



Connected **for Life**

September 6, 2022

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Attention: File Code CMS-1770-P

Submitted via www.regulations.gov

Re: Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts

Dear Administrator Brooks-LaSure,

The American Diabetes Association (ADA) is pleased to submit comments in response to the Medicare Physician Fee Schedule (PFS) proposed rule for Calendar Year 2023, published in the Federal Register on Friday, July 29, 2022.

About ADA

The ADA is a nationwide, nonprofit, voluntary health organization founded in 1940 and made up of persons with diabetes, healthcare professionals who treat persons with diabetes, research scientists, and other concerned individuals. The ADA's mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. The ADA, the largest non-governmental organization that deals with the treatment and impact of diabetes, represents the 133 million individuals living with diabetes and prediabetes, and has more than 500,000 general members, 15,000 health professional members, and more than one million volunteers. The ADA also reviews and authors the most authoritative and widely followed clinical practice recommendations, guidelines, and standards for the treatment of diabetes¹ and publishes the most influential professional journals concerning diabetes research and treatment.²

¹ American Diabetes Association: Standards of Medical Care in Diabetes 2022, Diabetes Care 45: Supp. 1 (January 2022).

² The Association publishes five professional journals with widespread circulation: (1) Diabetes (original scientific research about diabetes); (2) Diabetes Care (original human studies about diabetes treatment); (3) Clinical Diabetes (information about state-of-the-art care for people with diabetes); (4) BMJ Open Diabetes



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The ADA takes a considerable interest in Medicare physician payment system rules, as diabetes is a complex, chronic illness that requires continuous medical care, oftentimes from a wide variety of providers.³ It is of great importance to us to ensure the viability of the many practicing providers, and the related public health programs who touch our community. We would like to further thank the Centers for Medicare and Medicaid Services (CMS) for its continued attention to the deeply rooted health inequities in our healthcare system, which profoundly impact the diabetes population.

Below are a set of issues included in the CY 2023 Medicare PFS proposed rule that we consider most important to the interests of people with diabetes and prediabetes. The ADA looks forward to working with the agency on these proposals as it moves forward to finalize the rule.

Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (p. 45885)

As noted in the CY 2023 proposed rule, CMS is proposing to implement the telehealth provisions in the Consolidated Appropriations Act of 2022 (CAA, 2022) via program instruction or other sub-regulatory guidance to ensure a smooth transition after the end of the COVID-19 public health emergency (PHE). These policies extend certain flexibilities in place during the PHE for 151 days after the PHE ends. The ADA remains supportive of allowing telehealth services to be furnished in any geographic location and in any originating site setting, including the beneficiary's home; and allowing certain services to be furnished via audio-only telecommunications systems.

The ADA is pleased that CMS continues to recognize that telehealth has been especially important for Medicare beneficiaries who may experience mobility limitations, live in rural areas and may otherwise be financially or physically unable to receive the care they need in-person at a doctor's office at a given time. The PHE proved that care management flexibility is simply good public policy and helps provide access for those who need it most. We remain committed to working with the agency as it moves forward to making permanent the related telehealth policies.

Request for Information (RFI): Medicare Potentially Underutilized Services (p. 45941)

More people in the United States have diabetes today than ever before – and prevalence rates continue to rise. As noted above, more than 133 million Americans live with diabetes

Research & Care (clinical research articles regarding type 1 and type 2 diabetes and associated complications); and (5) Diabetes Spectrum (review and original articles on clinical diabetes management).

³ American Diabetes Association, Standards of Medical Care in Diabetes – 2018, Diabetes Care, January 2018, available at: http://care.diabetesjournals.org/content/41/Supplement_1

or prediabetes,⁴ which constitutes 37% of the U.S. population; 27.5% of Medicare fee-for-service beneficiaries had a diagnosis of diabetes in 2019.⁵ Diabetes, including prediabetes, is the most common underlying chronic condition in the U.S. – 98% of adults with type 2 diabetes have at least one comorbid chronic condition⁶ and 90% have at least two – all too often leading to life-threatening events like stroke, amputation, and end stage renal disease.

