American Association
of Diabetes Educators

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VIA ELECTRONIC SUBMISSION: http://www.regulations.gov

September 27, 2019

Administrator Seema Verma
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1715-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1715-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2020; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program, etc.

Dear Administrator Verma:

The American Association of Diabetes Educators (AADE) appreciates the opportunity to offer comments in response to the *Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2020 Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program, etc.* Proposed Rule (CMS-1715-P) as published in the *Federal Register* on August 14, 2019 (the "Proposed Rule").

AADE is an interdisciplinary association of healthcare professionals dedicated to integrated clinical and self-management as a key component in the care of people with diabetes and related chronic conditions. AADE represents over 14,000 diabetes care and education specialists including nurses, nurse practitioners, PAs, dietitians, pharmacists, exercise specialists, and others. AADE has a vast network of clinicians working with people who have, are affected by, or are at risk for diabetes. Our response to the Proposed Rule is detailed below.

Chronic Care Remote Physiologic Monitoring (RPM) Services

AADE was pleased to see CMS finalize reimbursement and provide clarification surrounding supervision requirements for the newly created CPT codes describing remote physiologic monitoring (RPM) treatment management services (CPT code 99457 and the new add-on code 994X0). RPM provides new opportunities for care management and improves outcomes in diabetes management and treatment. AADE hopes CMS continues to update payment policies to reflect the availability and use of new technology in the delivery of care.

Addressing Barriers to Diabetes Self-Management Training (DSMT)

AADE wishes to express our disappointment that CMS did not address the known barriers that prevent Medicare beneficiaries from utilizing the Medicare Diabetes Self-Management Training (DSMT) benefit. AADE remained hopeful that CMS would address these barriers in the Proposed Rule, especially given the ongoing conversations among AADE, CMS, and other stakeholders. Despite the undisputed benefits of DSMT for people with diabetes – lower hemoglobin A1C, weight loss, improved quality of life, healthy coping skills and reduced healthcare costs – only an estimated 5 percent of Medicare beneficiaries with newly diagnosed diabetes use DSMT services.[12] AADE has articulated our concerns to CMS and outlined barriers and proposed solutions in our CY 2017 Medicare Physician Fee Schedule proposed rule comments, as well as through our comments in subsequent years, additional written communications, and in-person meetings. Specifically, AADE and other stakeholders within the diabetes community are asking both Congress and CMS to address the barriers to DSMT by making the following changes to the benefit:

- Allow the initial 10 hours of DSMT to remain available until fully used;
- Cover an additional 6 hours of DSMT services during the first year and in subsequent years, if medically necessary;
- Permit DSMT and Medical Nutrition Therapy (MNT) services to be covered when provided on the same day;
- Exclude DSMT services from Part B cost-sharing and deductible requirements;
- Permit physicians and qualified nonphysician practitioners working in coordination with a treating physician or qualified nonphysician to refer for DSMT services;
- Revise the Medicare Benefit Policy Manual to ensure that hospital outpatient departments can provide DSMT services in community-based locations; and
- Establish a 2-year demonstration program for the coverage of virtual DSMT under the Medicare program.

AADE implores CMS to take action on these barriers, as approximately 25 percent of Americans age 65 and older have diabetes.[3] We look forward to continued dialogue with CMS on ways in which we can improve access and health outcomes for Medicare beneficiaries with diabetes.

Medicare Diabetes Prevention Program (MDPP) Expanded Model- Recommended Program Modifications

AADE supports the progress that CMS has made in the first year of the Medicare Diabetes Prevention Program (MDPP), while recognizing that additional actions must be taken to increase the number of organizations enrolling as MDPP suppliers, as well as the number of Medicare beneficiaries who utilize this benefit to prevent or delay type 2 diabetes. AADE hopes that CMS will prioritize the following modifications to support the ongoing success and national expansion of the MDPP.

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[1] American Diabetes Association. Standards of Medical Care in Diabetes–2017. *Diabetes Care* 2017; 40 (Suppl.1): S3
[2] Strawbridge LM, Lloyd JT, Meadow A, et al. Use of Medicare's diabetes self-management training benefit. *Health Education Behavior* 2015; 42: 530-8.

[3] https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

Allowing virtual programs to participate in MDPP

AADE hoped the establishment of a virtual MDPP pilot would be included in the Proposed Rule, as referenced in the CY 2017 Medicare Physician Fee Schedule final rule. AADE strongly supports Medicare coverage of CDC-recognized lifestyle change programs and believes that the availability of virtual programs will increase access and utilization for those unable to participate in an in-person program for 12-24 months. This directly aligns with CMS' focus on addressing the social determinants of health, as the populations who could most benefit from virtual MDPP include Medicare beneficiaries living in rural areas, those who are unable to readily access transportation in urban areas to attend in-person sessions, and those that face other factors, such as poverty and mobility impairments that present barriers to accessing the new MDPP benefit.

In-person MDPP suppliers simply do not have the capacity to serve millions of Medicare beneficiaries. Allowing virtual providers to participate in MDPP will ensure that beneficiaries are able to access the MDPP in the format that best meets their needs. AADE strongly supports and is willing to assist the agency in the development of a model test of virtual MDPP services as we share the common goal of ensuring access to diabetes prevention programs for all qualified Medicare beneficiaries.

Align MDPP services with the evidence base and CDC National DPP

AADE believes it is critical for CMS to align with the CDC's Diabetes Prevention Recognition Program (DPRP) guidelines. This alignment ensures that MDPP suppliers are not faced with the challenge of having to comply with two distinct and complex standards. AADE has identified specific examples of where CMS may pursue better alignment with the DPRP and the evidence base.

