April 6, 2020

Mr. Demetrios L. Kouzoukas
Principal Deputy Administrator and Director
Center for Medicare
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-4190-P

Dear Mr. Kouzoukas:

The Healthcare Leadership Council (HLC) appreciates the opportunity to provide comments on the Medicare and Medicaid Programs: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly.

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 commends the Centers for Medicare and Medicaid Services' (CMS) efforts to improve Medicare Advantage (MA) and the Medicare prescription drug benefit program (Part D) to give seniors more choices and lower out-of-pocket costs, and to encourage price transparency. As you know, MA continues to grow in popularity and today serves more than 24 million Medicare beneficiaries (35% of the total Medicare population) as the program appeals to new beneficiaries whose previous employer-sponsored health coverage resembled MA. We encourage CMS to finalize proposals that support the

continued growth and success of MA and Part D, while considering our recommendations provided below.

HLC members represent all healthcare sectors and touch the lives of Medicare beneficiaries in multiple ways. They have seen firsthand the positive impact of MA and Part D and urge CMS to continue to support these programs by addressing the following issues in the final rule.

Clear and Timely Guidance Needed During Public Health Emergency

HLC appreciates the Administration's work to actively respond to the COVID-19 pandemic and issue guidance to inform Medicare Advantage Organizations (MAOs) and Part D Sponsors of obligations and flexibilities related to disasters and emergencies resulting from the virus. Clear and timely guidance is needed on how CMS will account for the impact of COVID-19 on plan bids, benchmarks, potential mid-year rate adjustments, and Star Ratings to ensure the availability of adequate resources to care for those vulnerable to this infectious disease.

End Stage Renal Disease (ESRD)

HLC continues to urge CMS to ensure ESRD patient costs are accurately reflected in MA payment. The 21st Century Cures Act allows all ESRD beneficiaries to join MA plans beginning in 2021, and excludes organ acquisition costs for kidney transplants for MA beneficiaries from payment benchmarks. We are concerned CMS is overestimating the impact of excluding kidney acquisition costs, since we interpret the new rule as requiring MA Organizations (MAOs) to continue to be responsible for the costs associated with the transplant procedure and subsequent medical care. CMS estimates a weighted average impact of about $4 per member per month for MA, which we believe is inflated. Additionally, HLC encourages CMS to make the methodology more transparent and ensure the appropriate exclusion of kidney acquisition costs from the benchmark.

HLC appreciates CMS's acknowledgement in its proposal to increase maximum out-of-pocket (MOOP) limits that current ESRD reimbursement is not sufficient to prevent premium increases necessary to accommodate the higher costs of ESRD beneficiaries in MA. However, we are concerned that CMS's proposal to enable MAOs to increase MOOP limits will increase costs for all MA beneficiaries and, coupled with an inflated estimate of kidney acquisition costs, would lead to benefit cuts and drive adverse selection in plans that disproportionately attract ESRD beneficiaries. A study found applying the MOOP to ESRD beneficiary spending increases MA costs by an estimated 8 to 9 percent on average compared to fee-for-service spending. In addition, a recent Avalere Health study found that this proposal would result in MA payments that are less than FFS in 10 of the 15 largest metropolitan statistical areas which does not ultimately serve beneficiaries well.

Dual Eligible Special Needs Plans (D-SNPs)

HLC encourages CMS to allow at least an additional year to implement this policy if finalized. HLC supports the enrollment of full-benefit dual eligible members into D-

SNPs that meet new integration requirements. However, if CMS moves forward with its proposal to curtail D-SNP look-alike plans, we encourage this policy change be implemented in a way that minimizes beneficiary disruption and is informed by the requirements of state D-SNP policies. In addition, we request that CMS clarify its 80 percent threshold applies only to full benefit duals.

Star Ratings

Extreme and Uncontrollable Circumstances

Due to the COVID-19 pandemic, the 2021 and 2022 Star Ratings will not accurately measure the quality of MA and Part D plans across the country. In the short-term, CMS should ensure Star Ratings do not encourage activities counterproductive to the work of providers or health of beneficiaries, such as encouraging them to get preventive screenings or making a primary care appointment. In the long-term, HLC encourages CMS to develop an industry-wide standard that appropriately measures quality during this pandemic, and provides plans with 3.5 or 3 Star Ratings with the opportunity to earn a quality bonus payment (QBP) for contract years 2022 and 2023 (2021 and 2022 Star Ratings) of at least 3.5 percent. At a minimum, CMS should make adjustments to the "extreme and uncontrollable circumstances" policy to ensure plans are not adversely impacted by pandemics, emergencies or disasters.

Past Performance

While HLC appreciates CMS' efforts to clarify and simplify the past performance methodology, we are concerned that the proposal would be overly restrictive in its application. We do not believe the proposed methodology sufficiently takes into account the nature and context of performance issues over a long enough period of time, and thus would inadvertently limit new high-quality plan offerings for beneficiaries. We encourage the agency to consider at least two years of Star Ratings performance to allow for improvement efforts to be measured and reported. Additionally, given the narrow timeframe CMS proposes for review, HLC encourages the agency to provide an appeal opportunity to enable plans to show an issue was quickly addressed.