The burden of rising diabetes rates falls disproportionately on low-income communities, historically underserved Americans, and people of color. Diabetes prevalence among minority groups is nearly twice as high as it is for white Americans.⁷ Much of this is because the social, economic, and environmental factors that put people at a higher risk for developing diabetes are especially pervasive in America’s communities of color. Zip code, educational opportunity, and socioeconomic status often dictate how far someone lives from the nearest grocery store, whether they have access to healthy foods, and whether they have quality health care nearby, putting needed resources out of reach for many of those among us who need them most.

Below we highlight various diabetes-related management programs, along with suggested policy solutions that CMS may want to consider in future rulemaking.

The Medicare Diabetes Self-Management Training Benefit (DSMT)

The ADA’s *Standards of Medical Care in Diabetes (Standards)*, updated annually by a committee of U.S. experts in diabetes care, is the gold-standard for professionals in the medical field and includes vital new and updated practice guidelines to care for people with diabetes and prediabetes. The *Standards* shares information on how positive health behaviors and maintaining psychological well-being are foundational for achieving diabetes treatment goals and maximizing quality of life. Essential to achieving these goals is facilitating behavior change and well-being to improve health outcomes through diabetes self-management education and support (DSMES). High quality DSMES has been shown to improve patient self-management, satisfaction, and glucose results.⁸

DSMT is the Medicare benefit for DSMES services. In 2010, Medicare administrative and claims files were used to determine DSMT utilization among individuals diagnosed with

⁴ “Estimates of Diabetes and Its Burden in the United States” https://www.cdc.gov/diabetes/data/statistics-report/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fdiabetes%2Fdata%2Fstatistics%2Fstatistics-report.html, *National Diabetes Statistics Report 2020*

⁵ Centers for Medicare & Medicaid Services Office of Minority Health Data Snapshot, November 2021 “Diabetes Disparities in Medicare,” Chronic Conditions Data Warehouse:

<https://www2.ccwdata.org/web/guest/medicarecharts/medicare-chronic-condition-charts>

⁶ <https://www.tandfonline.com/doi/full/10.1185/03007995.2016.1168291>

⁷ ADA, “Statistics About Diabetes.”

⁸ American Diabetes Association: *Standards of Medical Care in Diabetes 2022*, Diabetes Care 45: Supp. 1, p.S60, (January 2022).

diabetes. Despite the supportive evidence of successful health outcomes for individuals following DSMES services and programs, only approximately 5% of Medicare beneficiaries with newly diagnosed diabetes used DSMT services.⁹

In its 2021 “Report to Congress on Leveraging Federal Programs to Prevent and Control Diabetes and Its Complications,” the National Clinical Care Commission (Commission) outlined recommendations to reduce administrative barriers to DSMT.¹⁰ The ADA was pleased to collaborate with the Commission on its report, and to provide our insights throughout its multi-year process. The Commission highlighted that Medicare DSMT is a prime example of how policies governing diabetes management programs unintentionally exacerbate health disparities. They acknowledge that since diabetes is primarily managed by individuals with diabetes, their families, and caregivers, exposure to DSMT can help them make better care decisions.¹¹ Unfortunately, because federal policies present barriers to the availability and appropriate use of DSMT, disparities based on race (lower for non-whites), health status (lower for those with comorbidities)¹², and in rural areas (limited access to accredited programs) have emerged. Indeed, 62% of rural counties lack any DSMT programs.¹³

Overall simplification in the way the DSMT benefit is regulated would be an ideal first step to ensuring that more people with diabetes on Medicare would learn about the program in the first place. The ADA recommends the following programmatic changes to help eliminate the barriers affecting the uptake of DSMT.

- **Expand the types of providers who can prescribe DSMT.** One way to ensure more people living with diabetes learn about DSMT services would be to expand the type of healthcare providers who would be able to write a prescription for the DSMT benefit. A substantial percentage of people with diabetes, especially those with type 2 do not see a Medical Doctor (MD) or a Doctor of Osteopathic (DO) Medicine for their diabetes. The ADA recommends that CMS expand the list of providers who would be able to write a prescription for their patients to receive DSMT services to include any physician (MD/DO), nurse practitioners, or physician assistants. This

⁹ Strawbridge, Larisa M, et al. Use of Medicare's Diabetes Self-Management Training Benefit. *Health Educ Behav.* (August 2015), <https://pubmed.ncbi.nlm.nih.gov/25616412/>.

