



March 5, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically to: <http://www.regulations.gov>

RE: Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model and Advance Notice of Methodological Changes for CY 2019 for MA Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter (CMS-2017-0163)

Dear Administrator Verma:

On behalf of Ascension, I welcome the opportunity to submit comments on the *Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model¹* and the *Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter²* (CMS-2017-0163).

Ascension is a faith-based healthcare organization dedicated to transformation through innovation across the continuum of care. As the largest non-profit health system in the U.S. and the world's largest Catholic health system, Ascension is committed to delivering compassionate, personalized care to all, with special attention to persons living in poverty and those most vulnerable. In FY2017, Ascension provided more than \$1.8 billion in care of persons living in poverty and other community benefit programs. Ascension includes approximately 150,000 associates and 36,000 aligned providers. Ascension's Healthcare Division operates 2,500 sites of care – including 141 hospitals and more than 30 senior living facilities – in 22 states and the District of Columbia, while its Solutions Division provides a variety of services and solutions including physician practice management, venture capital investing, investment management, biomedical engineering, facilities management, clinical care management, information services, risk management, and contracting through Ascension's own group purchasing organization.

Ascension is committed to a long-term vision of a sustainable, high-quality health system that serves individuals as whole persons throughout the course of their lifetime. Accordingly, we strongly support the movement towards innovative, value-based care and payment models that support population health. In accordance with this vision and guided by our Mission, Ascension offers the following comments and recommendations for consideration by the Centers for Medicare & Medicaid Services (CMS).

¹ <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part1.pdf>

² <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2019Part2.pdf>

Advance Notice of Methodological Changes for CY 2019 for the MA CMS-HCC Risk Adjustment Model (Part I)

With respect to CMS's use of 2014 diagnoses to predict 2015 costs, we appreciate CMS's concern around the stability of diagnosis coding patterns in 2015, which was the first year ICD-10 diagnoses were implemented. Going forward, we note that using ICD-10 in its second year will likely not offer a guaranteed solution to this concern. As such, CMS may want to again update the data years used to calibrate the model in subsequent years – rather than moving immediately to data years 2015/2016.

We support adding mental health, substance use disorders, and chronic kidney conditions to the risk adjustment model but respectfully disagree with CMS's proposal to exclude certain depression and anxiety disorders (HCC 61 and HCC 62, respectively) from the model. There is strong data supporting the increased cost when depression is a concomitant diagnosis. Our own analysis from 2015 reviewed 227 of our members with multiple chronic conditions and depression, and compared them to a cohort with similar multiple chronic conditions without depression. We found that the cost of those patients with depression averaged \$4,700 more than those without depression. Of that cost, \$4,000 was due to medical spending and \$700 was attributed to increased medication costs. This equated to a 53.7% increase in medical costs and a 33.5% increase in medication costs. Combined, the cost increase was nearly 50% for those with depression. These results show that depression is associated with higher cost, regardless of the co-morbid conditions a patient has, when compared to patients without depression and similar co-morbid conditions.

Depression is very common in those with co-morbid conditions and is multi-factorial. As providers increasingly work to improve care delivery for complex patients with multiple co-morbid conditions, focusing on diagnosing and treating depression is paramount to providing whole person care. Diagnosing depression, determining the underlying cause, and addressing the needs of patients with multiple co-morbid conditions can both reduce overall costs and improve the lives of patients in a holistic manner, by focusing on both the biomedical and psychosocial determinants of health. As such, we believe these HCCs meet all three of CMS's stated criteria for inclusion (*i.e.*, they are clinically meaningful, they are predictive of medical expenditures, and they do not comprise discretionary diagnoses). We appreciate CMS's argument as to why they have chosen not to include HCC 61, but recommend that the agency continue evaluating how to include depression. At the very least, we recommend CMS commit to looking at this issue for possible change in 2020.

Overall, we agree with CMS's proposal to use the alternative definition and modeling – counting only payment conditions (*i.e.*, those conditions included in the 2017 model, plus the additional conditions proposed for payment in this Advance Notice), rather than all conditions. We believe the payment condition count more closely aligns with clinical practice and chronicity of conditions. We would, however, ask CMS to clarify whether the proposed use of count variables would change the coefficient of risk of an individual HCC when used as a single diagnosis.

