October 16, 2020

The Honorable Diana DeGette
Committee on Energy and Commerce
Chair, Subcommittee on Oversight and Investigation
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
Committee on Energy and Commerce
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton:

The Diabetes Advocacy Alliance (DAA) is a coalition of twenty-five diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations, all united in the desire to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked to increase awareness among legislators of, and action on, the diabetes epidemic. The organizations that comprise the DAA share a common goal of elevating diabetes on the national agenda so we may ultimately defeat diabetes. The members of the DAA are pleased to submit comments related to the 21st Century Cures 2.0 concept paper. We have focused most of our comments on one question in the **Title VI: CMS Modernization** section; comments in support of other sections of the concept paper are included at the end of this letter.

- *Are the current coverage and reimbursement approaches to new medical products or other modern technologies adequate to keep up with the pace of innovation? If not, why? (Page 11 of the CURES 2.0 Concept Paper)*

In the Title VI section of the concept paper, this sentence appears on page 10: "Digital therapeutics hold hope that medical services can increase access for patients wherever they may reside." The DAA supports this concept wholeheartedly and believes CMS needs to modernize its view of this arena. In this letter, the DAA addresses 1.) the need for a more technologically up-to-date conception of "telehealth" and 2.) recommends specific innovations in virtual and community-based care. The DAA also asserts that CMS modernization must include coverage of evidence-based services, such as behavioral

counseling, that are delivered locally by community-based organizations. As national policy discussions look to bridge coverage and access gaps through technology, community-based services and digital care are powerful innovations yet to be fully utilized. Together, improved access to these two innovations could powerfully improve health outcomes for beneficiaries and lower costs for the Medicare program. Medicare coverage for evidence-based virtual prevention programs, including those that use community health workers, could substantially broaden access and reach, and improve the diversity of culturally competent preventive care services.

For example, WW International, Inc. (formerly Weight Watchers International, Inc.), a DAA member, has a healthy lifestyle and weight management program for people with type 2 diabetes that is based on a randomized controlled trial (RCT). Participants with diabetes receive the commercially available WW program combined with telephone and email consultation with a Certified Diabetes Care and Education Specialist (CDCES). Individuals in the trial showed greater improvements in glycemic control and in weight compared to participants receiving brief standard diabetes nutritional counseling.[1] Unfortunately, the program is currently not delivered in a way that is aligned with Medicare provider types and/or reimbursement rules, so while individuals in the private sector may have access to this innovative approach to diabetes management, Medicare beneficiaries do not because Medicare does not currently cover the service delivered in this manner. The DAA is concerned that CMS lacks flexibility to cover innovative diabetes technologies, as well as approaches to diabetes prevention and self-management, through reimbursed health care services.

CMS Should Expand Its Perspective, Moving from Telehealth to Digital Health

The DAA supports the broad concept of digital health – which for us includes digital therapeutics, telehealth, connected care (such as audio-only provider-patient care, medication management, and remote physiologic monitoring), and virtual behavior change and educational programs. We believe that digital health is a useful umbrella term for technology-enabled tools that can increase access to healthcare providers and services, to aid effective management for people with chronic diseases and those at risk. These tools also can give powerful engagement, health information and clinical decision support to community health workers.

While Medicare telehealth requirements have temporarily changed due to a series of waivers and flexibilities issued in response to the coronavirus public health emergency (PHE), the current definition of Medicare "telehealth" remains limited. Specifically, statutory and regulatory policies narrowly define telehealth as synchronous, two-way audio and video communication, provided by an eligible provider. To receive telehealth services, a beneficiary must meet geographic and originating site requirements. Although there are several legislative proposals to make the PHE flexibilities for the traditional (synchronous) telehealth permanent, these proposals do not extend to all

modes of healthcare services the under 65 population already benefits from, such as asynchronous care.