¹⁰ <https://health.gov/sites/default/files/2022-01/NCCC%20Report%20to%20Congress.pdf>

¹¹ Strawbridge LM, Lloyd JT, Meadow A, Riley GF, Howell BL. One-year outcomes of diabetes self-management training among Medicare beneficiaries newly diagnosed with diabetes. *Med Care.* Apr 2017;55(4):391-397. doi:10.1097/MLR.0000000000000653

¹² Strawbridge LM, Lloyd JT, Meadow A, Riley GF, Howell BL. Use of Medicare's diabetes self-management training benefit. *Health Educ Behav.* Aug 2015;42(4):530-538. doi:10.1177/1090198114566271

¹³ Rutledge SA, Masalovich S, Blacher RJ, Saunders MM. Diabetes Self-Management Education Programs in Nonmetropolitan Counties - United States, 2016. *MMWR Surveill Summ.* Apr 28, 2017;66(10):1-6. doi:10.15585/mmwr.ss6610a1

would bring to bear the reality of the many providers who are regularly treating members of the diabetes community.

- **Update the requirement that the number of hours of initial training be completed in a group setting.** Medicare requires that 9 of the 10 hours of initial training be provided to a beneficiary in a group setting.¹⁴ We recommend that there be more flexibility in the number of hours an individual may seek one-to-one training. For many people with diabetes, their diagnosis is a confidential matter which they would like to keep private. Having the opportunity to work directly with an educator would likely allow for candid conversations leading to long-term behavior changes. Additionally, for those individuals receiving their initial 10 hours of DSMT, the ADA recommends allowing the rollover of unused hours in first year, along with 2 hours in the subsequent year.

In the context of quality recognized DSMT services, we recommend that the diabetes care and education specialist (DCES), formerly diabetes educator, be allowed to determine the most appropriate scenario for treatment delivery. It would also be helpful for the DCES providing the direct support, to be able to amend, with supporting documentation, what the prescribing provider has included in the referral. There is oftentimes a lengthy and cumbersome back and forth between the prescriber and the DCES if changes need to be made, which lead to considerable delays in program delivery. Seeking treatment for a health condition on one's own is difficult enough and pursuing that treatment privately for more than the allotted one hour annually would provide beneficiaries greater value for these necessary services.

- **Allow for DSMT and Medical Nutrition Therapy (MNT) programs to provide treatment to beneficiaries on the same day.** CMS regulations do not allow for beneficiaries to receive covered DSMT and MNT services on the same day. These services are distinct, yet related programs, often offered by the same service entity. Prohibiting a beneficiary from receiving them simultaneously only deepens the inequities that already exist for many individuals who lack adequate transportation, those who may live in rural areas, or those who are unable to take consistent time away from work.
- **Allow for audio-only services.** We recommend that CMS make permanent the ability for DSMT to be provided in an audio-only format. The expanded use of telehealth through audio-only communication technology provides expanded treatment options for those who may be low-income, elderly, and lack access to

¹⁴https://www.ihs.gov/medicalprograms/diabetes/homedocs/resources/instantdownloads/dsmt_guidebook_508c.pdf

other forms of telecommunication, such as internet service.

- **Streamline reimbursement of DSMT and MNT services to track diabetes outcomes by home health providers.** When an individual with diabetes on Medicare receives treatment at their home for another condition, their diabetes is often discussed. For example, a home health provider might stay for an extra 15 minutes to review the patient’s insulin regimen or teach the patient about hypoglycemia. Unfortunately, there is no way for CMS to track these data for diabetes-related outcomes measures. More specifically, a home health provider would be unable to use the G0108 code¹⁵ for individual DSMT services since all services provided need to be filed under a code for home health. Further, the home health provider is unable to submit a reimbursement code for the diabetes care they provide to the patient. We recommend that CMS create an additional reimbursement code for diabetes care within the home healthcare setting in order to capture important data for people with diabetes, as well as increase reimbursement opportunities for home health providers.
- **Create an online repository to track total hours for DSMT, DPP, MDPP.** As our healthcare system continues to move toward full interoperability, we recommend the creation of a comprehensive online warehouse to track total hours used annually for all diabetes management programs, including but not limited to, DSMT, DPP, MDPP and MNT. This patient-centered approach empowers the beneficiary and their care team (specifically the referring provider and educator) to be able to better track the number of hours they have utilized for diabetes management at the time of diagnosis, and for subsequent years. The ADA would welcome the opportunity to assist the agency with this work, should it choose to move forward with this endeavor.