Advance Notice of Methodological Changes for CY 2019 for MA Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter (Part II)

Quality Payment Program

Given our strong support for transformation toward value-based care delivery models, we appreciate CMS's proposal to begin collecting from MA plans – and, eventually, providers –

information about Advanced Alternative Payment Model (A-APM) contracting. We believe the availability of this information will help promote the availability of and increase access to A-APMs. This, in turn, will foster more risk- and value-based contracting overall.

Many of our providers are currently engaged with MA plans, taking on varied degrees of risk today – or planning to do so in the future. While there has been greater movement toward value-based contracting in traditional fee-for-service Medicare under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), we strongly support increased opportunities and incentives to participate in such arrangements through MA and commercial insurance.

Meaningful Difference (Substantially Duplicative Plan Offerings)

Ascension appreciates CMS's interest in promoting increased competition and innovation around MA benefit design and services. We share CMS's goal of seeing increased availability of MA plan options that are specifically tailored to different beneficiary populations and move MA plans towards population health. We are concerned, however, that removing the meaningful difference requirements, without also including appropriate safeguards, could allow for the proliferation of plan choices offered by the same MA organization (MAO) in an area that contain only small, indiscernible, or confusing differences. These differences may occur unintentionally or as the result of an MAO seeking favorable risk selection through subtle benefit/cost-sharing and premium designs. Either way, this could ultimately make it more challenging for beneficiaries to make informed plan choices. Thus, if CMS finalizes removal of the meaningful difference requirements, we urge the agency to include appropriate checks on discriminatory plan designs and to closely monitor for gaming. We further recommend that CMS include more detailed information on plan differences on the Medicare Plan Finder and in outreach to beneficiaries.

Part C Cost Sharing Standards and Tiered Cost Sharing of Medical Benefits

For CY 2020, CMS is considering changes to its policies related to service category cost sharing limits. Although we favor providing greater cost-sharing flexibility for MA plans, we also recognize the need to ensure that flexibility does not result in excessive cost-sharing for specific services that may discourage sicker beneficiaries from enrolling in a given plan or result in unexpectedly high cost-sharing amounts for needed Medicare services. Thus, we support the continued use of some service-specific cost-sharing limits. We also appreciate the administrative simplification for plans associated with CMS's proposal to permit submission of tiered cost sharing for medical benefits through the bid process. We similarly encourage CMS to ensure that such tiering does not discourage sicker beneficiaries from enrolling in a given plan or result in unexpectedly high cost-sharing amounts for needed Medicare services.

Outpatient Observation Services

As CMS notes, the outpatient hospital services category in the plan benefit package (PBP) (B9a) includes a variety of services such as observation, outpatient palliative care, and outpatient surgical services. In an effort to make the cost sharing for observation services more transparent, CMS proposes to distinguish the cost sharing for observation services from other outpatient hospital services by modifying PBP category B9a to include separate cost sharing data entries. We appreciate CMS's efforts to ensure greater transparency for beneficiaries around the cost sharing associated with various covered services. We strongly encourage CMS to ensure that this information is clearly and accurately explained in all marketing materials so

beneficiaries understand when they are going to pay a particular copayment or coinsurance for a given service – and what that service entails.

Health Related Supplemental Benefits

CMS has not previously allowed an item or service to be eligible as a supplemental benefit if the primary purpose is daily maintenance. However, there is a growing body of evidence demonstrating the value of certain items and services that can diminish the impact of injuries or health conditions and reduce avoidable emergency and healthcare utilization. In light of these findings, CMS intends to expand the scope of the primarily health related supplemental benefit standard. Congress similarly gave MA plans the authority to offer expanded supplemental benefits that have a reasonable expectation of improving or maintaining the health or overall function of chronically ill enrollees and that may not be limited to being primarily health related benefits, as part of the Bipartisan Budget Act of 2018 (Pub. L. No. 115-123, Sec. 50322).

