March 1, 2019

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

Re: Advance Notice of Methodological Changes for Calendar Year (CY) 2020 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model, Medicare Advantage Capitation Rates, Part C and Part D Payment Policies, and 2020 Draft Call Letter

Dear Mr. Kouzoukas:

On behalf of the Healthcare Leadership Council (HLC), I am writing to share our thoughts on the 2020 Medicare Advantage (MA) and Part D Advance Notice and Draft Call Letter.

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 the Centers for Medicare and Medicaid Services' (CMS) payment and policy proposals to promote transparency, flexibility, and innovation within the MA and Part D programs. We were pleased to see CMS propose another payment increase for MA of 1.59 percent. As you know, MA continues to grow in popularity and today serves

more than 20 million Medicare beneficiaries (34% of the total Medicare population)[1] as the program appeals to new beneficiaries whose previous employer-sponsored health coverage resembled MA. HLC's *Medicare Today* coalition's *2018 Senior Satisfaction Survey* found that 8 in 10 seniors are satisfied with their Part D coverage and 8 out of 10 believe it is a good value.[2] This program's ability to keep prescription drug costs low for Medicare beneficiaries has expanded access and increased medication adherence. It has also provided beneficiaries with the opportunity to choose from many plans and find the coverage that works best for them. HLC encourages CMS to finalize proposals that support the continued growth and success of MA and Part D, while considering our below recommendations for other proposals that could negatively impact these important programs.

HLC Members come from 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 Rate Announcement and Call Letter:

Benchmarks

HLC believes that CMS should improve MA payment accuracy by using fee-for-service (FFS) data only from beneficiaries who have both Medicare Part A and Part B to calculate MA benchmarks. MA beneficiaries are required to have both Part A and Part B, and the benchmark calculation should reflect that requirement. Using only Part A data distorts the benchmark since beneficiaries with Part A often have lower costs than those with both parts A and B.

Additionally, HLC asks CMS to acknowledge plans with high Star Ratings by removing the benchmark cap. Beneficiaries in over 40% of counties are negatively impacted by the cap. This cap undermines the Quality Bonus Payment and leads to fewer benefits for MA beneficiaries. HLC believes that CMS has the regulatory authority to remove these caps.

Fee-For-Service Normalization

HLC would like CMS to reduce the fee-for-service normalization factors (FFSN) to account for the high FFS risk score trend and prevent benefit cuts to MA beneficiaries. As you are aware, risk scores that underlie the normalization factors have been increasing at a faster rate since 2016. Available data suggests the increasing FFSN trend is driven by the introduction of ICD-10 codes that occurred in late 2015. While the impact of ICD-10 implementation is expected to stabilize moving forward, we are concerned that artificially high FFS risk scores in the 5-year linear averaging methodology is leading to increased FFSN volatility. The proposed factors for 2020

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[1] Gretchen Jacobson, Anthony Damico, and Tricia Neuman, "A Dozen Facts About Medicare Advantage," The Henry J. Kaiser Foundation, November 13, 2018, https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage/.

[2] Medicare Today, "2018 Senior Satisfaction Survey," http://medicaretoday.org/wp-content/uploads/2016/07/8.21.18-Senior-Satisfaction-Survey-Fact-Sheet.pdf

yield a negative reduction of -3.1 percent from 2019, potentially leading to reductions in benefits and increased costs for beneficiaries. Therefore, HLC recommends CMS reduce the normalization factors to account for inflated FFS risk score growth following the introduction of ICD-10 codes to ensure FFSN is accurate in 2020 and beyond.

Risk Adjustment Model

HLC supports adding additional diagnosis codes for dementia and pressure ulcers in the proposed alternative Payment Condition Count model. These changes reflect the requirements of the 21st Century Cures Act and more accurately account for the high health costs of patients with those conditions. We also urge CMS to explore adding conditions to the risk adjustment model that reflect social determinants of health.

End Stage Renal Disease Risk Model

HLC continues to urge CMS to ensure ESRD costs are accurately reflected in MA payment. We are concerned that proposed model adjustments—in combination with the ESRD FFSN may result in yet another reduction in plan payments for a small, high-need beneficiary population. MA plans that serve ESRD patients have experienced significant swings in payment rates over the last several years that have a direct impact on beneficiaries by making it challenging to design stable benefit packages that limit year-to-year changes for beneficiaries.