Measure Weights

HLC encourages CMS to ensure the foundation of Star Ratings continues to be based on objective clinical measures. The proposed rule increases the weight of patient experience and complaint measures to 4, well above the weight of clinical outcome measures. Before making any changes, we encourage the agency to consider any changes to measure weights with a critical evaluation of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) or the Health Outcomes Survey (HOS) surveys given concerns about decreasing response rates, and the accuracy and reliability of the survey results.

Statin Use in Persons with Diabetes (SUPD) Measure

HLC believes that Star Ratings play an important role in improving standards of care in the MA and Part D programs. While HLC supports the goals of the statin use in the persons with diabetes measure, we believe the measure would be more appropriately categorized as a process improvement measure. For 2021 Star Ratings, CMS will increase the statin use in persons with diabetes (SUPD) measure weight from 1 to 3 for summary rating and quality improvement calculations. In the proposed rule, however, the agency proposes to revert the classification to a process measure from an intermediate outcome measure and decrease the measure weight from 3 to 1. HLC does not support the decision to increase the SUPD measure by classifying it as an intermediate outcome measure, thus increasing the weight from 1 to 3. We support reverting the classification to a process measure at a measure weight of 1.

HLC supports measuring outcomes, not processes. However, we believe that weighting the SUPD measure at 3 does not actually reflect outcomes; rather, it measures a single procedural intervention. The clinical benefit from statin use is not an immediate effect and is only seen with continued use over a multi-year timeframe (10 year). The SUPD measure does not encourage ongoing use of the medication and only evaluates a one-time fill of the therapy. While we agree that this is an important procedural step, there are no outcomes data associated with one fill of a statin as this measure is currently set up. Therefore, the measure itself looks at the procedure of starting the statin, not the outcome of lowering cardiovascular morbidity and mortality through continued usage over a multi-year span.

Beneficiary Real Time Benefit Tool (RTBT)

Real-Time Benefit Tools (RTBT) are technology innovations that deliver prescription benefit details, such as patient out-of-pocket costs, drug alternatives, and prior authorization information at the point of care. This empowers patients to discuss with their provider whether clinically appropriate options with lower cost sharing are available, avoid surprises at the pharmacy counter due to utilization management, and remain adherent to their prescribed treatment. HLC has advocated for the use of RTBT to provide point of care information on drug costs to beneficiaries and appreciates CMS's proposal to allow enrollees to view plan-provided, patient-specific, real-time formulary and benefit information. It is important to note the information plans provide to patients on lower cost formulary alternatives will vary by plan. Beneficiaries should be provided information that is specific to their medical needs and is clinically appropriate for that beneficiary. Given the expected variation across plans due to differences in formularies, this could result in increases in workload for prescribers, due to patient inquiries on treatment choice. Conversely, prescriber workload could also potentially reduce workload since prescribers may be asked only about formulary alternatives, rather than all possible drugs, such as drugs patients may hear about through advertisements.

Additionally, HLC believes that the information available in RTBT should be fully transparent to help pharmacists and manufacturers better support patient fulfillment in cases where the discussion between patients and providers did not occur. Having this information available in a transparent manner could also provide value to Medicare beneficiaries beyond their interactions with their providers. This information could help beneficiaries during their annual enrollment periods to help inform plan choices that best meet their needs.

We encourage CMS to take this information into consideration; however, we are encouraged by the agency's continued efforts to increase transparency around formularies and costs in order to better inform beneficiaries.

Medicare Advantage (MA) and Cost Plan Network Adequacy

HLC applauds CMS's efforts to strengthen network adequacy rules for MA plans, improve access in rural areas, and encourage the use of telehealth in all areas. HLC is a strong supporter of removing regulatory barriers to the use of telemedicine and remote patient monitoring. Telehealth can enable patients to connect with providers, increases access to care, improves the quality of care, and decreases the cost of care. HLC also supports using telemedicine to prevent chronic diseases and promote wellness among rural residents. Many chronic diseases are caused by a lack of physical activity, inadequate nutrition, and tobacco use, to name a few. Medicare beneficiaries need access to comprehensive and evidenced-based wellness programs that can help prevent these diseases. We encourage CMS to finalize the proposed rule reducing the required percentage of beneficiaries that must reside within the maximum time and distance standards from 90 to 85 percent.

Measurement of Network Adequacy for Dialysis

HLC believes that CMS should remove outpatient dialysis from the list of facility types for which MA plans need to meet time and distance standards. CMS should allow health plans to attest to providing medically necessary dialysis services in its contract application instead of requiring each MA plan to meet time and distance standards for providers of these services. Alternatively, CMS should allow exceptions to time and distance standards if a plan is instead covering home dialysis for all enrollees who need these services.

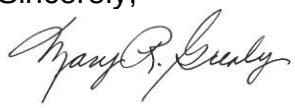
Medical Loss Ratio (MLR)

HLC supports enabling social investments to be included in the MLR numerator (as part of medical care), and appreciates CMS' proposed change to the definition of incurred claims to allow for accurate accounting of Supplemental Benefits for the Chronically Ill.

Given the public health emergency, we encourage CMS to allow investments in combating COVID-19 and expanding access to critical healthcare services to be considered an incurred cost, thereby allowing such investments to be applied to the numerator of the MLR. This proposed rule change would establish the leadership of this Administration, as the first to incorporate "drivers of health" into the national risk and quality frameworks.

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