We strongly support CMS's proposed expansion of the health related supplemental benefit standard to include items and services that diagnose, prevent, or treat an illness or injury, compensate for physical impairments, act to ameliorate the functional/psychological impact of injuries or health conditions, or reduce avoidable emergency and healthcare utilization. We have previously encouraged CMS to offer beneficiaries greater opportunity to access health-related services.³ We agree that such health-related items and services can be best managed to most effectively meet a beneficiary's needs when they are identified and ordered or provided by a collaborating team of health providers as part of a care plan. While these services largely exist outside the four walls of a provider setting or the traditional concept of "healthcare", they can be as—if not more—integral to a beneficiary's successful achievement of health and well-being than any traditional medical intervention. We believe providers increasingly recognize the need for these health-related services among their patients and can readily build them into a more broadly-defined plan of care when given the freedom and support to do so. For these reasons, as CMS develops additional guidance related to the availability of these supplemental benefits, we strongly encourage CMS to adopt the broadest approach possible.

Enhanced Disease Management (EDM) for Dual Eligible Special Needs Plans (D-SNPs) and Institutional Special Needs Plans (I-SNPs)

Over the past several years, CMS has sought to improve care coordination and enhance the experience of care for beneficiaries, particularly those that are a part of the SNP population. We agree with CMS that specialized, targeted care through enhanced disease management programs is one way to achieve this goal. We therefore support CMS's proposal to allow D-SNPs and I-SNPs to offer the EDM supplemental that is benefit currently available to Non-SNP MA plans.

MA Uniformity Flexibility and Segmented Service Area Options

We support CMS's proposal to permit MAOs, beginning in 2019, to: reduce cost sharing for certain covered benefits; offer specific tailored supplemental benefits; and offer lower deductibles for enrollees that meet specific medical criteria, provided that all enrollees who meet the identified criteria are treated the same. We believe the proposed flexibilities would promote greater availability of plan offerings that are better tailored to the needs of various

³ See, e.g., our letter to CMS regarding the *Request for Information: Innovation Center New Direction*, Nov. 20, 2017.

beneficiary segments and would encourage enrollees to seek the most effective coverage for their needs. If this proposal is finalized, however, we encourage CMS to monitor MAOs' proposed plan benefit and cost-sharing designs closely to ensure that the new flexibility does not result in unintended consequences or beneficiary harm. Specifically, as CMS recognizes, flexibility will need to be implemented hand-in-hand with enforcement of the prohibition on discrimination.

Ascension also supports CMS's proposal to allow MA plan benefits to vary by segments. We believe that, like the uniformity flexibility proposal, this initiative would promote more targeted benefit design options for beneficiaries who enroll in MA. Again, we encourage CMS to ensure that this policy is not used to undermine program non-discrimination requirements.

Rewards and Incentives for Completion of a Health Risk Assessment (HRA)

Enrollee health risk assessments (HRAs) are an important tool for plans to manage their enrollees' care and develop diagnosis data that is important to the implementation of appropriate care planning and in terms of how CMS pays plans. Allowing plans to offer enrollees incentives when they complete HRAs will likely lead to the increased use of these tools. We anticipate that this will, in turn, allow for earlier and more comprehensive detection of chronic or latent disease and improved treatment of same. At the same time, CMS previously noted that there is a potential for misuse of risk assessments in order to maximize beneficiary risk scores and associated financial benefit.⁴ We therefore encourage CMS to monitor for such behaviors, in order to balance the inherent benefit of this tool against the threat of improper utilization, so as not to diminish the usefulness or availability of HRAs in the future.

Transparency and Timeliness with Prior Authorization Processes

We appreciate CMS's reiteration that plans should be transparent and provide adequate notice of any coverage restrictions, such as prior authorization (PA) requirements, to providers and enrollees, and plans should make PA request forms available and easily accessible. Any opportunity to improve transparency for beneficiaries and ease administrative burdens can help ensure timely access to services, which can in turn have a significant impact on health outcomes.