Medicare Diabetes Prevention Program (MDPP)

The MDPP expanded model is a structured intervention program that aims to prevent or delay the onset of type 2 diabetes among eligible Medicare beneficiaries diagnosed with prediabetes. It is an expansion of the Centers for Disease Control and Prevention’s (CDC) National Diabetes Prevention Program (National DPP) model test. The ADA recommends that the MDPP be made permanent and should provide additional flexibilities for individuals with prediabetes who seek the benefits of taking part in the MDPP. We believe that CMS, through its suppliers, should make the program as accessible as possible and increase alignment with the CDC’s National DPP.

Further, more changes need to be made to the MDPP for it to reach its full potential. The CY 2022 Medicare Physician Fee Schedule proposed rule acknowledged that at the time more

¹⁵ https://www.cdc.gov/diabetes/dsmes-toolkit/pdfs/Participating-Medicare-DSMT-Coverage-Guidelines-11-20-17_508tagged.pdf

than 1,000 organizations nationally were eligible to become MDPP suppliers, but only 27 percent of them were actually participating. Based on an analysis of National Health and Nutrition Examination Survey (NHANES) data, an estimated 16.4 million people are eligible for MDPP¹⁶; and yet, to date, only approximately 3,600 beneficiaries are participating¹⁷. Further, an evaluation of the MDPP from the Center for Medicare & Medicaid Innovation in 2021, found that more than 74% of MDPP beneficiaries were female, white, non-Hispanic, and between the ages of 65 to 74 years old; hardly representative of the diverse population of Medicare beneficiaries with diabetes. The ADA posits that one of the main reasons for these low levels of participation in the program has to do with the difficulty in becoming an MDPP Supplier. While the ADA is grateful for the increased payments that CMS included in the CY 2022 PFS Final Rule¹⁸, the process to become a supplier remains cumbersome and challenging, especially as a smaller community organization. Even once an organization does become a supplier, it continues to be difficult to manage the uniqueness of Medicare billing. Even large health care systems who already bill Medicare for other services choose not to become a supplier because of the low return on investment. This is cumbersome logistically and financially and is further exacerbated by the fact that most suppliers are small, local community organizations, YMCAs, or county health departments, who must be nimble to subsist in the first place.

- **MDPP Once-Per-Lifetime Set of Services and Expansion of Virtual Services.** The ADA is supportive of lifting the “once in a lifetime” limit on participation in the MDPP and expanding coverage to include virtual delivery. There are several reasons why an MDPP beneficiary might need to suspend service, whether it is related to an 1135 waiver event, or simply a normal life event (e.g., an illness or injury for the individual or a family member, caring for grandchildren, or having to return to work). To ensure better success, the ADA supports relaxing the guardrails around the “once-per-lifetime set of services” to allow a beneficiary to re-start the program from the beginning at a time that is more amenable to them. As we are all aware, readiness to change can occur multiple times in one’s life.

The ADA is aware of a participant at one of its affiliate sites (note: all the ADA’s affiliate sites are part of the cooperative agreement with CDC, and others are working to become MDPP suppliers soon) who had been attending sessions regularly and was making good progress, but then her husband became critically ill. Between hospital stays and the additional responsibility of being caregiver to her

¹⁶ [Number and Characteristics of US Adults Meeting Prediabetes Criteria for Diabetes Prevention Programs: NHANES 2007–2016 \(springer.com\)](https://www.springer.com/journal/11148/issue/11)

¹⁷ Evaluation of the Medicare Diabetes Prevention Program – First Annual Report: <https://innovation.cms.gov/data-and-reports/2021/mdpp-firstannualrpt>

¹⁸ The Centers for Medicare & Medicaid Services, Medicare Physician Fee Schedule Final Rule CY 2022, Federal Register Vol. 86, No. 221, November 19, 2021: <https://www.govinfo.gov/content/pkg/FR-2021-11-19/pdf/2021-23972.pdf>, p. 65318

husband, the participant had to drop out of the program. After her husband passed away, the participant was interested in returning to the program, recognizing its benefit, and was able to begin again, because the service was covered as part of the cooperative agreement. It is important to note that if this specific site were already an MDPP affiliate site, this individual would not have been able to restart the program, due to the “once-per-lifetime” limitation. It is, of course, important for there to be guardrails around the program to discourage fraud, waste, and abuse, but the ADA believes that the stringent “once-per-lifetime” rule limits the program’s accessibility and penalizes those who have urgent, competing demands for their time.

