telehealth services to originating sites reduces patients' ability to receive important care in a setting they prefer. These

care options recognize the infrastructure challenges many rural communities face and ensure these patients are not left behind in future care innovations. In considering these additional modes of care delivery, we encourage Congress to make certain that patients are not unduly burdened by additional hurdles to receive telehealth.

We also commend Congress for extending the Acute Hospital Care at Home waiver program that allows patients to receive acute care in the home. These tools have shown the ability to deliver high quality and lower cost care where the patient resides. We encourage Congress to make this waiver and the telehealth waiver permanent.

Modernize the Physician Self-Referral (Stark) Law and the Anti-Kickback Statute (AKS)

We encourage Congress to grant the Secretary of Health and Human Services greater authority to create new safe harbors and exceptions to existing AKS regulations that recognize the changing landscape of the healthcare sector. These additional flexibilities would recognize the significant challenges required to make any revisions to the Stark Law or the AKS. The Phase III rulemaking process for the Stark Law, for example, was last finalized in September 2007.

While it is important to ensure that financial relationships are only for the purpose of improving care, many providers have struggled to comply with the Stark Law, given its imposition of a strict liability framework for all violations. Violations of the AKS are an intent-driven analysis. We support Congress taking steps to harmonize the standard for violations to ensure providers who unintentionally violate the Stark Law are not unduly punished.

In order for all stakeholders to fully participate in value-based arrangements without threat of legal repercussions, we hope that future legislative changes include all groups excluded from the Office of the Inspector General (OIG) 2020 final rule implementing revisions to the AKS, particularly medical device and pharmaceutical manufacturers.[1] Prohibiting pharmaceutical and medical device manufacturers from taking advantage of safe harbors to promote care coordination fails to recognize the extensive information sharing and individual care assistance these stakeholders provide. Pharmaceutical and medical device manufacturers regularly work with providers in collecting data and assisting in tailored care plans so that a patient can receive optimal care.[2] A medical device manufacturer has the capacity to work with a payer to provide monitoring services to patients suffering from chronic conditions and carefully watch for any diagnostic changes. This collaboration requires extensive involvement with the manufacturer, payers, providers and patients.[3] Unfortunately, such a collaboration would be unlikely to occur without the safe harbors applying to manufacturers. OIG's approach in determining which entities may participate in safe harbors fails to consider innovative ways that stakeholders can contribute to the care delivery process by applying new payment methods that encourage value-based arrangements.

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[1] Eligibility for the Value-Based Safe Harbors, the Patient Engagement and Support Safe Harbor, and the Personal Services and Management Contracts Safe Harbor for Outcomes-Based Payment, Office of the Inspector General, U.S. Department of Health and Human Services (November 20, 2020), https://oig.hhs.gov/reports-and-publications/federal-register-notices/Ineligible-Entities-Chart.pdf.

[2] Impact of Value-Based Care on the Medical Device Industry: Three Takeaways from the Case for Transformation, Ropes & Gray (September 7, 2017), https://www.ropesgray.com/en/newsroom/alerts/2017/09/Impact-of-Value-Based-Health-Care-Medical-Device-Industry-Three-Takeaways.

[3] Fred Donovan, Medical Technology Focuses on Patient Engagement, Care Coordination, HIT Infrastructure (June 24, 2019), https://hitinfrastructure.com/news/medical-technology-focuses-on-patient-engagement-care-coordination.

Realign Incentives for Efforts to Address Fraud, Waste, and Abuse

Fraud, waste, and abuse (FWA) are estimated to account for up to 10 percent of costs for health plans, and efforts to combat fraud and wasteful spending play a crucial role in ensuring that healthcare resources are directed towards actual patient care.[4] We believe Congress can make significant strides in reducing medical spending and improving patient care by recharacterizing FWA mitigation efforts costs as part of quality improvement rather than administrative functions.This reclassification would incentivize organizations to engage more actively in fraud prevention and waste reduction, ultimately leading to a more efficient, cost-effective, and patient-centered healthcare system.

Protect and Invest in Medicare Advantage

We urge Congress to protect and invest in Medicare Advantage (MA), a popular program that a majority of seniors choose for their care that has been shown to reduce utilization and costs without sacrificing quality.

MA now serves over half (51 percent) of the Medicare-eligible population.[5] A recent Avalere Health analysis compared utilization, spending, and quality outcomes between MA and Medicare FFS beneficiaries with chronic conditions. MA beneficiaries had lower utilization rates of high-cost services such as inpatient stays and ER visits, and, regardless of condition, MA beneficiaries spent less overall on healthcare. The analysis found quality outcomes to be similar. Additionally, MA serves a higher proportion of beneficiaries with clinical and social risk factors as well a much higher percentage of beneficiaries who identify as a racial or ethnic minority (28.1 percent in MA vs. 12.8 percent in FFS).[6]

Incorporate Preventive Health Savings into CBO's Modeling Approach

Improving access to preventive health services and factoring these investments into budget scoring are critical elements to reducing healthcare spending and improving patient health outcomes. Chronic diseases are responsible for 7 of 10 deaths among Americans each year, and they account for 90 percent of the $4.1 trillion our nation spends annually on medical care.[7]

We thank Chair Burgess for introducing H.R. 766, the "Preventive Health Savings Act," which will allow the Congress to more easily request CBO estimates of preventive health initiatives beyond the ten-year scoring window in order to capture potential long-term health savings in federal programs. Research has demonstrated that certain expenditures for preventive health interventions generate savings when considered in the long term, but those cost savings may not be apparent when assessing only the first ten years—those in the "scoring" window. This legislation will allow Congress to see the full savings of enacting prevention-focused policy measures and is an important step to addressing the chronic disease epidemic.

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[4] US Department of Justice, Health Care Fraud (January 21, 2020), https://www.justice.gov/archives/jm/criminal-resource-manual-976-health-care-fraud-generally

[5] Medicare Advantage in 2023: Enrollment Update and Key Trends, Kaiser Family Foundation ((August 2023), https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2023-enrollment-update-and-key-trends/.

[6] Analysis of Medicare Advantage Enrollee Demographics, Utilization, Spending, and Quality Compared to Fee-for-Service Medicare Among Enrollees with Chronic Conditions, Avalere Health (June 2023), https://bettermedicarealliance.org/wp-content/uploads/2023/06/BMA-MA_FFS-Outcomes-Among-Beneficiaries-with-Chronic-Conditions_FIN-1.pdf.

[7] Health and Economic Costs of Chronic Diseases, Centers for Disease Control and Prevention (October 2023), https://www.cdc.gov/chronicdisease/about/costs/index.htm.

HLC and its member organizations stand ready to work with you to invest in innovative programs to improve patient outcomes while also reducing medical spending. If you have any questions, please do not hesitate to contact Debbie Witchey at dwitchey@hlc.org or 202-449-3435.

Sincerely,

Mary R. Grealy
President