Given these concerns, HLC requests that CMS take steps to improve ESRD payment adequacy. Beginning in 2021, all individual with ESRD will be eligible to enroll in MA. Therefore, it’s particularly important for CMS to ensure payment adequacy for this vulnerable population.

More broadly, HLC requests that future updates to the ESRD risk adjustment model be communicated under a similar timeline as the CMS-HCC model, allowing stakeholders at least 60 days to review and submit comments on all risk adjustment model proposals in order to give plans enough time to properly analyze any contemplated updates.

HLC also suggests the CMS office of the Actuary publish the underlying Part A and Part B cost data for the ESRD population similar to the information released for the non-ESRD population.

Coding Pattern Adjustment

HLC agrees with CMS decision to apply the statutory minimum MA coding adjustment factor of 5.90 percent in CY 2020. We support the agency’s decision to maintain and not exceed the statutory minimum adjustment level.

In addition, HLC encourages CMS to provide stakeholders with a detailed advance notice of contemplated methodologies. Stakeholders need significantly more details about any potential changes to the Coding Pattern Adjustment (CPA) in order to provide meaningful and accurate feedback.

The first-and only-time CMS published its methodology for calculating the CPA was in the 2010 Advance Notice, which was released February 20, 2009. In the intervening ten years, the Medicare program (both FFS and MA) has changed considerably. Changes in enrollment, demographics, standards of care, treatment patterns, payment policies, and even legislation must be considered in first determining the relevance of the CPA and then, if appropriate, the level of the adjustment.

Encounter Data

A Government Accountability Office (GAO) report found that CMS has not fully validated encounter data.[3] GAO stated, and HLC agrees, that complete validation is key to ensuring data quality. For 2020, CMS proposes to calculate risk scores by adding 50% of the risk score calculated with diagnoses from encounter data and FFS with 50% of the risk score calculated using the risk adjustment process system (RAPS) and FFS diagnoses.

HLC urges CMS to not expand the use of this data until the reliability and accuracy of its extended use is verified to ensure that it does not inadvertently decrease overall risk scores and plan payments. Until the data is fully validated, CMS should revert back to using zero percent encounter data. HLC recommends CMS work with stakeholders in a transparent process to evaluate the data, address implementation barriers, and analyze stakeholder impacts.

Special Supplemental Benefits for the Chronically Ill

HLC applauds CMS' efforts to offer a broad, flexible set of conditions for innovators and health plans to explore product/market fits for new approaches to address Social Determinants of Health to chronically ill enrollees if the Special Supplemental Benefits for the Chronically Ill has a reasonable expectation of improving or maintaining the health or overall function of the enrollee as it relates to their chronic disease. HLC looks forward to learning more specifics about which services CMS will be covering and at what cost. We support plan flexibility in the delivery of supplemental benefits and the eligible population of chronically ill beneficiaries. We also encourage CMS to include industry representatives on the technical advisory panel to review the list of conditions considered chronic to ensure that it reflects experience serving chronically ill beneficiaries. In addition, we encourage CMS to improve the resources available for beneficiaries to more fully and accurately compare plans by incorporating the value of new supplemental benefits in its out-of-pocket (OOPC) model calculations and eliminating the total beneficiary cost (TBC) evaluation in future years.

Star Ratings

HLC believes that the Star Ratings play an important role in improving standards of care in the MA and Part D programs and supports the proposed changes to the Star Ratings. We believe these changes will help MA plans measure their improvements more effectively. Increased transparency on the improvement measures will help MA plans to better assess how they are improving care delivery. Additionally, these measures should also be aligned across all public programs.

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[3] Government Accountability Office, "Medicare Advantage: Limited Progress Made To Validate Encounter Data Used to Ensure Proper Payments," January 2017, https://www.gao.gov/products/GAO-17-223

In addition, CMS currently applies a weight of 1 to the Part D statin measure and proposes that for the subsequent years the Part D statin will be categorized as an intermediate outcome measure with a weight of 3. We are concerned that the measure is a process measure, rather than an outcome measure, and support appropriate medical exclusions for beneficiaries for whom statin use may not be medically appropriate. For consistent treatment of these measures and to ensure that weighting changes occur prospectively, HLC recommends Part D Statin measures continue to be weighted at 1 for 2020 Star Ratings. Further, we recommend that any substantive changes, including changes to the weighting of the Part D Statin measure, should be considered and proposed through the future Star Ratings rulemaking process.