Accordingly, the DAA believes Congress and CMS should work together to broaden this definition, by removing geographic and originating site requirements, expanding the list of eligible telehealth providers, allowing federally qualified health centers and rural health clinics to be distant site telehealth providers, and including coverage for virtual behavior change and education programs, such as the virtual Medicare Diabetes Prevention Program (MDPP) and virtual Diabetes Self-Management Training (DSMT). The DAA also believes there is an opportunity to improve access to care by adding coverage for components of connected care, such as audio-only provider-patient care, medication management, and remote physiologic monitoring. Further, CMS must synchronize its coverage and billing rules to state law scope of practice. For example, if medication management through asynchronous technology is within the scope of practice of a nurse practitioner outside of the Medicare program, coverage for such a service provided by a nurse practitioner should also be extended to Medicare beneficiaries.

These changes, which CMS has hardly begun discussing let alone planning for, have the substantial potential to:

- Expand access, coverage and use of virtual programs, telehealth, connected care, and other services;
- Improve health outcomes for people with chronic diseases such as type 2 diabetes and health conditions such as prediabetes; and
- Reduce costs to the Medicare program.

The DAA also recognizes that to bring meaningful digital tools to all beneficiaries, more needs to be done to give more Americans access to broadband service in rural areas, where it is often nonexistent, and also in urban areas, where it is available but too expensive for many individuals. We appreciate and support Representative Upton's bipartisan efforts with Representative Clyburn to pursue legislation to achieve universal broadband access, which is necessary for digital health to fulfill its promise. A recent research letter published in JAMA Internal Medicine provides data that underscore the importance of addressing the broadband issue. Researchers analyzed 2018 data from the robust American Community Survey, which showed the clear need to address the digital divide in community dwelling Medicare beneficiaries, especially in populations with low socioeconomic status. From the JAMA Internal Medicine article:

- "Overall, 41.4% of Medicare beneficiaries lacked access to a desktop or laptop computer with a high-speed internet connection at home, and 40.9% lacked a smartphone with a wireless data plan.
- The proportion of beneficiaries without either form of digital access was 26.3% and this proportion varied across demographic and socioeconomic groups. For

example, 50.1% of beneficiaries with income of 100% below the federal poverty level lacked digital access compared with 11.5% of those with income 400% or more above the federal poverty level.
- The proportion of Medicare beneficiaries with digital access was lower among those who were 85 or older, were widowed, had a high school education or less, were Black or Hispanic, received Medicaid, or had a disability."

CMS Should Allow Beneficiaries to Access Evidence-Based Virtual Behavior Change and Educational Programs Already Successfully Serving Hundreds of Thousands of People Under age 65.

Why CMS Should Permit Virtual Behavior Change and Educational Programs

According to the CDC's National Diabetes Statistics Report 2020, nearly half of all Medicare-aged beneficiaries – about 24 million – have prediabetes and thus are eligible to participate in MDPP (after obtaining a qualifying blood test). Many of these beneficiaries live in frontier and remote, exurban and suburban areas that lack a DPP provider with preliminary or full recognition from the CDC, making potential providers in those areas ineligible to *apply* to serve Medicare beneficiaries. In urban areas, providers face challenges in providing sufficient, culturally tailored programming for the large numbers of Medicare beneficiaries among the populations they serve. Additionally, these beneficiaries lack access to in-person MDPP programs due to restrictions during the COVID-19 PHE. Without the addition of virtual MDPP suppliers, large rural areas or underserved communities will not have reasonable access to MDPP suppliers. The fundamental value of evidence-based programs is delivery of needed services where consumers live and work, and the success of DPP programs relies heavily on lowering barriers to participant access.

Lack of widespread access for eligible beneficiaries will also result in decreased cost savings for the Medicare program. Further, in-person MDPP suppliers do not have the capacity to serve millions of seniors; allowing virtual providers to participate in MDPP will ensure Medicare beneficiaries have access to MDPP in the format of their choosing, regardless of where they live.