Further, while no two behavioral intervention programs are entirely analogous, Medicare does cover “up to two quit attempts per year” for tobacco cessation programs.¹⁹ Further, the ADA supports that all MDPP sessions, including the first core session, may be offered virtually. The ADA further supports the flexibility of allowing MDPP suppliers to obtain weight measurements from beneficiaries through the following methods: (1) in-person; (2) via digital technology, such as “Bluetooth™ enabled” scales; or (3) self-reported weight measurements from an at-home digital scale via video, as it will allow for continued active and likely expanded engagement by beneficiaries.

(e) Developing Quality Measures That Address Amputation Avoidance in Diabetic Patients Request for Information (p. 46282)

The ADA welcomes the opportunity to share our clinical expertise on the potential adoption and modification of an existing Medicare quality measure, or the development of a new quality measure to address the prohibitive amount of amputation rates in people with diabetes, and the devastating – and often unnecessary – impacts it has on the broader population of people living with diabetes.

To address this crisis, the ADA will soon be launching a multi-year partnership with clinical experts, innovators, health foundations, and other leaders in the diabetes community to disrupt the curve of unnecessary amputations among low-income and minority individuals with diabetes. To that end, we are grateful to be aligned with the agency on such an important pursuit, and we look forward to sharing what we learn and accomplish as we embark on this crucial work.

¹⁹ [Tobacco Cessation Treatment: What Is Covered? | American Lung Association](#)

Today in the United States, a person with diabetes has a limb amputated every 4 minutes²⁰ and that rate is 75 percent higher than what it was less than a decade ago. . Diabetes is the single greatest factor in amputations: more than 60 percent of non-traumatic lower-limb amputations happen in the diabetes population²¹. An individual who has had an amputation has a worse chance of 5-year survival than someone with coronary artery disease, breast cancer and colorectal cancer); 85 percent of diabetes-related amputations are preventable.

While the ADA does not have to convince CMS of the drastic implications of these statistics, we do feel it is important to continue to highlight their prevalence. Every American with diabetes should have access to the care they need to prevent diabetes-related amputations, as well as high quality care should they develop a diabetic foot ulcer, peripheral artery disease (PAD), neuropathy, or critical limb ischemia (CLI). As noted in the proposed rule, amputations in the United States are substantially more prevalent among people of color. In the Black community, an individual is up to four times more likely to undergo an amputation than whites, while Native Americans face amputations more than twice as often.²² Exceedingly high rates of amputation amongst communities of color is one of the reasons why ADA launched its Health Equity Now campaign²³ in 2020 and published the related [Health Equity Bill of Rights](#) – a set of principles, which continue to guide our ongoing efforts to tackle the systemic barriers to health and health care that persist in our country today.

CMS is seeking feedback on the following questions to understand, account for, and address challenges that may be experienced during development, testing, and implementation of the process measure. ADA is providing the following responses:

- **Are neurological and vascular assessments, and the determination of risk the most important care processes in the prevention of foot ulceration among individuals with diabetes?**
 - **ADA Response:** While we may not think of neurological and vascular assessments and the related determination of risk the most important care

²⁰ Centers for Disease Control and Prevention, National Diabetes Statistics Report, 2020.

