

**RFI Due 11/04**

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## **Tell Us About Yourself**

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### **TOPIC 1: Accessing Healthcare and Related Challenges**

More people in the United States have diabetes today than ever before – and prevalence rates continue to rise. More than [133 million Americans](#) live with diabetes or prediabetes, which constitutes 37% of the U.S. population; 27.5% of [Medicare](#) fee-for-service beneficiaries had a diagnosis of diabetes in 2019. 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 condition 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 these rising diabetes rates falls disproportionately on low-income communities, historically underserved Americans, and people of color. Diabetes prevalence today among minority groups is nearly twice as high as it is for white Americans. 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.

Diabetes is the [most expensive chronic disease](#) in the United States, and Americans with diabetes spend two and a half times more on health care than those who do not have diabetes. Further, people with diabetes account for \$1 in every \$3 spent on prescription drugs, and 25 cents of every dollar spent on health care, in America today. While we are pleased that the [Inflation Reduction Act of 2022](#) placed a cap on the cost of insulin for Medicare beneficiaries, there is more work to be done to ensure patients with Medicaid, private insurance, or with no insurance are offered equitable accessibility to this life-sustaining medication. As recently as October 2022, the *Annals of Internal Medicine* published a study sharing that [1.3 million individuals are rationing their insulin](#).

The ADA continues to focus its attention on the following policies to ensure medicines and insurance coverage are accessible and affordable for our population and we welcome the opportunity to work with the agency on these important topics below.

- Increasing transparency throughout the pharmaceutical supply chain, including efforts to shed light on pricing practices, to improve accountability in the pharmacy benefit manager (PBM) market, and to ensure that middleman rebates are being shared with and otherwise directly benefiting patients.
- Speeding competitive generic drug and biosimilar alternatives to market by, among other things, addressing loopholes in our patent system that allow manufacturers to stave off competition.
- Cracking down on insurance practices that push patients to choose between quality and affordability, including prior authorization and step therapy (or “fail first”) policies that force patients to try the least expensive drug in a class first, even if their prescribing physician believes a different therapy is in the patient’s best clinical interest.
- Increasing oversight and regulation of specialty drug tiers used by insurers that shift the cost-sharing burden disproportionately onto patients with rare and/or chronic conditions who rely on these medications, or worse yet, keep vital therapies economically out of reach for those who need them.

***Promote Uptake of Diabetes Management Programs in Medicare***

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 the Diabetes Self-Management Training (DSMT) Benefit. 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, and [exposure to DSMT](#) can help them make better care decisions. 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), and in rural areas (limited access to accredited programs) have emerged. Indeed, 62% of [rural counties](#) lack any DSMT programs. 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 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](#). 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 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 code](#) 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.

## **TOPIC 2: Understanding Provider Experiences**

ADA recommends the following CMS policies and program initiatives that could support provider well-being and increase provider willingness to serve certain populations.

### ***Provide equitable reimbursement for Medicaid (Cross-cutting among all topics, especially health equity)***

Unfortunately, Medicaid often reimburses less than Medicare. The Kaiser Family Foundation [Medicaid to Medicare Fee Index](#) demonstrates disparities in reimbursement. For example, Medicaid programs in Rhode Island paid physicians at 32% of Medicare fees in 2019 for primary care services, yet Alaska reimbursed at 110% the same year. Fee gaps between Medicare and Medicaid exist particularly in primary care. In turn, doctors may not see a Medicaid patient or participate in Medicaid due to low reimbursement. Without investing in primary care, providers then only see patients when they are critically ill and extreme intervention measures are needed. Medicaid and CHIP Payment and Access Commission ([MACPAC](#)) notes similar findings in which physicians were significantly less likely to accept new Medicaid patients, and acceptance of Medicaid and Medicare insurance varies by specialty.

Despite wanting to “do no harm,” policies and reimbursement rates often prevent providers from delivering the best care to their patients. Repeatedly, the ADA hears about reduced access to patient care due to punitive reimbursement, coverage policies, or prior authorization barriers. Anecdotally we have heard some providers state that a diabetes-related amputation is the most “cost-effective” measure for reimbursement, yet the patient, their family, and friends experience the significant toll of mental, physical, and emotional stress.

