August 22, 2023

The Honorable Martin Heinrich
Chairman, Joint Economic Committee
U.S. Senate
709 Hart Senate Office Building
Washington, D.C. 20510

The Honorable David Schweikert
Vice Chairman, Joint Economic Committee
U.S. House of Representatives
460 Cannon House Office Building
Washington, D.C. 20515

Dear Chairman Heinrich and Vice Chairman Schweikert:

On behalf of the undersigned member organizations of the Diabetes Advocacy Alliance (DAA), we are pleased to submit comments to the Joint Economic Committee (JEC) in relation to the Committee's hearing that occurred on July 27, 2023, entitled "The Economic Impact of Diabetes." We believe we have useful information to share with you and your staffs as you move forward following the hearing.

The DAA is diverse in scope, with our members representing patient, professional and trade associations, other non-profit organizations, and corporations, all united to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked with legislators and policymakers to increase awareness of, and action on, the diabetes epidemic.

DAA members share a common goal of elevating diabetes on the national agenda so we may ultimately defeat this treatable, but deadly chronic disease. We are committed to advancing person-centered policies, practical models, and legislation that can improve the health and well-being of people with diabetes and prediabetes. Our advocacy to policymakers highlights key strategies to prevent, detect and manage diabetes and care for those affected by it. Our educational outreach also illustrates the health equity implications of existing or new policies, regulations, and legislation, and provides alternatives to address the drivers of these inequities.

Thank you, Chairman Heinrich, and Vice Chairman Schweikert, the members of your committee, and your staff members, for hosting this hearing on the costs of diabetes. The DAA appreciated the depth, breadth, and urgency of the discussion during the hearing and the passion for this topic expressed by the Members who were present. We agree with Rep. Ferguson that "diabetes is the cruelest and one of the most underrated diseases in America."

Background and details are provided in the sections, below, in which we elaborate on several specific topics covered in the hearing, as well as some that were not, and include these and several other recommendations to further advance diabetes care and prevention in the United States.

Here is a summary of our top recommendations. We strongly urge the Committee to work with Congress to:

Improve Prevention of Diabetes

- Expand Medicare coverage of MNT services to patients with prediabetes or obesity.
- Support reintroduction of and pass the **PREVENT DIABETES Act** [H.R. 2807, S. 2173], which would require CMS to permit participation in the Medicare Diabetes Prevention Program (MDPP) by online suppliers that have achieved CDC's Diabetes Prevention Recognition Program (DPRP) recognition. (CDC defines online suppliers as those that include "100% online delivery of sessions with multiple opportunities for live lifestyle coach interaction.")
- Pass the **Treat and Reduce Obesity Act (TROA)** (H.R. 4818; S. 2407), which improves Medicare coverage for intensive behavioral therapy for obesity and directs CMS to cover anti-obesity medications.

Improve Treatment and Care of Diabetes

- Encourage and support states continuous glucose monitoring (CGM) coverage policies to match those of Medicare.
- Remove cost-sharing requirements for the Medicare Diabetes Self-Management Training (DSMT) benefit to align with other preventive benefits.
- Pass the **Special Diabetes Program Reauthorization Act of 2023 (**H.R.2550; S.1855), which reauthorizes the Special Diabetes Program (SDP) and the Special Diabetes Program for Indians (SDPI) for a full two-years (FY 24 and 25) plus extends funding through calendar year 2025.

Improve Prevention, Detection, and Treatment/Care of Diabetes through Research

- Continue to fund diabetes research through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH).

Improve Prevention of Diabetes

Medical Nutrition Therapy

The DAA appreciated that Rep. Malliotakis raised the importance of Medical Nutrition Therapy (MNT), an important educational service for people with diabetes. Currently, Medicare Part B coverage for MNT is only for a beneficiary who has diabetes or kidney disease or has had a kidney transplant within the past 36 months, and a physician referral. Medicare does not currently cover MNT for prediabetes or obesity even though early intervention of MNT can successfully lower the risk of progression to diabetes in these individuals.

