August 21, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program; CY 2018 Updates to the Quality Payment Program (CMS–5522–P)

Dear Administrator Verma:

The Healthcare Leadership Council (HLC) respectfully submits these comments in response to the Centers for Medicare and Medicaid Services' (CMS) proposed regulation updating the Quality Payment Program for eligible clinicians in CY2018. HLC strongly supported the Medicare Access & CHIP Reauthorization Act of 2015 (MACRA) and is pleased to provide feedback that we expect will strengthen the broader transition to a payment system that emphasizes value.

HLC is a coalition of chief executives from all disciplines within American healthcare that serves as the exclusive forum for the nation's healthcare leaders to jointly develop policies, plans, and programs to achieve their vision of a 21st century 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, biotech firms, health product distributors, pharmacies, laboratories, post-acute care providers, and information technology companies – envision a quality-driven system that fosters innovation. HLC members advocate measures to increase the quality and efficiency of American healthcare by emphasizing wellness and prevention, care coordination, and the use of evidence-based medicine, while utilizing consumer choice and competition to enhance value.

HLC applauds CMS for its leadership in ensuring the transition to a new payment system that emphasizes value, while prioritizing feasibility and minimizing new

administrative burdens. We are pleased to see significant action on key recommendations provided by HLC in previous years. In particular,

- HLC encourages CMS to continue to push forward with its efforts to facilitate the movement of organizations to pay-for-performance and Advanced Alternative Payment Models (AAPMs). A critical element of this effort will be incorporating complementary value-based arrangements (such as Medicare Advantage) into AAPM thresholds as soon as possible.
- HLC appreciates CMS allowing Merit-based Incentive Payment System (MIPS) eligible physicians the opportunity to "pick their pace" by submitting data from a 90-day performance period, rather than a full year.
- HLC is pleased to see efforts to reduce the quality measure reporting burden on clinicians. HLC continues to stress that these and other flexibilities are necessary as it may be difficult – particularly in the initial years – to design APMs that meet the financial risk standards and are attractive to a variety of providers. CMS must ensure, however, that these flexibilities do not lessen important incentives for provider engagement.
- HLC welcomes additional CMS proposals designed to address the challenge of attracting providers without prior risk-bearing experience into new alternative payment arrangements (such as the virtual groups proposal). We encourage CMS to continue to implement these proposals in a way that acknowledges the wide range of technological and reporting capabilities of providers, including the provision of regular outreach, training, and education to allow for wider adoption.
- HLC supports the creation of a new improvement activity for clinician leadership in clinical trials, research alliances, or community-based participatory research (CBPR) – especially around minimizing disparities in healthcare access (Achieving Health Equity IA_AHE_XX). HLC supports this effort to improve clinical trial enrollment and encourages CMS to consider including other physicians or even a counseling service payment to incentivize providers to provide information on clinical trials.

HLC has concerns with CMS's proposal to subject Part B payments for drugs to the clinician's payment adjustment (whether positive or negative). This means that a low performing physician who receives a negative adjustment could see Part B drug or vaccine payments effectively reduced close to average sales price (ASP), whereas a high performing physician could see Part B payments increase significantly. These cuts and increases will grow over time as the MIPS adjustment increases/decreases from +/-4% in 2019 to +/-9% by 2022.

While we support efforts to reward value, we are concerned that this could lead to situations in which clinicians who are subject to payment reductions shifting patients to

other therapies, non-drug treatments, or to other settings of care (e.g., hospital outpatient department) in order to avoid the consequence of the MIPS adjustment reducing their payment. It could also put some clinicians in an untenable position in which they would be reimbursed less than their cost for the drug or vaccine. This would be a significant change, as it would be a reversal of CMS policy and interpretation under the Physician Quality Reporting System (PQRS), Value-Based Payment Modifier (VBPM), and Electronic Health Record (EHR) Incentive Programs, where CMS applied payment adjustments only to professional services. CMS recognizes that this change would be operationally challenging in some cases, recognizing that there may be unjustified disparities among clinicians in how the MIPS payment adjustments are applied.

Due to the complexity and potential unintended consequences of this change, HLC recommends CMS not finalize the Part B payment proposal at this time, and instead seek additional stakeholder input on how to implement MACRA requirements on Part B drug payments.

Program Feedback:

As shared in previous comments, HLC would like to continue to emphasize several broader priorities that we believe are critical for the overall success of value-based care programs.