Where and How Virtual Services Are Being Used Today

As discussed, there are multiple-delivery models available for critical diabetes and prediabetes services, like MDPP, DSMT, and other services critical to diabetes management. These delivery models include in-person services, real-time (synchronous) telehealth services, telephone or web-based counseling, and services provided virtually via web-based platforms such as tracking functions and artificial intelligence/machine learning-powered messaging.

Specifically, CMS policy does not permit Medicare beneficiaries to enroll in evidence-based MDPP programs that are offered as a virtual-only service, even though these programs have been recognized by the CDC's Diabetes Prevention Recognition Program and are covered by most private insurers. Similarly, CMS policy does not permit virtual delivery of DSMT services, even if the virtual DSMT provider is a recognized or accredited DSMT program. This lack of coverage limits beneficiary access to services that can help prevent or delay the onset of type 2 diabetes and prevent serious complications of diabetes, an issue that has emerged with critical urgency during the COVID-19 pandemic.

Virtual behavior-change and educational programs are provided asynchronously at a pace designed to meet the individualized needs of participants. Despite the options available and the fact each delivery mode adheres to a set of standards (i.e., DSMT accreditation or recognition, or CDC-DPRP recognition), or follow disease management best practices, and despite the fact that these other delivery modes already successfully serve hundreds of thousands[1] of people in the commercial insurance population, most of these options are not available to Medicare beneficiaries.

In response to the pandemic, CMS issued waivers that have allowed MDPP programs to shift from the in-person setting to virtual delivery, which has been helpful to the suppliers and those beneficiaries enrolled in these programs. But even in light of the constraints of the pandemic, CMS is currently still requiring any beneficiaries who may wish to start a diabetes prevention program to take their first session at an in-person site for the remainder of 2020. The DAA believes this restriction is unnecessary and is a barrier to access for beneficiaries with prediabetes, as many if not most in-person DPP providers have not reopened, due to the ongoing pandemic. Further, the DAA anticipates that it may be years before many older adults feel safe attending in-person programs.

Additionally, the DAA hoped to see CMS explore digital technology in the Medicare Physician Fee Schedule (MPFS) proposed rule for 2021 released in early August. In the 2021 MPFS proposed rule, CMS removed requirements that the MDPP must be started in person in 2021 and for future public health emergencies. Though the DAA supports this change, the proposal still falls short, as this change only applies to in-person DPP providers who have been recognized as Medicare suppliers. The 2021 MPFS rule does not allow CDC fully-recognized virtual-only diabetes prevention program providers to offer services to beneficiaries even in a pandemic. CMS exclusion of virtual providers and virtual-only services reflects the agency's short-sightedness on this issue and is just

[1] The most recent CDC tally for the Diabetes Prevention Program shows it has cumulatively served over 450,000 people in a wide variety of care modalities. Similarly, the Association of Diabetes Care and Education Specialists (ADCES), a National Accrediting Organization (AOs) approved by CMS accredit/certify DSMT programs for Medicare reimbursement, has accredited virtual DSMT programs that collectively serve tens of thousands of individuals.

one example of its failure to really explore, let alone embrace, the capabilities of digital technology.

To no avail, the DAA has raised these illogical ironies to CMS on many occasions since 2017, when CMS first decided to exclude CDC fully recognized virtual diabetes prevention programs from the Medicare DPP expanded model. Even if the problem is a lack of authority to add coverage for fully virtual programs, as CMS claims but cannot adequately document, we have asked CMS to tell us what authority is needed for CMS to more quickly evaluate, and if appropriate, adopt digital care? The DAA also has suggested that CMMI/CMS conduct a pilot program of virtual diabetes prevention programs recognized by the CDC's DPRP. All of these actions have been unsuccessful.