Improving Drug Utilization Review Controls in Medicare Part D

Ascension strongly supports drug utilization review (DUR) that can successfully identify individuals at risk for opioid abuse and allow for intervention in ways that can prevent a downward spiral of abuse, addiction, and possibly even drug poisoning death. There must be a careful balance of the review process and interventions in place to ensure that access to pain medications is not impeded where there is a true medical need for them. As such, we support CMS's proposed DUR policy, as we believe it maintains access to pain management for Medicare beneficiaries who are in true need of pain relief without adding unnecessary or onerous burdens for providers. We support automatic exemptions for patients receiving palliative care, with a terminal illness, or who are in hospice care. Ascension also supports universal coverage of safer topical medications to treat pain in the Medicare population. Because of increasing evidence of adverse effects of systemic pain medications, topical

⁴ See Advance Notice of Methodological Changes for Calendar Year (CY) 2016 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2016 Call Letter, at 139.

diclofenac and topical lidocaine should be widely available as they represent effective and safer alternatives when treating pain in the elderly population. As providers work to prescribe the minimum effective doses of opioids, we request that all sponsors limit opioid co-payments to once per month to allow for prescriptions that span fewer days or provider fewer pills; a limit of one monthly co-payment would offer patients the understanding that a new prescription could be dispensed without requiring additional cost sharing payments, should they demonstrably require additional opioids.

We appreciate CMS's efforts to balance beneficiary access to medically necessary drug regimens and reduce the potential for any unintended consequences for patients already on higher doses of opioids, such as withdrawal symptoms. We support the requirement that when establishing hard edits for cumulative daily morphine milligram equivalents (MME) that reach or exceed 90 mg, sponsors should continue to apply specifications to account for known exceptions such as hospice care; patients with terminal illness, receiving palliative care, cancer diagnoses; reasonable overlapping dispensing dates for prescription refills or new prescription orders for continuing fills; etc. All sponsors should allow a 6-12 month window of time for patients on high dose opioids to be compassionately and safely weaned down to 90 MME.

Ascension has previously recommended that, in addition to finalizing a discrete set of diagnoses or disease states as the bases for exemption, CMS should also consider establishing a process by which a beneficiary or their provider could seek and obtain an exemption. Such a process would allow for an exemption for patients who are not otherwise automatically exempted from a drug management program, but whose providers believe pain management is medically necessary and clinically appropriate. We therefore very much appreciate CMS's proposal that coverage determination requests seeking exceptions to the MME edit would meet the criteria for expedited review. We also appreciate CMS's position that if the only issue in dispute is the MME, the Part D sponsor is expected to rely only on prescriber attestation that the higher MME is medically necessary to approve dosing that is higher than the hard edit when a coverage determination is requested. We also appreciate that plans will not be permitted to instruct an enrollee who is requesting coverage that only their prescriber can initiate the request and that edits should not impede access to buprenorphine for medication-assisted treatment (MAT).

Finally, we support CMS's decision to align with clinical guidelines from the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (CDC Guideline) for plan year 2019. We encourage CMS to continue aligning clinical guidelines with the CDC Guideline in future years, as most prescribers are aware of and generally seek to conform to those guidelines in their own practices. Choosing clinical guidelines that are already widely known and accepted will help reduce burden on providers by creating greater consistency across various coverage programs.

Access to Medication-Assisted Treatment

We agree that it is imperative to ensure Medicare beneficiaries have appropriate access to MAT. We support and appreciate CMS's decision to not approve PA criteria that require a beneficiary to need an authorization any more frequently than once during a plan year and to carry over authorizations from one plan year through to the next.

Conclusion

Ascension thanks you for the opportunity to comment on these issues. If you have any questions, please contact Mark Hayes, Senior Vice President for Federal Policy and Advocacy at 202-898-4683 or mark.hayes@ascension.org.

Sincerely,

A handwritten signature in blue ink that reads "Rev. Dennis H. Holtschneider" followed by a horizontal line.

Reverend Dennis H. Holtschneider, C.M.
Executive Vice President and Chief Operations Officer
Ascension