<https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf>

²¹Walicka, Magdalena; Marta Raczyńska; Marcinkowska, Karolina; Lisicka, Iga ; Czaicki, Arthur; Wierzba, Waldemar; Franek, Edward. “Amputations of Lower Limb in Subjects with Diabetes Mellitus: Reasons and 30-Day Mortality,” Journal of Diabetes Research: <https://pubmed.ncbi.nlm.nih.gov/34350296/>

²² Holman, Kerianne; Henke, Peter; Dimick, Justin; Birkmeyer, John: “Racial Disparities in the Use of Revascularization Before Leg Amputation in Medicare Patients,” Journal of Vascular Medicine; August 2011: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3152619/>

²³ American Diabetes Association, “#HealthEquityNow,” <https://www.diabetes.org/healthequitynow>; American Diabetes Association, “Health Equity Bill of Rights,” https://www.diabetes.org/sites/default/files/2020-08/Health%20Equity%20Bill_2nd_v2.pdf.

processes in the prevention of foot ulceration among people with diabetes, we do agree that they are important assessments to be performed. We draw your attention to a recent *Health Affairs* article from July 2022, which highlights that “despite the evolution in diabetes care quality measurement in the US, there has been no commensurate improvement in the health of people with diabetes.”²⁴ The article cites a recent population-based study from 2015–2018, where just 21 percent of US adults with diabetes achieved diabetes management goals for HbA1c, blood pressure, and low-density lipoprotein control.²⁵ Further, data from the CDC show that rates of hard diabetes-related outcomes, including atherosclerotic cardiovascular disease, lower extremity amputation, and other acute and chronic complications, have not improved meaningfully since 2015.²⁶ This, along with the uneven access to care for people of color and those with lower means leads to poor outcomes like PAD, neuropathy and CLI, among others, for people with diabetes.

The RFI specifically asks whether the agency should work to expand the existing Merit-based Incentive Payment System (MIPS), diabetes quality measures, or create new ones. The 2022 MIPS Quality Measures include two foot-related care related measures:

1. **Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation** (National Quality Forum (NQF) number: 0417): Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months.
2. **Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear** (NQF number: 416): Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing.

While both measures noted above are important, we recommend that the agency create measures that encompass all aspects across the continuum of amputation prevention. In doing so, we suggest adding “regular” neurological and vascular assessments to demonstrate the importance of ongoing examination and reevaluation. Therefore, distinct measures, each with appropriate populations in the denominator, would understand and track the following:

²⁴ David H. Jiang, Patrick J. O’Connor, Nathalie Huguet, Sherita Hill Golden, and Rozalina G. McCoy, “Modernizing Diabetes Care Quality Measures,” *Health Affairs*, July 2022

²⁵ Wang L, Li X, Wang Z, Bancks MP, Carnethon MR, Greenland P, et al. Trends in prevalence of diabetes and control of risk factors in diabetes among US adults, 1999–2018. *JAMA*. 2021;326(8):704–16.

²⁶ Centers for Disease Control and Prevention. United States Diabetes Surveillance System [Internet]. Atlanta (GA): CDC; 2022 [cited 2022 May 19]. Available from: <https://gis.cdc.gov/grasp/diabetes/DiabetesAtlas.html>

- Prevention
- Evaluation and Potential Specialty Referral
- Follow-up

Having distinct measures allows for a two-pronged approach of 1-evaluating risk factors of getting a foot wound and 2-understanding risk factors for limb threat and thus addressing secondary and tertiary prevention of amputation by addressing infections and foot ulcers. The overarching goal of these measures should be to ensure that an actual amputation should be used as a last resort and should not occur without employing other preventive measures throughout other phases of care.

We encourage CMS to incorporate guidelines for all practitioners who care for people with diabetes (this includes specialists like endocrinologists, as well as general practitioners, family physicians, physician assistants, and nurse practitioners, among others) on how to perform basic 3-minute foot checks on their patients with diabetes. Additionally, providers should be teaching their patients how to monitor their feet at home in between appointments.

- **Once a process quality measure concept would be fully developed and implemented, would high performance on the measure contribute to a reduction in diabetes-related LEA? Why or why not?**
 - **ADA Response:** While high performance on a process measure could contribute to a reduction in diabetes-related LEA, CMS should be mindful that the continuum of care requires regular monitoring from the clinical staff as well as cooperation from the patient for general diabetes and blood glucose control measures. Diabetes is the most expensive chronic disease in the United States, and 61% of diabetes costs come from Americans 65 years or older, the Medicare population²⁷.

