December 21, 2018

The Honorable Seema Verma
Administrator, Centers for Medicare and Medicaid Services
Hubert Humphrey Building
200 Independence Avenue, S.W. 445-G
Washington, D.C. 20201

Re: CMS-4185-P

Dear Administrator Verma:

The Healthcare Leadership Council (HLC) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments in response to the notice of proposed rulemaking entitled "Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Program of All-inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021" (CMS-4185-P).

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.

We have reviewed the notice of proposed rulemaking and offer comments on the following provisions:

Requirements for Medicare Advantage Plans Offering Additional Telehealth Benefits

HLC strongly believes in the value that telehealth services can provide to the Medicare program and its beneficiaries enrolled in both Medicare Advantage (MA) and original Medicare. Medicare beneficiaries may encounter challenges getting to their medical appointments, whether due to functional limitations, lack of transportation, or geographic barriers. In these instances, and, in others, telehealth can ease connections between Medicare enrollees and providers. Telehealth improves healthcare quality and lowers costs, while giving more people access to quality healthcare. We welcome the flexible approach that CMS proposes to

implement provisions in the Bipartisan Budget Act (BBA) of 2018 to expand telehealth services to MA enrollees.

HLC supports CMS's proposal to permit MA plans to include "additional telehealth benefits" in their basic benefit packages to enrollees beginning in plan year 2020. Additionally, we support the agency's proposal to allow MA plans to identify those "additional telehealth benefits" that are "clinically appropriate" for their enrollees. MA plans are well-suited for determining what telehealth services are "clinically appropriate" and have the incentive to stay informed on the latest standards and innovations in medicine. We concur with CMS that restricting telehealth services to the more limited set of services payable under Section 1834(m) of the Social Security Act would not allow MA plans "to take full advantage of the flexibility that Congress has authorized for the MA program."

HLC appreciates CMS's proposed definition of "electronic exchange" for expanded MA telehealth benefits as "electronic information and telecommunications technology." The proposed definition of "electronic exchange" enables MA plans to implement a technology neutral approach. Restrictive requirements on rapidly emerging telehealth technology would create unnecessary barriers to access and limit the benefits of innovation. A technology neutral approach allows for the incorporation of innovative telehealth technologies into clinical practice as they develop and enables patients to access telehealth through the technologies that are available to them (i.e., live-audio videoconferencing, asynchronous store-and-forward technology, secure messaging, etc.). HLC believes payment for telehealth services should always connect to the type of service being provided, not the method by which it is provided, so providers are able to choose that which is most effective for each patient. Telehealth is a medical practice tool, not a separate form of medicine, and any definition should be technology neutral.

HLC supports CMS's proposal to allow MA plans to implement differential cost sharing for the same Part B service available through in-person and telehealth settings. Currently, CMS allows MA plans to implement differential cost sharing for original Medicare benefits. HLC supports CMS's proposal to extend this flexibility to "additional telehealth benefits" offered by MA plans because it provides beneficiaries with a choice of services that are clincally appropriate and permits MA plans to deliver Part B services in a manner that captures the cost-saving potential of telehealth technologies.

HLC supports CMS's proposal to continue authority for MA plans to offer supplemental benefits via remote access and/or telemonitoring for services that do not meet the requirements of "additional telehealth benefits." MA plans, MA beneficiaries, and their providers should continue to have access to and benefit from the advantages of high-quality clinical care these services offer.

HLC supports CMS's proposed requirements for providers delivering "additional telehealth benefits." HLC believes telehealth service providers should be held to the same standard of care as those offering such services in the in-person setting. Equivalent levels of care quality will ensure that beneficiaries and MA plans feel secure in utilizing and benefitting from care delivered via telehealth.

Dual Eligible Special Needs Plans

Dual Eligible Special Needs Plans (D-SNPs) have been successful in targeting clinical programs to care more effectively for beneficiaries who are eligible for both Medicare and Medicaid services. These specialized models of care better include care management tools, such as care managers, interdisciplinary teams, specialized provider networks, and quality improvement plans that can enable data sharing across health plans and providers in a more effective way. By coordinating care and providing access to supplemental benefits, these plans improve the health of dual eligible beneficiaries and reduce costs for taxpayers.

HLC agrees that integration of Medicare and Medicaid services in D-SNPs is an important goal for states, plans, and beneficiaries**. We applaud CMS's flexibility in implementing minimum Medicaid integration standards for D-SNPs required by the BBA of 2018.** We believe that specific consideration should be given to ensure states and plans have multiple pathways to work together to tailor integration. HLC supports a move toward integration while accounting for state differences in Medicare and Medicaid integration levels and allowing states to retain the flexibility to define their programs requirement such as populations to be served and services to be provided. However, as states work with interested D-SNPs to comply with new integration requirements by calendar year 2021, CMS should consider that plans not be penalized for state decisions that might impede integration.