Categorical Adjustment Index

HLC appreciates CMS efforts to test the inclusion of stratification by age, gender, dual eligible, low income status, and disability status. However, we urge CMS to develop a long-term solution that addresses the socio-economic challenges faced by low-income MA beneficiaries. Additionally, HLC supports the proposal to advance opioid-related measures through the Star Ratings development process, by updating the methodology for measures currently on or under consideration on the display page.

Supplemental Benefits

HLC strongly supports CMS proposal to give MA plans flexibility to provide certain enrollees with a broader range of supplemental benefits tailored to specific needs. Traditionally, MA plans have only been allowed to offer "primarily health related" supplemental benefits and must offer them to all enrollees. The Bipartisan Budget Act of 2018 allows MA plans, beginning with CY2020, to offer non-primarily health related supplemental benefits to chronically ill enrollees such as transportation for non-medical needs, home-delivered meals beyond the current allowable limited basis, food, and produce. These benefits will improve the health of vulnerable and low-income Medicare beneficiaries with chronic conditions. HLC also asks CMS to encourage the use of Community Health Workers (CHWs) who can link beneficiaries to these types of benefits.

Integrated Dual Eligible Special Needs Plans

HLC strongly supports CMS' proposals to improve beneficiary communications and reduce burden for Dual Eligible Special Needs Plans. We agree that CMS should partner with states to align and integrate Medicare and Medicaid coverage for dual eligible.

Medication-Assisted Treatment

HLC is pleased that CMS is moving forward to implement provisions of the SUPPORT Act that require the coverage of opioid treatment programs. We support improvements for plans to provide access to Medication-Assisted Treatment which will help to ensure beneficiaries with substance use disorders can more readily get the help they may need. According to a GAO report, in 2018, over 14 million Part D beneficiaries received

an opioid prescription.[4] The current opioid abuse epidemic and the misuse of these drugs poses to Medicare beneficiaries, point to the need for an effective form of treatment for beneficiaries with an opioid addiction.

Additionally, HLC has collaborated with over 70 organizations from the healthcare, employer, patient advocacy, and addiction treatment sectors to release a "Roadmap for Action" consisting of over 30 achievable, high-impact solutions to address opioid misuse and addiction. The Roadmap identifies five key priorities as essential, including:

- Improving healthcare system approaches to pain management
- Improving current approaches to prevent opioid misuse
- Expanding access to evidence-based substance use disorder treatment and behavioral health services
- Promoting improved care coordination through data access and analytics
- Developing sustainable payment systems that support coordination and quality care

Medication Therapy Management

Under the current criteria, plans can address opioid use only within the Medication Therapy Management (MTM) population that is already identified. Plans cannot identify members based on their specific opioid use. HLC recommends MTM criteria be adjusted to include members filling opioids.

Part D Mail Order

HLC supports permitting interested Part D sponsors to offer the opt-in voluntary auto-ship program. We recommend additional flexibility around the requirement that a beneficiary must be on a drug for at least 4 consecutive months before the option is available. We also recommend simplifying the administration of this program by eliminating the requirements of two advanced shipping reminders since beneficiaries voluntarily opt into the auto-ship program.

Formulary Tier Composition

HLC supports the development of a robust pharmaceutical marketplace which includes generics, biosimilars and branded innovator drugs for Medicare beneficiaries. Each beneficiary based on their medical history and in consult with their physician should be able to choose the most appropriate treatment for their needs. As such, HLC believes in establishing a competitive marketplace whereby the choice of one product is driven by clinical attributes, not driven by payment or formulary placement. The agency seeks comments on whether biosimilars should be considered as generics for purposes of the revised formulary tier composition proposal. It has been shown within the existing marketplace that current regulatory and reimbursement systems are enough for biosimilar biological products to thrive.

In addition, the agency has previously determined that biosimilars are not generics under the Part D program based on their unique regulatory approval process. Treating biosimilars as generic drugs would encourage policies that create an arbitrary

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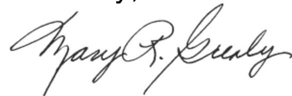
[4] Government Accountability Office, "Prescription Opioids: Medicare Needs to Expand Oversight Efforts to Reduce the Risk of Harm," October 2017, https://www.gao.gov/assets/690/689438.pdf

imbalance between branded innovators, biologics, and their biosimilars. As such, HLC encourages the agency to remain committed to maintaining the market-based structure of the Part D program and not classify biosimilars as generics for purposes of formulary placement.

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