### ***Align Quality Measures to Promote Care Coordination***

In a recent [survey](#) of people living with diabetes, despite diabetes being the leading cause of amputations, 65 percent of those surveyed said they believed they were not at risk for amputation and just 1 in 4 of those surveyed understood the signs and symptoms of conditions that can lead to an amputation such as peripheral neuropathy, peripheral artery disease (PAD) or critical limb ischemia (CLI).

A recent Health Affairs [article](#) from July 2022 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. Additionally, currently there are [no quality measures](#) that evaluate quality of life and shared-decision making for diabetes care 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 exist.

We caution that specific quality measures may not paint the entire story for the quality of care an individual receives, yet provider payment is tied to those quality measures. For example, some patients are referred to specialists knowing that they have diabetes, and quality measures do not show or measure that 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. Particularly, we urge CMS to work with ADA so that measures accurately evaluate the (1) prevention, (2) evaluation and potential specialty referral, and (3) follow-up for pre-diabetes and diabetes patients. Preventing diabetes-related amputations is multi-factorial, and can be achieved through the following: accurate quality measures, SDOH considerations, flexibilities that support the diabetes community, proper screenings for PAD and CLI, proper reimbursement to the appropriate clinical staff (particularly for revascularization services for office-based specialists who often serve patients in the most need), proper reimbursement for Diabetic Foot Ulcer (DFU) care, and little to no cost-sharing for at-risk patients. It is imperative that these patients are seen by the appropriate, highly trained, and highly qualified health professionals who can provide the preventative care necessary to avoid

amputations through earlier interventions, including accessing services performed by a podiatrist.

***Promote culturally and linguistically competent care, particularly through training for providers and increasing the health literacy of patients.***

[Approximately 1.4 million](#) Americans are newly diagnosed with diabetes each year; the number diagnosed has doubled in the last 20 years. Even more staggering are the disparities seen within the diabetes community; African Americans and Hispanics are [50% more likely](#) to have diabetes than non-Hispanic Whites.

Diabetes prevention and intervention is a team-based approach, including the patient. 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. Empowering patients helps build trust and is fundamental for improving health literacy for a patient.

We urge CMS to promote training regarding health disparities, cultural competence, and implicit bias to strengthen patient-provider relationships, which in turn can improve health outcomes.

***Make patient and claims data accessible and understandable in a timely manner to reduce workforce burden. Note to CMS: This is cross-cutting with Topic 3: Advancing Health Equity. However, we urge the agency to understand how data affects providers.***

Providers handle patients with different types of insurance. Providers may participate in various Alternative Payment Models (APMs). However, APMs vary in payment structure, incentives, and financial risks. Value-based care rewards quality, but demonstrating improved health outcomes relies on data, technology infrastructure, workforce and workflow improvements, and processes for accurate reporting.

Despite value-based care efforts, even providers participating in APMs must report different measures to various systems, creating additional burdens for an already overburdened population of providers. For example, providers must report and provide different outcomes to private payers and for Medicaid fee-for-service (FFS) beneficiaries in states with managed care organizations. While CMS would like all Medicare beneficiaries in an accountable care relationship by 2030, providers are expected to operate in both an alternative payment and FFS world. Requiring providers to report different quality measures to multiple sources further burdens the workforce. It is especially difficult for smaller provider practices, rural providers, and safety-net providers to participate in APMs. These providers may not have the additional administrative staff, or the technological infrastructure built into their operations to stay in regulatory compliance, which may change annually. Further, any incentive payments

that physicians may receive may still not cover general costs, particularly as practices face inflation, making this an unlikely opportunity for investment. Many practices continue in a loop where any generated savings still only cover illness in their patient population. In turn, many providers are unable to invest savings into system-wide wellness, preventive practices, and upstream value-based strategies.

The ADA urges CMS to prioritize its Meaningful Measures Initiative, which aims to streamline quality measurement across payers, and work with Office of the National Coordinator for Health Information Technology (ONC) to promote interoperability and advance health equity.

### **TOPIC 3: Advancing Health Equity**

*Note to CMS: We strongly urge CMS to consider all recommendations across topics to address health equity. We urge the agency to center health equity in Medicare and Medicaid policies to reduce barriers to enrollment, coverage, and access.*

#### ***ADA and Health Equity***

The COVID-19 health pandemic and its disproportionate toll on minority, low-income, and historically underserved Americans has shined a troubling light on historic, systemic inequities in American health care. In 2020, the ADA published [The Health Equity Bill of Rights](#), which envisions a future without unjust health disparities. It ensures the 133 million Americans living with diabetes and prediabetes, along with the millions more who are at high risk for diabetes – no matter their race, income, zip code, age, education, or gender – get equal access to the most basic of human rights: their health.