Therefore, the members of the DAA are pursuing legislative solutions to address these issues. We believe that legislation represents the best path forward given the lack of regulatory action. DAA members are now working with members of Congress to support passage of a bill that would require CMS to add, to the MDPP Expanded Model, fully virtual diabetes prevention programs delivered by suppliers that have achieved recognition by CDC's Diabetes Prevention Recognition Program, and overall, to explore the adoption and coverage of clinically effective healthcare services delivered through digital technology. The PREVENT DIABETES Act (S.4709), was introduced in the Senate on September 24, 2020 by Senators Tim Scott (R-SC), Mark Warner (D-VA), Kevin Cramer (R-ND), Kyrsten Sinema (D-AZ), Tom Cotton (R-AR), and Tina Smith (D-MN). Senators Scott and Warner, the bill's bipartisan leads, are now working to get companion legislation introduced in the House. On a similar note, DAA members are actively supporting the Expanding Access to DSMT Act (S.814, H.R.1814). Representative Diana DeGette and Representative Tom Reed (R-NY) have championed this legislation, which asks CMS to establish a demonstration project for virtual DSMT.

As an attachment to this letter, the DAA has included a copy of our 2020 comments to the Center for Medicare and Medicaid Innovation (CMMI), which further expand upon the principles and concerns outlined in this section.

Why CMS Should Permit Virtual Diabetes Self-Management Training Programs

CMS has publicly recognized the significant underutilization of the DSMT benefit in Medicare. Although the evidence base for DSMT is very strong, and even though DSMT is a covered benefit under the Medicare program, only 5% of Medicare beneficiaries with newly diagnosed diabetes participate in this evidence-based service.[2,3,4] [5] To

[2] https://www.google.com/url?q=https://www.govinfo.gov/content/pkg/FR-2016-07-15/pdf/2016-16097.pdf&sa=D&ust=1597850551595000&usg=AFQjCNFtQygWs_uaoDs2UBtol4Hr4z8InA

improve access to DSMT for beneficiaries and help to ensure that older adults can prevent life-threatening and costly complications, the DAA is pursuing two efforts simultaneously. First, we are urging CMS to implement regulatory reforms to expand access to DSMT, including DSMT offered through virtual and community-based programs. Second, we also are advocating for the passage of the aforementioned Expanding Access to DSMT Act (H.R. 1840, S. 814).

The DAA has identified several CMS barriers to DSMT, two of which are highlighted in bold and align with the intent of the 21st Century Cures 2.0 concept paper:

- Extend the initial 10 hours of DSMT covered by Medicare beyond the first year until fully utilized and cover additional hours based on individual need;
- Allow medical nutrition therapy and DSMT to be provided on the same day;
- Remove patient cost-sharing;
- Broaden which providers can refer to DSMT beyond the provider managing the beneficiary's diabetes to include other providers caring for the patient;
- **Pilot the use of virtual DSMT programs through the Center for Medicare and Medicaid Innovation (CMMI); and**
- **Expand telehealth for DSMT so that all DSMT programs, eligible to Medicare Part B, are considered distant site practitioners approved to furnish telehealth services.**

DAA Support for Other Sections of the 21st Century Cures 2.0 Concept Paper

The DAA supports these sections of the concept paper and offers some examples from diabetes and prediabetes to support the new legislation.

- With regard to policy recommendations listed for **Title 1 (Public Health), Section___: National Testing and Response Strategy for Current and Future Pandemics,** the DAA offers it full support for the value of a national strategy in general, and especially given that people with diabetes, and some of those with prediabetes, are at the highest risk of severe and life-threatening complications with COVID-19. Also, some new evidence is showing that COVID-19 may trigger the onset of diabetes in some patients.

- With regard to policy recommendations listed for **Title 1 (Public Health), Section ___: Pandemic Preparedness Program for Patients**, the DAA notes that any preparedness program should include a plan for people with diabetes and other

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[3] American Diabetes Association. Standards of Medical Care in Diabetes–2017. *Diabetes Care* 2017; 40 (Suppl.1): S3.

[4] Strawbridge LM, Lloyd JT, Meadow A, et al. Use of Medicare's diabetes self-management training benefit. *Health Education Behavior* 2015; 42: 530-8.