CMS should adopt changes to the federal fraud and abuse legal framework in order to facilitate stronger provider performance in MIPS measurement categories and facilitate growth into full AAPMs. HLC strongly supports the effort to move Medicare payment toward value-based, high-quality care. Modernization of the current legal framework is needed to make it more compatible with healthcare delivery system transformation while retaining appropriate protections against fraud and abuse. CMS should create Anti-Kickback Statute and Stark Law waivers for stakeholders engaged in alternative payment arrangements (both AAPMs and MIPS-reporting APMs) that meet certain conditions. (An unpredictable and burdensome system of "one-off" waivers is not sufficient for alternative payment goals). CMS should also extend existing Anti-Kickback Statute and Stark Law exceptions for donation and financial support of electronic health information products that facilitate care coordination, cyber security protection, and compliance with Advancing Care Information performance category goals. CMS should ensure that a range of relevant and appropriate technologies are included as part of an exception, based on the evolving technological environment.

CMS must plan now to implement a strategy that will facilitate the introduction of innovative private-sector alternative payment arrangements when permitted in 2021. HLC believes that MA plans, commercial health plans, Medicaid managed care organizations (MCOs), and other appropriate entities should be eligible for consideration as Other Payer Advanced APMs. It is critical that CMS offer clear and consistent guidance over the next several years as these entities prepare to participate in the program. Including other payers as Advanced APMs would help advance CMS' movement toward value-based care. Making the Other Payer Advanced APM category as broad and as flexible as possible will help move the entire health system toward care focused on value and optimal patient outcomes. HLC encourages CMS to be transparent, flexible, and consistent regarding the criteria for APM "eligibility" for advanced model consideration. It is equally important for CMS to consider the sensitivity of patient and proprietary contractual information to ensure that transparency efforts are also protective of disclosure. Similarly, the Other Payer certification process and timelines will need to reflect the realities of the market, and would be best supported by a flexible, rolling AAPM certification process.

CMS should focus on the alignment of measurement across all programs to ensure current incentives (such as MA benchmark calculations) facilitate the transition to Other Payer Advanced APM arrangements. CMS should recognize that MA plans forming Other Payer Advanced APM arrangements will need to adjust their bids to account for increased risk and the requirements of other value-based initiatives; and the benchmarks must be adjusted accordingly.

One approach to facilitating a strategy for Other Payer Advanced APMs would be use of the Center for Medicare and Medicaid Innovation (CMMI) demonstration projects (under 1115A waiver authority). Treating providers who contract with private sector alternative payment arrangements and who meet requirements regarding EHR usage, quality, and financial risk as participating AAPMs would allow for consistent application of APM requirements across the Medicare program while reducing provider burden. A voluntary demonstration project designed to test risk contracts between health plans and other stakeholders for inclusion as Other Payer Advanced APMs would allow both CMS and the private sector time to perfect the rules for MA and other programs to become a qualifying MACRA AAPM. A CMMI demonstration could also allow for experimentation in harmonizing performance measures across programs. HLC and CMS share a goal of moving clinicians to advanced alternative payment models – we believe the inclusion of MA plans would create a meaningful path for clinicians to pursue the five percent MACRA bonus.

CMS quality measurement should better incorporate socieoeconomic status adjustments to incentivize alternative payment arrangements in areas of high need. It is critical that all efforts to move to outcome-based payment properly account for both complexities of patients as well as the socioeconomic challenges that providers face in caring for patients. Without these adjustments, efforts to reward higher performing providers may result in lower funding for those serving the most vulnerable. In order to ensure appropriate payment and risk-adjustment, CMS quality programs under MACRA should include a reasonable number of measures that truly capture variance in patient populations. We support the use of a limited number of standard, vetted measures and urge CMS to synchronize measures, expectations, and reporting requirements with existing efforts in the private sector. By working closely with experts in the private sector, a system that appropriately reflects health system challenges – such as the social and economic status of consumers – can create a more accurate payment system.

It is imperative that CMS continue to work closely with private-sector health leaders during MACRA implementation. The law provides CMS with an unprecedented ability to shift healthcare delivery through incentives. These shifts, which will have far-reaching and significant effects on consumers nationwide, should be validated by healthcare experts across the healthcare system. These changes must be deliberate, transparent, and allow for meaningful collaborative effort. Similarly, we urge CMS to provide clear, concise, and actionable feedback on a timely and regular basis in order to allow providers to improve the quality of care delivered to patients and enhance program performance.

HLC sincerely appreciates the opportunity to comment on the proposed rule. Please contact Tina Grande, SVP for Policy, at tgrande@hlc.org or 202-449-3433 with any questions.

Sincerely,

Mary R. Grealy
President