The right to avoid preventable amputations is a centerpiece of the ADA's Health Equity Now platform, and in September 2022, the ADA launched its latest initiative to tackle health inequities in our community – the [Amputation Prevention Alliance](#). [Every three minutes in America, a limb is amputated due to diabetes](#) and the Alliance seeks to reduce the tens of thousands of unnecessary, diabetes-related amputations that take place every year and make amputations a last-resort option for Americans.

Unfortunately, amputations are on the rise in the United States. There [were over 154,000 diabetes-related amputations](#) that took place in the United States last year – a 75% increase in just a decade; and even worse, rates of amputations are significantly [higher among minority communities](#). Black Americans are [four times more likely to have an amputation](#) than a non-Hispanic white American. LatinX communities are 50 percent more likely to have an amputation and Indigenous communities face amputations rates that are two times higher than those among non-Hispanic white Americans.

An amputation [significantly reduces a person's quality of life](#), and an individual who has had an amputation has a worse chance of five-year survival than someone with coronary artery disease, breast cancer, and colorectal cancer.

Every American with diabetes should have access to the care and treatment they need to prevent diabetes-related amputations, and the appropriate health care professionals

should they develop a Diabetic Foot Ulcer (DFU), peripheral artery disease (PAD), neuropathy, or critical limb ischemia (CLI). This includes proper coverage of services and flexibilities for the types of healthcare professionals that can provide such services. For example, access to podiatrists allows patients receive appropriate care and avoid unnecessary diabetes-related amputations through earlier interventional and often cost-effective treatments.

Unfortunately, policy barriers can impede provider participation and ultimately affect patient care. As President Biden states in his [2022 Proclamation on National Diabetes Month](#), “Health care should be a right, not a privilege.”

Amputation prevention begins with screening interventions. Minimally invasive procedures are now available for at-risk patients that can help improve blood flow and ultimately save limbs and lives. Additionally, most amputations are preceded by a DFU, which with the application of new evidence-based therapeutics can in many cases be healed. But the reality is that these procedures are not covered widely enough by government insurance programs, severely restricting their potential benefit.

***ADA recommendations for how CMS can promote efficiency and advance health equity through policies and programs for amputation prevention.***

1. Cover earlier screening and interventions for DFU, PAD, and CLI

We urge CMS to appropriately cover and reimburse for DFU treatments and revascularization for patients with diabetes, those most at risk for preventable amputations. For example, Medicare beneficiaries who are Black are three times more likely to receive an [amputation](#) than those who are white; and Latino beneficiaries are twice as [likely](#). Decreased reimbursement rates for lower extremity revascularizations done in labs (Codes: 37225-37221) only further increase amputation rates for individuals of color with diabetes, deepening existing health inequities.

2. Align meaningful quality measures

We encourage Congress to work with ADA and other stakeholders to understand the unique challenges for people living with diabetes and with diabetes-related amputations, and quality measures alone may not evaluate if there are improvements in patient health outcomes. The overarching goal of quality measures should ensure that amputations occur only as a last resort. Please see our comments under topic 2 (provider experiences) for more information.

3. Incentivize and reimburse a team-based approach across the entire healthcare team

Diabetes care and amputation prevention involves a team-based approach, and patients often see any number of providers, including general practitioners, podiatrists, physician assistants, community health workers, endocrinologists, interventional cardiologists, and vascular surgeons. For example, the [ACO Reach](#) model allows 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 beneficiary. The agency is also understanding how community health workers are trusted voices and advocates for patients. In the more recent final rule for the CY 2023 Physician Fee Schedule ([CMS-1770-F](#)), CMS is considering ways to incorporate community health workers into Medicare Part B service payments. These types of flexibilities for the entire health team help close the gaps in health disparities for the patient.