[5] https://www.cdc.gov/diabetes/dsmes-toolkit/background/benefits.html

chronic diseases as part of a larger pandemic preparedness plan, so that these patients can maintain communication with and access to their health care providers and access to their medications.

- With regard to policy recommendations listed for **Title 1 (Public Health), Section ___: Vaccine and Immunization Programs**, the DAA notes that vaccines in general, and especially the seasonal flu vaccines, have been demonstrated to be critical for people with diabetes, who are more likely to suffer severe consequences if infected. The DAA strongly supports public education on vaccines, in general, and increased funding for CDC's Immunization Information System.

- With regard to policy recommendations listed for **Title II (Caregiver Integration), Section ___: Educational programs and training for caregivers,** the DAA strongly supports policies to provide grants for educational programs and training sessions for caregivers, especially given that many are caring for people with diabetes with multiple comorbidities. Both caregivers and diabetes self-management training are vital for people with diabetes, since almost all care occurs outside of a health care clinical setting.

- With regard to policy recommendations listed for **Title III (Patient Engagement in Health Care Decision-Making), Section ___: Increasing Health Literacy to Promote Better Outcomes for Patients**, the DAA notes that lack of health literacy is an important social determinant of health and can contribute to adverse outcomes for some people with diabetes. Health literacy is extremely important for people with diabetes and their caregivers, so that they can understand how to better manage diabetes and its many complications.

- With regard to policy recommendations listed for **Title IV (Clinical Trials), Section ___: Diversity in Clinical Trials,** the DAA strongly supports policies that would help increase the public's awareness and understanding of clinical trials and make the clinicaltrials.gov website more user friendly. It is critical that new medication research include diverse members of the general population, especially those disproportionately affected by diabetes, who currently may have the least access or desire to participate in clinical trials.

- With regard to **Title V: (FDA) Section ___: Improve FDA-CMS communication regarding transformative new therapies,** the DAA urges regulatory reforms that would allow CMS flexibility to cover innovative diabetes technologies and services, so that as new diabetes technologies and services are approved by the FDA, there is a coverage pathway in Medicare for them. Rapid advances in this space have outpaced Medicare's existing coverage and reimbursement guidelines resulting in overly complicated – or even a lack of – access processes

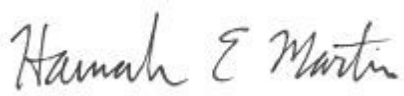
for patients, health care professionals and suppliers. The DAA believes the following steps are needed:

  - Improving CMS coverage for innovative technologies;
  - Better coordination between FDA and CMS for coverage pathways for innovative technologies; and
  - Reducing existing coverage barriers to diabetes technology, such as eliminating the "four times per day" testing that Medicare requires for coverage of continuous glucose monitors (CGM).

- With regard to **Title V: (FDA**), **Section ___: Increasing Use of Real-World Data/Evidence,** the DAA supports the efficient review and approval of innovative digital and other technologies for people with diabetes and prediabetes. Particularly in the area of caring for those with diabetes, continuous glucose monitors, digital mats that scan feet for sores, and other technology already are providing real-world evidence (RWE) that patients can use to manage their diabetes.[6] Also, the DAA supports policies to enhance real-world data generation and RWE, and more specifically, Title V's recommendation of policy to ensure that patients are at the center of RWE. The DAA also supports the establishment of a task force, comprised of representatives of patient groups, CMS, FDA, and private sector companies and organizations, to develop a list of recommendations on ways to encourage patients to engage in real-world data generation.

In conclusion, the DAA would like to thank you for the opportunity to provide these comments to the 21st Century Cures 2.0 concept paper. Please contact Hannah Martin at hmartin@eatright.org or Kate Thomas at kthomas@adces.org should you have any questions regarding DAA's comments.

Sincerely,



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6 https://www.google.com/url?q=https://www.podimetrics.com/&sa=D&ust=1597850551729000&usg=AFQjCNFEzr0viYivxGifRxVt2VMuMtyTTA