The American Diabetes Association (ADA), in its *Standards of Care in Diabetes – 2023*, states that "MNT is one of the services...that are essential for achieving diabetes treatment goals and maximizing quality of life." (Page S68). The ADA recommendations state that that individuals with diabetes should be referred for individualized MNT provided by a Registered Dietitian Nutritionist (RDN) who is knowledgeable and skilled in providing diabetes-specific MNT at diagnosis and as needed throughout the lifespan, similar to DSMES." (p.S70.) The ADA goes on to say that MNT, delivered by an RDN, "is associated with absolute A1C decreases of 1.0-1.9% for people with type 1 diabetes and 0.3-2.0% for people with type 2 diabetes." (p.S70-71)

The American Medical Association also includes MNT as an evidence-based treatment intervention for patients diagnosed with prediabetes in its Prediabetes Quality Measures.

Yet, uptake of MNT by people with diabetes is very low. The CY 2022 Medicare Physician Fee Schedule reported that between 2018-2020, participation of MNT utilization among Medicare beneficiaries was less than two percent. While the benefit has undergone policy changes aimed at increasing beneficiary utilization of MNT, barriers still exist. Lack of Medicare coverage of MNT services for beneficiaries with prediabetes or diabetes coupled with a lack of awareness of MNT by both patients and referring physicians have contributed to low utilization of MNT services. **We strongly urge the Committee to work with Congress to:**

- Expand Medicare coverage of MNT services to patients with prediabetes or obesity.
- Fund and direct HHS to create an Awareness campaign for when and how to refer these patients to MNT in accordance with state scope of practice provisions.
- Improve transparency regarding access to MNT and nutrition care services for all Medicare beneficiaries, including those who are receiving care through Medicare Advantage (MA) plans. As MA plan participation increases, more data collection is needed to capture utilization of nutrition-related services beyond the Part B benefit.

Strategies to Prevent or Delay Disease Onset

The population of U.S. adults with prediabetes, many of whom will go on to develop type 2 diabetes, is huge, estimated to be 96 million by the Centers for Disease Control and Prevention (CDC). With no intervention, millions of these adults will go on to develop type 2 diabetes and add to the total population of people with diabetes in the U.S, currently estimated to be 37 million. These individuals will likely develop one or more of the costly health complications of the disease.

Multiple research studies have examined the costs of care for people who went on to develop diabetes in the years prior to their diagnosis, and compared those costs to people who did not develop diabetes. **These studies underscore the importance and cost saving potential of preventing the onset of type 2 diabetes**:

- In an article published in *Population Health Management* in February 2021, researchers reported that "the incremental rise in costs of diabetes is shown to begin at least 5 years before diagnosis of the disease and accelerate immediately after diagnosis. Results of the matching model suggest that the newly diagnosed case subjects spent $8,941 more than control subjects not diagnosed with diabetes over the span of 5 years, with approximately $4,828 in the year of diagnosis." They go to say that their findings "support the need to encourage physicians to implement timely identification and prevention efforts to reduce the economic burden of the disease."
- In another study published in *Population Health Management* in October 2017, a research team reported that their study illustrated "how reducing the risk of developing diabetes by participation in an evidence-based lifestyle change program could yield both positive net savings on medical care expenditures and return on investment. Annual expenditures are found to be nearly one third higher for those who develop diabetes in subsequent years relative to those who do not transition from prediabetes to diabetes, with an average difference of $2,671 per year. At that cost differential, the 3-year ROI for a National DPP is estimated to be as high as 42%. The results show the importance and economic benefits of participation in lifestyle intervention programs to prevent or delay the onset of type 2 diabetes."

1. Lifestyle Change Program

Scientific and medical research has shown conclusively that type 2 diabetes can be prevented or delayed through lifestyle change programs,. These evidence-based lifestyle change programs include instruction

in what prediabetes is, nutrition and how to eat to be healthier, and how their weight and the amount of physical activity they do can affect whether they will go on to develop type 2 diabetes.