#### **TOPIC 4: Impact of the COVID-19 Public Health Emergency (PHE) Waivers and Flexibilities**

Between February and May of 2020, a disproportionately high [40% of Americans](#) who died of COVID-19 had diabetes, though the condition affects [10% of the U.S. population](#). Further, among patients hospitalized with severe COVID-19 complications, 39.7% also had diabetes as an underlying medical condition. The percentage increased to [46.5% for patients 50 to 64](#). The impact that COVID-19 has had on the diabetes population is staggering, and we are grateful to CMS for its leadership and decision making in expanding access to diabetes care, management, and devices through telehealth flexibilities during the PHE. The agency's quick action ensured that Medicare beneficiaries living with diabetes and prediabetes were able to receive accessible and uninterrupted treatment and guidance from their health care providers via telehealth communications. We are grateful to the agency for finalizing a policy in the CY 2023 Medicare Physician Fee Schedule (PFS), which extend certain flexibilities initially put in place during the PHE, for 151 days after the PHE ends.

As noted in the ADA's CY 2023 PFS comments, we remain 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. In particular, we support allowing Medicare beneficiaries to continue to use telehealth appointments with their providers to meet coverage requirements for diabetes technology like insulin pumps, continuous glucose monitors (CGM) and supplies. 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. It is our hope that CMS does not pull back the expanded access to and coverage of telehealth services after the PHE period has ended, and we remain committed to working with the agency as it moves forward to making permanent the related telehealth policies.

#### ***Broad Access to Diabetes Technology***

One way to address gaps in coverage is by addressing the technology access differences between more affluent white Americans and underserved populations with diabetes who are typically low-income, older people of color. Expanding access to diabetes management technologies – like CGM and insulin pumps – in both Medicare

and Medicaid are one way to help underserved people better manage their diabetes, and prevent adverse health outcomes or even premature deaths.

We appreciate the many flexibilities that were put in place during the PHE for people with diabetes to be able to have continued access to their diabetes management technology and devices. One of the first PHE flexibilities made permanent by the Durable Medical Equipment (DME) Medicare Administrative Contractors (MACs) was the requirement that a beneficiary use a blood glucose monitor (BGM) and perform frequent testing—four or more times a day—to qualify for coverage of a continuous glucose monitor (CGM).

The ADA had strongly supported the initial flexibility to remove this requirement and then to advocate for its permanent removal from the CMS local coverage determination (LCD), stating that it would better align Medicare coverage criteria for CGMs with peer-reviewed clinical evidence and standards of practice recommended by our organization. As we get closer to winding down the PHE, the ADA strongly urges you to consider beneficiaries with diabetes who received access to a CGM during this period to continue to have permanent access to their CGMs. Many of these beneficiaries have now realized the benefits of these devices and we want to make sure they are able to continue to use them, which may have been helpful in providing them with the extra tools they need to manage their diabetes.

We raise for your attention the October 2022 proposed LCD by the DME MACs to make further changes to CGM coverage criteria under Medicare. The ADA is supportive of the following proposed changes below to the criteria and looks forward to continuing to work with the DME MACs and CMS more broadly on ways to make diabetes technology more accessible to our population.

- The removal of the requirement that a beneficiary with diabetes take “multiple daily administrations” of insulin to be eligible for a CGM, replacing it with a once-daily requirement.
  - We suggest one minor adjustment to this provision, which may make it even more straightforward for people who are taking insulin. We recommend the statement be written as: “the beneficiary is treated with insulin,” which would take into consideration the once-weekly insulins that are nearing FDA consideration.
- The removal of the requirement that a beneficiary frequently adjusts their insulin treatment regimen to be eligible for a CGM.
- The addition that the visit with a practitioner in the 6 months prior to ordering a CGM, as well as the 6-month follow-up visit may now happen via telehealth.
- The addition of “Problematic Hypoglycemia” as an acceptable diagnosis for coverage.

### ***Real-time continuous glucose monitoring (CGM) in the inpatient hospital setting***

While we are aware that this topic is outside CMS’ purview, we flag for your attention the ADA’s recommendation that patients using diabetes devices like a CGM, which

provides frequent measurements of glucose levels as well as direction and magnitude of glucose trends for better management of an individual's diabetes and better outcomes, should be allowed to use them in an inpatient setting when appropriate supervision is available. The FDA provided a waiver for inpatients to be able to use their CGM device while in the hospital during the PHE. Even though CGM has advantages over point-of-care glucose testing in detecting and reducing the incidence of hypoglycemia, it has not been approved by the FDA for inpatient use. We encourage this to be made permanent.