Similar to what the *Health Affairs* article points out, currently there are no quality measures that evaluate quality of life for diabetes or people living with diabetes-related amputations. A recent systematic review of Patient Reported Outcome Measures (PROMs) for Major Lower Limb Amputation caused by PAD or diabetes also demonstrates that such a measure does not currently exist²⁸. Therefore, we recommend CMS convene with ADA and

²⁷ American Diabetes Association. Economic costs of diabetes in the US in 2017. *Diabetes Care*. 2018; 41:917–928

²⁸ Miller R, Ambler GK, Ramirez J, Rees J, Hinchliffe R, Twine C, Rudd S, Blazeby J, Avery K. Patient Reported Outcome Measures for Major Lower Limb Amputation Caused by Peripheral Artery Disease or Diabetes: A Systematic Review. *Eur J Vasc Endovasc Surg*. 2021 Mar;61(3):491-501. doi: 10.1016/j.ejvs.2020.11.043. Epub 2020 Dec 30. PMID: 33388237.

other stakeholders to understand the unique challenges of this patient population. Amputation immeasurably affects the patient, their families, as well as their ability to work. As Dr. Foluso Fakorede states, “For people with diabetes, amputations lead to permanent disability, high rates of chronic pain and depression, and sometimes the loss of the ability to be productive in society.”²⁹

- **Once a process quality measure concept would be fully developed and implemented, would clinicians be able to report performance without undue burden? Why or why not?**
 - **ADA Response:** Burden can be reduced via templates in Electronic Health Record systems. However, we recommend technical assistance be available to support and improve any infrastructure and data needs. Most importantly is understanding which physician would be responsible for the measure. Due to diabetes’ complex care management, primary care physician, non-physician practitioners, endocrinologists, vascular surgeons, and podiatrists all play key roles in amputation prevention efforts.

It should be noted that while we are aware that CMS is requesting information specifically related to quality measures in MIPS, we would be remiss if we did not highlight the fact that MIPS remains an underutilized and unpopular program within the physician community. Given the fact that 27.5% of Medicare fee-for-service beneficiaries live with diabetes, we would like to highlight our support for creating a separate quality measure outside of the confines of the MIPS program, should the agency choose to go in that direction, in order to reach as many patients as possible.

We recommend that these quality measures and efforts also work with Medicare Advantage plans, Managed Care Organizations, states, Medicaid, and applicable waivers, and as well as work with the CMS Innovation Center (CMMI) on innovative ways to improve quality of care. For example, the ACO Reach model providers a waiver such that a nurse practitioner can certify the need for diabetic shoes, when the nurse practitioner is practicing incident to the physician supervising the beneficiary³⁰. Additionally, *Health Affairs* reviewed value-based care for diabetes³¹ which should be considered when understanding the landscape of quality measures.

²⁹ <https://www.niddk.nih.gov/health-information/professionals/diabetes-discoveries-practice/reducing-disparities-in-diabetic-amputations>

³⁰ <https://innovation.cms.gov/media/document/aco-reach-rfa>

³¹ Wang S, Weyer G, Duru OK, Gabbay RA, Huang ES. Can alternative payment models and value-based insurance design alter the course of diabetes in the United States? *Health Aff (Millwood)*. 2022;41(7).

- **Once a process quality measure concept would be fully developed and implemented, should performance be measured at the clinician level or group level? Is the measure appropriate for all clinicians? If not, to whom should the measure apply?**
 - **ADA Response:** ADA appreciates this thoughtful question. Individual measurements are crucial for a patient; however, group reporting can show patterns of improvement and effectiveness. The more types of providers able to report, the higher likelihood of preventing amputations for a diabetic patient.

- **What would be the benefits and/or unintended consequences of the process quality measure concept?**
 - **ADA Response:** We caution that providers are required to report multiple quality measures across different payers. However, the benefit includes monetary incentives for physicians. The best approach involves clinical staff who can also perform certain measures. The patient benefits from more care, and the physician is reimbursed for their time. Again, the measures should evaluate the continuum of care, not just screening.