The federal government has created two frameworks for the private and nonprofit sectors to develop and implement type 2 diabetes prevention programs that are research based and have been proven to work in the real world. The National Diabetes Prevention Program (National DPP) administered by the Centers for Disease Control and Prevention (CDC), accredits private sector Diabetes Prevention Programs in all available modalities:

- Fully in-person (such as at a YMCA or other community-based organization)
- Distance learning (via synchronous "live" sessions)
- Combination of in-person and distance learning formats
- Online programs (content delivered asynchronously with available "live" interaction with a lifestyle coach).

The Medicare Diabetes Prevention Program (MDPP), currently administered as a model test by the Center for Medicare and Medicaid Innovation (CMMI) at the Centers for Medicare and Medicaid Services (CMS) through 2025, is **not equivalent** to the CDC's DPP in several important ways, including this critical difference:

- The MDPP prohibits CDC-recognized providers of online programs (as defined above) from applying to be MDPP suppliers. Under the MDPP, only organizations with an in-person accreditation may apply to supply diabetes prevention program services to Medicare beneficiaries.

The MDPP has been vastly underutilized. **According to the CDC's Evaluation of the Medicare Diabetes Prevention Program Second Evaluation Report (November 2022), "Between April 2018 and December 31, 2021, 4,848 Medicare beneficiaries participated in the MDPP, including 2,325 fee-for-service beneficiaries and 2,523 Medicare Advantage beneficiaries." (p.3)**

The DAA believes that with the following fixes through policy and legislation, Medicare's DPP can attract more suppliers and be more effectively scaled, so that more adults with prediabetes who are Medicare Beneficiaries can be served.

- Allow CDC-recognized suppliers of online programs to be suppliers of MDPP services. Currently, CMS does not permit these suppliers to apply for the MDPP despite that fact that online providers have proven to be effective modes of delivery that produce successful participant outcomes that meet or exceed those of the National MDPP quality standards and are recognized by CDC's NDPP.
- **Specifically, the DAA urges Congress to pass the PREVENT DIABETES Act [H.R. 2807, S. 2173], which would require CMS to permit online suppliers that have achieved CDC's DPRP recognition to participate in the MDPP**. DAA member representatives are working with Members of Congress to reintroduce these bills, last introduced in 2021, in the current Congress.
- Lower MDPP supplier organizations from "high" to "medium" level fraud risk. DAA members remain very concerned about CMS requirements regarding submission of social security numbers and other personally identifiable information by board members that remains one of the single greatest barriers to community-based nonprofit organizations, such as the YMCA, a DAA member, from applying for participation in the MDPP. Community-based organizations are stymied by this ongoing, burdensome requirement, which contributes to the MDPP benefit being vastly underutilized.

- Approve the MDPP as a permanent Medicare covered benefit – not only a model expansion.
- Remove the "once in a lifetime" limit on participation in the MDPP.
- Direct CMS to reduce or eliminate differences in program eligibility, delivery modalities, and duration between the National DPP and the MDPP.
- Direct CMMI to fund the testing of new payment models that allow for greater upfront payments and more equitable risk-sharing between CMS and MDPP program delivery organizations.
- Direct HHS to cover Medical Nutrition Therapy for Medicare beneficiaries with prediabetes in addition to those with diabetes.
- Fund and direct HHS to implement an Awareness campaign for physician-led care teams on when and how to refer their patients to lifestyle change interventions to prevent diabetes.
- Adopt the AMA's quality measure set for prediabetes, which includes a measure to incentivize referrals to lifestyle change interventions ("Diabetes Prevention Interventions for Patients at High Risk for Developing Diabetes"). The measure tracks the percentage of adult patients identified as high-risk for developing type 2 diabetes who were offered a diabetes prevention intervention during the measurement period.

2. Preventive Medications

The original Diabetes Prevention Program clinical trial, which concluded in 2001, included the use of the generic medication metformin, which proved effective (but less effective than the lifestyle intervention). There currently are no medications (including metformin) that the FDA has approved specifically for use in preventing or delaying the onset of type 2 diabetes.