- **Allow Program to be Delivered in Multiple Delivery Modes:** As mentioned above, AADE strongly advocates for the inclusion of virtual programs in the MDPP. This aligns with the CDC's DPRP guidelines. AADE notes that the CDC allows for services to be provided through different delivery modes, such as in-person, online (virtual), distance learning (telehealth), and a combination of those delivery modes.[4] As CMS looks at virtual programs, AADE urges the agency to also consider the positive impact that offering programs via telehealth, distance learning, or a combination of online and in-person programs may have in improving beneficiary access and uptake of the MDPP.
- **Weight Loss Threshold (9 percent):** AADE requests that CMS align with the DPRP on weight loss thresholds. There is no evidence to support the 9 percent weight loss threshold included in the MDPP.

Remove the Once-Per-Lifetime Limit

Requesting that CMS remove the once-per-lifetime limit for DPP is a top priority for AADE. Weight loss is a complex, challenging, and ongoing process, with individuals often needing multiple attempts to achieve their weight loss goals[5]. Medicare beneficiaries may experience life events, such as a change in

[4] https://www.cdc.gov/diabetes/prevention/pdf/dprp-standards.pdf
[5] Wing RR and Phelan S. Long-term weight loss maintenance. American Journal of Clinical Nutrition 2005; 82: 2225-2255.

health status for themselves or for a loved one, surgery, or even the death of a loved one that may impact their ability to attend MDPP sessions over 12-24 months. By retaining a once-per-lifetime limit, CMS is denying Medicare beneficiaries the benefits of this important program. AADE asks that CMS provide beneficiaries with additional opportunities to participate in the MDPP, much like Medicare coverage for obesity counseling and tobacco cessation.

Adjust reimbursement to cover reasonable costs

Adequate and appropriate reimbursement continues to be a problem for MDPP suppliers. AADE remains concerned that current MDPP reimbursement levels do not cover MDPP supplier costs. AADE asks that CMS consider a more sustainable payment structure for MDPP suppliers to support them in their efforts to provide beneficiaries with the services they need to achieve better health outcomes. Additionally, AADE asks that CMS ensure MDPP suppliers receive payment in a timely manner. This is especially important to support small, community-based programs that lack the capital to wait months to receive payments. Reimbursement challenges, delayed payments, and financial sustainability all play a significant role in the ability of MDPP suppliers to delivery services to beneficiaries.

Provide targeted solutions for special populations

AADE requests that CMS allow for targeted solutions for special populations accessing the MDPP, such as dual eligible beneficiaries. Low-income participants lose, on average, one percentage point less weight than other participants**.** Given that evidence shows that type 2 diabetes is most prevalent in underserved communities and the CDC has identified this as a priority area of DPP expansion,[6] AADE urges CMS to allow for targeted solutions, including, but not limited to, payment adjustments, for special populations.

AADE appreciates CMS' consideration of our recommended modifications to the MDPP and is a ready partner to work with the agency to identify and implement meaningful programmatic changes to support utilization of the MDPP.

Updates to the Quality Payment Program (QPP)

AADE has been closely monitoring the evolution of the Quality Payment Program (QPP) and the introduction of the Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs). AADE appreciates CMS' efforts to streamline program requirements, reduce clinician burden, and empower Medicare beneficiaries to make informed decisions about their health care. AADE supports CMS' commitment to work with clinicians and beneficiaries to achieve better outcomes, and we were encouraged to see CMS include an example of an MVP for diabetes prevention and treatment in the Proposed Rule.

As CMS develops the MVPs, AADE believes there is an opportunity to take a more comprehensive approach to how we address chronic diseases, especially diabetes management. The MVP for diabetes could include measures that look beyond measurement for A1C and address and monitor other glycemic outcomes like hypoglycemia, time in range, and glycemic variability. In addition, AADE suggests that

[6] https://www.cdc.gov/diabetes/programs/national-dpp-foa/index.html

CMS include common comorbidities like obesity, hypertension, cardiovascular disease, and chronic kidney disease when developing measures related to chronic diseases like diabetes.

AADE also urges CMS to consider the role that both the MDPP and the DSMT benefits play in supporting the diabetes prevention and treatment MVP. These programs are vital to preventing the onset of diabetes in the Medicare population, slowing the progression of the disease, reducing diabetes-related complications, and improving health outcomes, as well as the quality of life for Medicare beneficiaries.

In particular, AADE recommends the inclusion of measures that evaluate outcomes related to referrals and participation in DSMT – both in-person and virtual – for Medicare beneficiaries. MVPs built across all performance categories and incentivizing health IT functionalities could serve as an important foundation to leverage the use of digital technologies in providing DSMT to people with diabetes. AADE has long advocated for expanding Medicare coverage for virtual DSMT provided through a qualified online platform, and the development of an MVP for diabetes may provide the opportunity to explore this further. As previously mentioned, in order to continue to support Medicare beneficiaries through both the MDPP and DSMT, AADE asks that CMS make the necessary changes to reduce barriers and improve access to these programs in order to fully support clinicians and beneficiaries in the delivery and availability of high-quality diabetes care.

AADE is a ready resource to support CMS as they develop MVPs, and we offer our expertise to assist. AADE looks forward to working with CMS on the future development of an MVP set for diabetes care.

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AADE appreciates the opportunity to comment on this Proposed Rule. Please contact Kate Thomas, Director of Advocacy, by phone at 312-601-4821 or via email at kthomas@aadenet.org should you have any questions regarding AADE's comment letter.

Sincerely,

Charles Macfarlane, FACHE, CAE, Chief Executive Officer

Leslie E. Kolb, RN, BSN, MBA, Chief Science and Practice Officer