HLC supports unification of Medicare and Medicaid grievance and appeals requirements for D-SNPs to the greatest extent possible, including timelines and processes, while allowing state flexibility. Aligning and improving this process would enable individuals and their caregivers to better navigate the process.

Medicare Advantage and Part D Prescription Drug Plan Quality Rating System

HLC believes that the Quality Star Ratings play an important role in improving standards of care in MA and Part D. We urge CMS to develop a strategic plan that includes defined goals for the Quality Star Ratings and creates a framework for the inclusion and retirement of measures. CMS should ensure that the Quality Star Ratings are simplified, accurately reflect plan performance, and place the most emphasis on measures plans can influence and that improve beneficiaries' health. CMS should also focus on data-driven measures with objective clinical relevance, rather than survey-based measures.

It is critical that the Quality Star Ratings take into account social risk factors for Medicare beneficiaries. As recommended by the National Academies of Sciences, Engineering, and Medicine (NASEM), HLC believes that Medicare should adjust for social risk factors. NASEM identified four approaches that could be used to account for these social risk factors, including stratified public reporting by risk factors to identify which providers are serving these patients, adjustment of performance measures to standardize estimates of quality, adjustment of payments to providers, and the restructuring of payment incentives to reward improvement in quality or achievement of high-value care. HLC agrees with NASEM that a combination of these methods, including changes to both public reporting and payment, would best account for social risk factors. MA plans should also be allowed to offer a wide array of supplemental services to help address social determinants of health, including non-medical social services such as transportation to medical appointments and access to healthy foods. CMS should encourage the use of Community Health Workers (CHWs) who can link beneficiaries to these types of services.

However, it is also important for CMS to closely monitor the effect of any adjustment to the Quality Star Ratings for potential unintended consequences. These could include a declining quality of care for low income/dually eligible and disabled enrollees, or the potential risk of disincentivizing plans from enrolling these populations.

Medicare Advantage Risk Adjustment Data Validation Provisions (RAD-V)

The MA RAD-V Provisions of the proposed rule pose several problems, including creating instability in MA, a program that CMS projects will cover 37% of Medicare beneficiaries in 2019. **HLC supports CMS developing a fair and legal audit process to ensure accurate MA payments, but the proposed rule in its current form should be abandoned for reasons stated below.** At its root, the proposed rule will increase costs in the MA program, make the program less efficient, and have the potential to harm competition.

Inadequate Notice-and-Comment Rulemaking Process

The process that CMS has followed for this proposed rule violates the requirement for notice-and-comment rulemaking in the Medicare Act and Administrative Procedure Act (APA). Although CMS suggests this proposal is subject to notice-and-comment rulemaking, as part of this process, key data and studies (i.e., the underlying analysis used to determine an FFS adjuster is no longer needed) that are necessary to permit a full and meaningful public comment period have not been made available.

Not Having a FFS Adjuster Is Based On A Flawed Analysis By CMS And Is Problematic

CMS' decision not to implement a FFS Adjuster, despite stating in 2012 that it would do so, is based on a flawed analysis that fails to justify CMS' recent decision that a FFS adjuster is no longer needed. A rigorous statistical and actuarial analysis of the FFS adjuster study demonstrates its weak theoretical underpinnings and its conclusions are simply incorrect. Not having a FFS adjuster is a violation of the Medicare statute, which requires risk adjustment in MA to be implemented in a manner that maintains actuarial equivalence between MA and FFS.

Retroactive Application of Extrapolation is Unlawful and Lacks Appropriate Due Process

Even if the new methodology were otherwise valid, it represents a significant change in approach by CMS that should not be applied retroactively. After indicating six years ago that CMS believed a FFS adjuster is needed in order to account for coding differences between MA and FFS, CMS is now indicating the FFS adjuster is not needed. In addition to this major change in thinking, CMS wants to apply extrapolated RAD-V audit results retroactively dating back as far as payment years 2011 and onward. This is unfair to MA plans that developed their rates and submitted bids based on understandings—and representations from CMS in 2012 about the inclusion of a FFS Adjuster in any RAD-V audits. This would also be damaging to providers and physicians that care for MA patients, as any return from the plans would be passed down to provider groups and ultimately the patient. Further CMS is not permitted, as a matter of law, to apply its new methodology retroactively.

Thank you for the opportunity to comment on this proposed rule. Should you have any questions, please do not hesitate to contact Tina Grande at (202) 449-3433 or tgrande@hlc.org.

Sincerely,

Mary R. Grealy

President