Physicians can prescribe metformin for this purpose, but awareness is low, as is awareness of the specific populations most likely to benefit from the medication: those with prediabetes with body mass index (BMI) ³ 35, those less that 60 years old, and women with a history of gestational diabetes. According to a study in the Journal of the American Board of Family Medicine in 2022 of a large sample (n = 53,551) of people with prediabetes, only 4.1% received a prescription for metformin within 3 years post-diagnosis of prediabetes. Among the two high-risk populations for which data were available, only 3.9% of people with prediabetes less than 60 years old and 14.0% of people with BMI ³ 35 received a metformin prescription.

The American Diabetes Association (ADA) states, in its Standards of Care in Diabetes – 2023, that metformin and other drugs for diabetes "have been shown to lower the incidence (new cases) of diabetes in specific populations. (p. S44) Also, the ADA says that "several medications evaluated for weight loss (e.g., orlistat, phentermine topiramate, liraglutide, semaglutide, and tirzepatide) have been shown to decrease the incidence (new cases) of diabetes to various degrees in those with prediabetes." (p. S44) While these medications have not been approved specifically for prevention of delay of onset of type 2 diabetes, physicians may prescribe them for this purpose.

Accordingly, the DAA offers the following recommendations regarding diabetes prevention through medication:

- Fund and direct HHS to conduct an awareness campaign for prescribing metformin to prevent onset of diabetes and prediabetes.
- Pass the **Treat and Reduce Obesity Act (TROA) (H.R. 4818; S. 2407)**, which improves Medicare coverage for intensive behavioral therapy for obesity and directs CMS to cover anti-obesity medications. (*See also related content in the following section.*)

- Continue to fund Type 1 Diabetes research through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH). In November 2022, the FDA announced its approval of Tzield, a first of its kind therapeutic that can be used by people at high risk of developing type 1 diabetes. It is an important first step in type 1 diabetes prevention, and it shows the importance and promise of continued funding for basic and clinical science.

Newer Diabetes and Obesity Therapies

The DAA appreciated the recognition given during the hearing to the **importance of newer diabetes therapies**, particularly **glucagon-like peptide-1 receptor agonists (GLP-1s**), which work to lower levels of blood glucose and help people with diabetes lose weight. Since most adults with prediabetes and type 2 diabetes are people with overweight or obesity, access to the full continuum of care to treat obesity is critical for addressing diabetes prevention, treatment, and care in Medicare beneficiaries. In fact, the American Diabetes Association, in its *Standards of Care in Diabetes – 2023*, states that:

"There is strong and consistent evidence that obesity management can delay the progression from prediabetes to type 2 diabetes and is highly beneficial in treating type 2 diabetes. In people with type 2 diabetes and overweight or obesity, modest weight loss improves glycemia and reduces the need for glucose-lowering medications, and larger weight loss substantially reduces A1C and fasting glucose and has been shown to promote sustained diabetes remission through at least 2 years. Several modalities, including intensive behavioral counseling, obesity pharmacotherapy, and bariatric surgery, may aid in achieving and maintaining meaningful weight loss and reducing obesity-associated health risks." (p. S128)

Yet, even though clinical guidelines recommend treatment of obesity through intensive behavioral therapy delivered by all modalities including community, online/telephonic, pharmacotherapy, and/or surgery, Medicare does not currently cover the full spectrum of interventions for obesity – interventions that are also important to curbing cases of prediabetes and type 2 diabetes. The COVID-19 pandemic has clearly shown and reinforced the urgent need to address diabetes and obesity, as these two conditions have been shown to be major risk factors for hospitalizations and death from COVID-19.

Current CMS guidance does not permit coverage for drugs that treat obesity under Part D, on the grounds that such drugs are excluded under the Part D statute as agents "used for anorexia, weight loss, or weight gain." CMS has held this policy for almost two decades, and in the meantime the scientific understanding of obesity and how to treat it have evolved substantially. The DAA believes that the CMS Part D policy which currently denies coverage of anti-obesity medications has the unintended effect of creating and perpetuating an unnecessary gap in access to an important standard of care.