- **Would a process quality measure concept contribute to health equity? Why or why not?**
 - **ADA Response:** We recommend that there be a new quality measure that is specifically focused on health inequities. We caution that specific quality measures may not paint the entire story for the quality of care an individual receives. For example, some patients are referred to specialists knowing that they have diabetes, and quality measures do not equate that to increased access to care, particularly in rural or under-served areas. Additionally, quality measures do not address social determinants of health (SDOH) in which a person with diabetes may not seek care due to lack of transportation, lack of trust in the system, or lack the health literacy to understand how to manage their diabetes at home. The ADA urges CMS to incentivize the use of a broader team-based approach, which may be more effective than the measures themselves. It is additionally important to support broad infrastructure changes to the healthcare system and technical assistance for federally qualified health centers. Specifically, health equity for amputations can be achieved through quality measures coupled with SDOH consideration, flexibilities that support the diabetes community, PAD screening, proper reimbursement to the appropriate clinical staff (particularly for revascularization services for office-based specialists who often serve patients in the most need), and little to no cost-sharing for at-risk patients.

The information noted above is also applicable to section **(B) Request for Information on Risk Indicators Within Complex Patient Bonus Formula to Continue to Align with CMS Approach to Operationalizing Health Equity** (p.46318) in the CY 2023 PFS proposed rule. The ADA believes that the examples and suggestions noted above relate to this RFI, as well, since health literacy and SDOH are applicable both across the continuum of care for diabetes and for preventing diabetic LEA.

CMS may also consider the development of a composite quality measure. A composite measure is a measure that combines two or more individual measures and yields a single score. Composite measures are intended to capture information about complex, multidimensional care processes. Within the context of diabetes and LEA, a composite measure may include individual measures focused on A1C control, cardiovascular risk factors (such as blood pressure control, tobacco non-use), peripheral neuropathy screening, PAD screening, evaluation of footwear, medical imaging, and screenings, and offloading when ulcers occur. CMS requests the following feedback:

- **Would the single measures comprising the composite be appropriate? Why or why not?**
 - *ADA Response:* We advise that the individual measures within of the composite measure involve a team-based approach. Therefore, a composite quality measure is not appropriate at this time. For example, a podiatrist may not check A1c levels, but may receive lab test results from other clinical staff. Similarly, a primary care physician may not know what other tests or diabetic shoes are appropriate for a patient.
- **Once a composite quality measure concept would be fully developed and implemented, would high performance on the measure contribute to a reduction in diabetes related LEA? Once a process quality measure concept would be fully developed and implemented, should performance be measured at the clinician level or group level? Would the measure be appropriate for all clinicians? If not, to whom should the measure apply? Once a quality measure concept would be fully developed and implemented, would clinicians be able to report performance without undue burden? Why or why not? What would be the benefits and/or unintended consequences of a composite quality measure concept?**
 - *ADA Response:* Again, a composite measure may be burdensome and may only benefit larger health systems and hospitals in which all specialists are located in the same building and share the same electronic health record system. Similar to a process quality measure, screening and follow up must

occur regularly since the needs and health of these at-risk patients change regularly. While data reporting is important, CMS should be cognizant of the healthcare workforce's already busy schedule.

- **Would a composite quality measure concept contribute to health equity? Why or why not?**
 - **ADA Response:** We do not recommend a composite quality measure which may exacerbate disparities in diabetic LEA. In addition to quality measures, health equity in diabetic LEA involves increased awareness, updating clinical guidelines, training clinicians to screen properly and involving a multidisciplinary care team. The prevalence of diabetes is projected to increase in 55 million people by 2060.³² Therefore, the time to act is now, and quality must measure across the continuum of care and involve a intersectionality framework.

Conclusion

The American Diabetes Association appreciates the opportunity to submit comments on the CY 2023 Medicare Physician Fee Schedule. On behalf of the community of 37 million Americans with diabetes, we appreciate the attention that CMS is paying to ensure that access to quality healthcare is broad and even.

We stand ready to provide assistance to the agency as it updates and develops new proposals for individuals with diabetes and prediabetes. Should you have any questions or seek additional information regarding these comments, please reach out to Laura Friedman, Vice President, Regulatory Affairs at lfriedman@diabetes.org.

Sincerely,



Robert A. Gabbay, MD, PhD
Chief Scientific & Medical Officer

³² Mohebi R, Chen C, Ibrahim N, et al. Cardiovascular Disease Projections in the United States Based on the 2020 Census Estimates. *J Am Coll Cardiol.* 2022 Aug, 80 (6) 565–578.
<https://doi.org/10.1016/j.jacc.2022.05.033>