American Diabetes Association®

January 16, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Ms. Verma:

On behalf of the more than 30 million Americans with diabetes and the 84 million more with prediabetes, the American Diabetes Association (ADA) is pleased to provide the following comments and recommendations on the *Medicare Program: Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program* (CMS-4182-P) proposed rule.

The Medicare population shoulders a large portion of the diabetes epidemic in the United States. Already, an estimated 12 million Americans over age 65 (25.2 percent) have been diagnosed with diabetes.[1] Moreover, nearly half of all Americans age 65 or older have prediabetes, putting them at high risk for developing diabetes. Currently one out of every three Medicare dollars is spent caring for somebody with diabetes.[2]

Access to affordable, adequate health coverage is critically important for all people with and at risk for diabetes. When people are not able to afford the tools and services necessary to manage their diabetes, they scale back or forego the care they need, leading to costly complications and even death. The ADA supports enacting policies in Medicare to reduce the incidence of diabetes and prevent costly and devastating complications in those with the disease. We respectfully provide the following comments and recommendations to ensure the Medicare Advantage and Medicare Prescription Drug Benefit programs continue to meet the needs of people with prediabetes and diabetes.

<u>Flexibility in the Medicare Advantage Uniformity Requirements</u>

The ADA supports innovative health insurance designs, including value-based insurance design (VBID). We appreciate CMS' examples in the preamble of the proposed rule of ways Medicare Advantage (MA) plans can eliminate cost-sharing for certain benefits to enable beneficiaries with diabetes to access needed care. However, **we are concerned with CMS' proposal to increase flexibility related to the MA**

plan uniformity requirements. As discussed in the preamble of the proposed rule, CMS is currently conducting demonstrations to test various VBID models in Medicare Advantage. We strongly recommend CMS continue those demonstrations and draw upon those results to identify specific flexibilities that lead to improved health outcomes.

Standardized plans make it easier for consumers to compare plans on an apples-to-apples basis. We are concerned that CMS' move to increase flexibility in the uniformity requirements, along with the elimination of the meaningful difference plan standard, will result in consumers having to sort through many more seemingly similar MA plans with differences that are difficult to discern. *Simply put, we are worried this proposal increases the likelihood beneficiaries with diabetes will end up in a plan that does not meet their needs.*

While we support the goals of affordability, quality and access to care, we caution CMS to ensure any innovative models implemented by MA plans do not deter individuals with diabetes from obtaining needed care and that any incentive programs do not serve a proxy for discrimination against those with diabetes. We appreciate that CMS will review benefit designs to ensure the overall impact is non-discriminatory and that higher-cost enrollees are not being excluded in favor of healthier populations. We also strongly encourage CMS to ensure the marketing of any of these innovative plans targeting individuals with chronic diseases like diabetes does not provide the misleading impression that the plan is the best option for every person with that chronic disease. Interventions vary among individuals with diabetes, and therapies change over the lifespan of a person with diabetes. While tools such as primary and specialist physician services, blood glucose testing supplies, prescription drugs, diabetes self-management education and support, and medical nutrition therapy are commonly used to manage diabetes and prevent complications, each individual's specific needs will vary, which is why treatment must be patient-centered.

<u>Meaningful Differences in Medicare Advantage Bid Submissions and Bid Review</u>

The meaningful difference standard helps beneficiaries make informed comparisons between MA plans by making it easier for them to identify the way or ways in which their plan options are meaningfully different. The standard empowers consumer choice by reducing consumer confusion and making the task of plan selection more manageable. **The ADA does not support the proposal to eliminate the meaningful difference standard for MA plans and believes that, if finalized, this change would make it harder for Medicare beneficiaries to find coverage that suits their needs.**

As CMS recognizes in the preamble to the proposed rule, this change would substantially increase beneficiary confusion. Beneficiaries already face complex choices when shopping for an MA plan, particularly if they have a chronic disease like diabetes. Empirically, more choice may be detrimental if there are too many or overly complex options, particularly in high-stakes decisions that involve health or money. Beneficiaries may choose inferior options or make no choice at all as a result of cognitive

overload, anticipated regret, or bias toward the status quo.[3,4] Although a great deal of information is available, beneficiaries often have difficulty understanding its significance and using it correctly to make decisions. Most beneficiaries have difficulty correctly interpreting even simple displays of Medicare health plan information.[5] Considering this, we are encouraged that CMS is interested in improving the Medicare Plan Finder tool in an effort to mitigate these problems. However, we do not believe improving this tool will completely mitigate the potential impact of removing the meaningful difference requirement for MA plans.

Part D Tiering Exceptions

A wide array of medications and supplies are correlated with improved glycemic outcomes and a reduction in the risk of diabetes-related complications. Because no single diabetes treatment regimen is appropriate for all people with diabetes, providers and patients should have access to a broad array of medications and supplies to develop an effective treatment modality. While Medicare Part D Plan (PDP) enrollees are able to compare and choose a PDP based on whether their medications are covered under the plan, requiring PDP sponsors to provide a means through which beneficiaries can request tiering exceptions ensures continued access to needed medications. **The ADA supports the proposed changes to the regulations which help ensure beneficiaries who receive a tiering exception have access to the lowest cost-sharing available and that PDP sponsors cannot limit availability of the exception option.**

Establishing Limitations for the Part D Special Election Period for Dually Eligible Beneficiaries

The ADA is concerned by CMS' proposal to limit special election periods (SEP) for dually eligible beneficiaries. While dually eligible beneficiaries would still be provided at least one annual SEP, some beneficiaries require multiple changes in their plans throughout the year because of changes to their own medical needs, including new medications, or because of other changed circumstances or preferences, including changes to their plan's formulary or provider network. The ability of this vulnerable group to choose plans and best manage their care should not be limited.

Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS Cost Sharing

The ADA supports CMS' proposed revision to include follow-on biologic products in the definition of generics as it relates to beneficiary cost-sharing. This will ensure low-income Medicare beneficiaries have affordable access to biosimilar medications when available.

Eliminating the Requirement to Provide PDP Enhanced Alternative (EA) to EA Plan Offerings With Meaningful Differences

While the ADA supports CMS' goal of encouraging competition and plan flexibility in Part D, we are concerned about the removal of the meaningful difference requirement in Part D. As discussed in our comments regarding Medicare Advantage, the meaningful difference standard helps beneficiaries make informed comparisons between plans and empowers consumer choice by reducing consumer confusion and making the task of plan selection more manageable. Therefore, it should be maintained.

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Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at Point of Sale

The ADA supports high-quality diabetes therapies that are available and affordable for all people with diabetes. Insulin, in particular, is a unique medication, in that when it is necessary, there are no alternative therapies to preserve health and life. Unfortunately, as the cost of insulin climbs, millions of Americans with diabetes are paying a steep price to stay alive. We believe that no individual in need of life-saving medications should ever go without due to prohibitive costs or accessibility issues. Considering this, **the ADA supports CMS' proposal to apply both manufacturer rebates and pharmacy price concessions to drug prices at the point of sale.** While we recognize this proposal could result in modestly higher premiums for PDP enrollees, premiums are only one factor in determining Medicare beneficiary costs – particularly for individuals with chronic diseases like diabetes. If beneficiaries are unable to afford the cost-sharing requirements for needed medications, their prescription drug coverage is rendered useless. Using the reduced prescription drug price savings to lower plan premiums disparately impacts the beneficiaries who need costly medications by shifting the full cost burden to them. The ADA supports CMS' efforts to reduce Medicare beneficiaries with diabetes' prescription drug cost-sharing burdens by ensuring they have access to the lowest possible negotiated price for their medications.

Beneficiary Outreach and Education

While many of the changes CMS has proposed will add flexibility for plans, it will also add complexity for beneficiaries. This includes eliminating the meaningful difference requirement for plan offerings in both Medicare Advantage and Part D; giving plans more leeway in benefit design; and limiting the availability of SEPs for dually eligible beneficiaries. As CMS has noted, studies show that many beneficiaries are already overwhelmed and report that they feel unable to make a choice.

In proposing these changes, CMS has expressed confidence that improvements in the Medicare Plan Finder will help beneficiaries to navigate the new complexities. We appreciate that CMS is developing Plan Finder enhancements and ask that they be thoroughly tested with SHIPs and beneficiaries. Further, we urge CMS to ensure that those enhancements are implemented before any rule changes and before beneficiaries are confronted with even more difficult choices. Beneficiary choice is meaningless if beneficiaries do not have the tools to reasonably exercise that choice.

At the same time that CMS is proposing significantly more flexibility for plans, it also is proposing to eliminate the continuous SEP for dual eligibles and beneficiaries who qualify for the Low Income Subsidy (LIS), and replace it with a confusing set of limited SEPs. These restricted SEPs will be complicated to communicate to beneficiaries, and will lead to confusion about when and whether a beneficiary can change plans. Older adults and people with disabilities who use LIS do not have the financial resources to weather any disruption or denial of care. When plan design becomes more complex, and beneficiaries experience passive and default enrollments, those who qualify for LIS need the protections that a

continuous SEP can provide. Furthermore, they need enrollment procedures that they can easily understand.

The ADA strongly encourages CMS to consider beneficiary impact before finalizing any of these proposed changes, and to implement a robust outreach and education initiative to ensure the changes are fully understood by beneficiaries.

We appreciate the opportunity to provide our comments on the proposed Medicare Advantage and Medicare Prescription Drug Benefit Program proposed rules. If you have any questions please contact Krista Maier, JD, Vice President, Public Policy, at 703-253-4365 or KMaier@diabetes.org.

Sincerely,

LaShawn McIver, MD, MPH
Senior Vice President, Government Affairs & Advocacy
American Diabetes Association

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[1] Centers for Disease Control and Prevention. National Diabetes Statistics Report: Estimates of Diabetes and Its Burden in the United States, 2017. Atlanta, GA: U.S. Department of Health and Human Services; 2017.
[2] Centers for Medicare and Medicaid Services. Medicare Health Support Overview. Baltimore, MD: Centers for Medicare and Medicaid Services. Available at: http://www.cms.gov/ccip.downloads/overview_ketchum_70116.pdf
[3] Quincy L and Silas J, The Evidence is Clear: Too Many Health Insurance Choices Can Impair, Not Help Consumer Decision Making, Consumers Union, November 2012. Available at: http://consumersunion.org/wp-content/uploads/2012/11/Too_Much_Choice_Nov_2012.pdf
[4] McWilliams JM, Afendulis CC, McGuire TG and Landon BE, Cognitive Functioning and Choice between Traditional Medicare and Medicare Advantage Health Affairs, September 2011. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3513347/)
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