During the Committee's hearing, Rep. Moore mentioned the **Treat and Reduce Obesity Act (TROA) (H.R. 4818; S. 2407)**, which would amend title XVIII of the Social Security Act to provide for the coordination of programs to prevent and treat obesity. **The DAA strongly urges Congress to pass the Treat and Reduce Obesity Act (H.R. 4818; S. 2407) because it would:**

- Cover intensive behavioral therapy (IBT) for obesity furnished by any of the following:
    - Qualified primary care physicians and other primary care practitioners
    - A physician (as defined in subsection (r)(1)) who is not a qualified primary care physician.

    - Any other appropriate health care provider (including a physician assistant, nurse practitioner, or clinical nurse specialist (as those terms are defined in subsection (aa)(5)), a clinical psychologist, a registered dietitian or nutrition professional (as defined in subsection (vv))).
    - An evidence-based, community-based lifestyle counseling program approved by the Secretary.
    - IBT would be covered only if is furnished upon referral from, and in coordination with, a physician or primary care practitioner operating in a primary care setting, or any other setting specified by the Secretary.
    - In an office setting, a hospital outpatient department, a community-based site that complies with the Federal regulations concerning the privacy of individually identifiable health information promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996, or another setting specified by the Secretary.
- Cover obesity medication in Medicare Part D if the drug is used for the treatment of obesity or for weight loss management for an individual who is overweight and has one or more related comorbidities.

Improve Treatment and Care of Diabetes

Continuous Glucose Monitoring (CGM)
We appreciate that the importance of CGM and other new technologies was mentioned multiple times during the hearing.

The American Diabetes Association (ADA), in its *Standards of Care in Diabetes – 2023*, discusses CGM as one important component of technology now available to help people with diabetes self-manage their disease and provide important data to their health care providers to adjust their treatment therapies as may be needed. The ADA recommends that people with diabetes who use insulin daily should be offered the use of CGM (p. S115) and states that "multiple randomized controlled trials have been performed using CGM devices, and the results have largely been positive in terms of reducing A1C levels and/or levels of hypoglycemia, as long as participants regularly wore the devices." (p. S115)

In a move celebrated by DAA members, beginning April 16, 2023, CMS coverage of CGM systems changed for the better, to cover more beneficiaries, by removing a requirement that the beneficiary had to inject insulin multiple times a day.

- **The DAA recommends the Committee work with Congress to encourage and support states to improve their CGM coverage policies to match those of Medicare.**

Diabetes Self-Management Education and Support (DSMES)/Diabetes Self-Management Training (DSMT), i.e., Medicare's name for its DSMES benefit

We were disappointed that DSMES/DSMT was not covered by the committee, despite the strong evidence base for its effectiveness in the treatment of diabetes. In its *Standards of Care in Diabetes – 2023*, the American Diabetes Association states that "all people with diabetes should participate in DSMES to facilitate the knowledge, decision-making, and skills mastery for diabetes self-care." (p. S68) The ADA goes on to say that "DSMES is associated with improved diabetes knowledge and self-care behaviors, lower A1C, lower self-reported weight, improved quality of life, reduced all-cause mortality

risk, positive coping behaviors, and reduced health care costs." (p. S69) People who receive DSMES are more likely to see a primary care provider, follow treatment recommendations, and use preventive services, and less likely to use emergency rooms and in-patient hospital services. (p. S69)

Yet, utilization of DSMES/DSMT is abysmally low. The *ADA Standards of Care in Diabetes – 2023* states that "Despite the benefits of DSMES, reports indicate that only 5-7% of individuals eligible for DSMES/DSMT through Medicare or a private insurance plan actually receive it." (p. S70)

Therefore, the undersigned organizations offer the following recommendations to the Committee to increase uptake of DSMES/DSMT services:

- Remove cost-sharing requirements for the Medicare DSMT benefit to align with other preventive benefits.
- Reform the Medicare DSMT benefit to remove the 1-year timeframe for use of the initial benefit.
- Create alignment between CDC's DMSES and Medicare's DMST by allowing all forms of accredited DSMT programs to enroll with Medicare's DSMT, including virtual modalities.
- Simplify Medicare's referral criteria so physicians can easily refer all patients with diabetes to DSMT. (This would partially be accomplished under the CY2024 Medicare Physician Fee Schedule which proposes to cover A1c as a diabetes diagnostic screening test and to no longer specify the exact diagnostic criteria that must be documented for the purposes of referral to DSMT or MNT).
- Allow beneficiaries access to more than 2 hours of DSMT per year if they have a change in treatment plan that warrants extra training.
- Fund and direct HHS to implement an Awareness campaign for when and how to refer patients to DSMES/DSMT in accordance with state scope of practice provisions.

Special Diabetes Program for Indians

As we watched the hearing, we were pleased that many of the issues discussed align with priorities of the DAA. For example, the DAA recently sent a letter to Congressional Leadership in support of **reauthorization of the Special Diabetes Program (SDP) and the Special Diabetes Program for Indians (SDPI**), which was mentioned multiple times during the Committee's hearing. We appreciated the remarks of Buu Nygren, Ed.D., President of the Navajo Nation, about how the SPDI has been of benefit to his tribe, by, for example, spurring community events that encourage walking and running for physical activity, and how the program overall has helped reduce the number of new cases of diabetes and decreased diabetes-related mortality among tribal populations.

Improve Prevention, Detection, Treatment/Care of Diabetes

The Importance Ongoing Basic Science and Clinical and Translational Research

The members of the DAA encourage Congress to continue to fund diabetes research through the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) at the National Institutes of Health (NIH). According to the NIDDK's website, "The NIDDK supports basic, clinical, and translational research to combat diabetes and its associated complications. For example, NIDDK-supported researchers are:

- studying genetic and environmental factors that contribute to the development and progression of diabetes.
- studying ways to preserve insulin-producing cells of the pancreas.

- identifying new methods to improve blood glucose monitoring and insulin delivery in type 1 diabetes.
- examining behavioral approaches to prevent type 2 diabetes and to enhance diabetes self-management.
- conducting clinical trials testing new prevention and treatment strategies for diabetes and its complications; and
- uncovering the fundamental cellular and molecular pathways underlying development of diabetes and its complications to develop new approaches to prevention and management."

Over the years, for example, NIDDK/NIH funded studies have given the medical and patient communities the evidence they need to prevent or delay the onset of type 2 diabetes (The Diabetes Prevention Program randomized controlled trial) and manage blood glucose levels to prevent the serious and life-threatening complications of type 1 diabetes (The Diabetes Control and Complications Trial and many follow-up studies).

National Clinical Care Report on Diabetes Prevention and Treatment

Finally, the DAA would like to alert the Committee and its staff to an excellent resource that came from the work of a Congressionally mandated commission: The **final report of the National Clinical Care Commission**. This report, sent to Congress in January 2022, represents a thorough analysis of the depth and breadth of the state of prediabetes and diabetes today, and outlines what can be done to improve diabetes prevention, detection, treatment, and care, and ultimately reduce costs. We highly encourage the joint committee and others to review and leverage this report in their future work.

Conclusion

On behalf of the members of the DAA, we are pleased to submit this letter to the Joint Economic Committee. In an Appendix that follows, we have included information on the economic costs of diabetes and upstream causes of diabetes.

We thank you for your leadership in bringing much needed attention to diabetes and what can be done to improve care and reduce costs. If you have any questions, please contact Katie Adamson, DAA Co-Chair with the YMCA of the USA, at katie.adamson@ymca.net.

Sincerely,

Undersigned organizational members of the Diabetes Advocacy Alliance:

Academy of Nutrition and Dietetics
American Diabetes Association
American Medical Association
Association of Diabetes Care & Education Specialists
Weight Watchers (WW)
YMCA of the USA