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To: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services

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Re: Request for Information – Landscape Analysis to Leverage Novel Technologies for Chronic Disease Management for Aging Underserved Populations

The Diabetes Advocacy Alliance (DAA) appreciates the opportunity to provide comments in response to a Request for Information – Landscape Analysis to Leverage Novel Technologies for Chronic Disease Management for Aging Underserved Populations – issued by the Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

The DAA is a coalition of 26 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 with legislators and policymakers to increase awareness 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 this potentially devastating chronic disease.

The DAA recognizes that health inequities have had, and continue to have, a tremendous negative impact on our society's ability to identify those at risk, prevent new cases of diabetes, and effectively treat people with diabetes and obesity to help prevent the many serious complications of the disease. The DAA believes that increased use of new technologies to deliver information and evidence-based interventions that facilitate behavior change is crucial for addressing diabetes, prediabetes and obesity; but we also recognize that there may be little significant progress in America in addressing these three, unless our country addresses the many social determinants of health that contribute to increased susceptibility to them and poor health outcomes from them – such as systemic racism; food insecurity; lack of access to health care, transportation and broadband; and poverty.

We have chosen to focus on three of the 18 questions in the Request for Information.

Section A. Barriers and Opportunities for Technology-Driven Solutions

A2. What federal policies currently limit the capacity to deploy and scale technology-driven solutions for aging populations?

Communicating, connecting, and interacting with people with diabetes, prediabetes, and obesity is essential to achieving information exchange, education, and ongoing support for behavior change, medication adherence, and monitoring of relevant conditions. Technology can enable the delivery of evidence-based interventions that can help people prevent type 2 diabetes, manage and monitor their diabetes, and make behavior changes necessary to improve their health and quality of life. But as your question suggests, there are some current federal policies that are limiting the capacity to currently deploy available technology in optimal ways to benefit people with diabetes, prediabetes, and obesity.

We also would like to note that, although you have asked for information about federal policy barriers, there are statutory barriers to wider adoption and use of telehealth in Medicare and Medicaid, which only Congress can change. Because of the pandemic, there has been wide adoption and experimentation with use of telehealth services and other technologies. The DAA expects to see increased energy by the DAA and other groups and individuals in advocating for making permanent the changes to telehealth policy that CMS has issued for the time of the pandemic.

Diabetes Self-Management Training

Current federal policies limit the ability of people with diabetes to avail themselves of diabetes self-management training (DSMT) programs that are vital to helping them learn how to self-manage their disease. **Most relevant to this Request for Information, Medicare coverage of DSMT services provided via telehealth or through online platforms is limited and restrictive.** (Some exceptions have been made for the coronavirus pandemic, but these exceptions have not been made permanent.) This restriction is a significant barrier for people with diabetes in all localities, but especially for those who reside in rural areas. One study from the CDC showed that 62% of the 1,976 nonmetropolitan counties in the US did not have a DSMT program. Even for the minority of such counties that did have at least one DSMT program, the number of programs was small, ranging from 1 to 8, with an average of 1.4 programs.[1]

CMS has publicly recognized the significant underutilization of the DSMT benefit in Medicare. Although the evidence base for DSMT is very strong,[2,3,4] 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.[5] Thus, the DAA urges the Commission to recommend to Congress that CMS implement regulatory reforms to expand access to DSMT so older adults with diabetes can prevent costly complications. The DAA is working to implement regulatory reforms in addition to advocating for legislation to expand access to DSMT, most recently the Expanding Access to DSMT Act (H.R. 1840, S. 814) in the 116th Congress, so older adults with diabetes can prevent costly complications.

The DAA has identified several CMS barriers to DSMT and has urged the National Clinical Care Commission to address all of these barriers in the recommendations of its report to Congress, expected in 2021:

- Pilot the use of virtual DSMT programs through the Center for Medicare and Medicaid Innovation (CMMI).
- Expand telehealth for DSMT so that all DSMT programs, eligible to Medicare Part B, are considered distant site practitioners approved to furnish telehealth services.
- 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 (MNT) 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.
- Clarify agency policy that hospital outpatient department-based DSMT programs can expand to community-based locations, including alternate non-hospital locations.

Diabetes Prevention

Most relevant to getting more access to diabetes prevention program for older adults in rural counties are the current CMS policies that do not allow Medicare beneficiaries with prediabetes to avail themselves of the option of virtual only evidence-based diabetes prevention programs. (Some exceptions have been made for the coronavirus pandemic, but these exceptions have not been made permanent.) To address this barrier, the DAA has advocated to directly to CMS, and also to Congress, that CMS align its Medicare Diabetes Prevention Program (Medicare DPP) with CDC's National Diabetes Prevention Program (National DPP) and with the standards in the CDC's Diabetes Prevention Recognition Program. (DAA members also are supporting the Prevent Diabetes Act (H.R.8861 and S.4709), which would require CMS to cover virtual only diabetes prevention programs that have received recognition by CDC's National Diabetes Recognition Program.) Alignment of CMS with CDC would help reduce confusion among prevention program providers, and among health care professionals who refer individuals to these programs; increase the number of organizations able to offer the Medicare DPP due to increased/adequate reimbursement; and increase the number of Medicare beneficiaries able to access programs either in-person or virtually. Alignment is needed in these areas:

- **Taking advantage of technology and making virtual diabetes prevention programs available in the Medicare DPP (as they are now in the National DPP)**
- Weight loss thresholds (expressed as % of weight loss needed)
- 2 year program duration (CMS) versus 1 year (CDC)
- Reimbursement rates
- Payment adjustments for special populations
- Once per lifetime benefit

- Screening guidelines for eligibility (CMS uses WHO guidelines while CDC uses ADA cut points for defining prediabetes)
- Use of A1c test to screen for prediabetes and diabetes (CMS does not allow; CDC allows)

Diabetes Care and Technology

Regulatory reforms are needed to allow CMS the 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 recommends:

- 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).

Section B. Key Indicators & Data Sources of Technology-Driven Chronic Disease Management

B3. What selected health conditions should be addressed as priority conditions to assess technology-driven capacity to influence access, timeliness, and quality of healthcare treatment and preventive services to aging populations living in rural areas?

The DAA recommends that OASH/HHS recognize **diabetes, prediabetes, and obesity** as priority diseases and conditions to assess technology-driven capacity to influence access, timeliness, and quality of healthcare treatment and preventive services to aging populations living in rural areas. The use of technology to inform, educate, and support behavior change, as well assist health professionals in monitoring patient progress at home, is critical to helping people with or at risk of diabetes to improve dietary choices, increase physical activity, lose weight or maintain a healthy weight, and improve medication adherence.

Diabetes and Prediabetes

Almost three of every four adults ages 65 and older has either diabetes (26.8%) or prediabetes (46.6%)[6], and the CDC reports that diabetes is about 17% more prevalent in rural areas compared with urban areas.[7] In 2011, the CDC issued a report that labeled a 644-county area of the United States as the "diabetes belt," with much of this belt being in the South. However, about one-third of those counties lie in the rural areas of central and southern Appalachia.[8]

Regarding prediabetes and diabetes in rural areas, an article in US News & World Report (2017) states that there are many social determinants of health that combine to place rural residents at higher risk including lower levels of income and education; cultural differences, which may emphasize less healthy habits; lack of access to fresh produce and other healthy foods; lack of access to physicians and diabetes care and education specialists; and lower rates of health insurance.[9]

A study published in 2017 showed that people with diabetes in rural areas are more likely to forego necessary medical care than those living in metropolitan areas, which could be related to social determinants of health.[10] As rurality increases in America, so too does diabetes-related mortality. Compared to large central metros, which are comprised of large cities of at least 1 million inhabitants, residents of the noncore – the most rural classification – have a 12.4-point higher mortality rate.[11] Among those in rural areas, mortality rates are highest for Black adults.[11]

Obesity

According to one recent study, nonmetropolitan residents, compared with those living in metropolitan areas, have a higher prevalence of obesity-associated chronic diseases such as diabetes, coronary heart disease, and arthritis.[12]

Rates of obesity, which are very often related to type 2 diabetes, are higher in rural areas.[12] When the CDC examined 2016 state-level data from the Behavioral Risk Factor Surveillance System, the data showed an overall obesity rate of 34.2% among adults living in non-metropolitan counties versus a rate of 28.7% among those living in metropolitan counties.[12] Among adults ages 65 and older, those rates were 30.1% versus 27.5%.[12]

Section D. Public-Private Partnerships

D2. What organizations, groups, and/or, associations should HHS engage as part of such a collaborative effort?

We recommend that HHS engage with the Diabetes Advocacy Alliance (DAA) as a resource for HHS staff responsible for developing and implementing a "public-private partnership model to leverage the adoption of technology-driven solutions to improve outcomes for at-risk populations such as aging Americans living in rural areas."

The DAA has an eight-year history of partnership with OASH's Healthy People program. (See a recent blog post on health.gov entitled "The Diabetes Advocacy Alliance and Healthy People: Putting Diabetes on the National Agenda.") OASH/Healthy People staff members are familiar and comfortable working with representatives of DAA member organizations, to exchange information and jointly address some of the most pressing public and clinical health care challenges related to preventing and treating diabetes. Our joint work has included webinars on topics such as diabetes prevention and diabetes self-management education and support

(DSMES), and several in-person (pre-pandemic) meetings of a variety of federal government agency professionals with DAA member organization representatives, to exchange research and discuss issues on topic such as diabetes screening, and diabetes and rural health.

Regarding the webinars: Together, we have produced six events with very large attendance (around 800 participants, on average, with one drawing 1,200+ participants). We have been able to draw and sustain large audiences because of our different strengths. Healthy People has a large and loyal following of state, country, and local public health professionals, while the DAA has member organizations of clinical health care professionals, and can thus attract physicians, nurses and other diabetes education specialists, and dietitians to attend these webinars, to learn more about Healthy People and various diabetes topics of interest. (See a PDF of the presentation slides from one of our joint webinars entitled "Healthy People 2020 Spotlight on Health Presents: Empowering People to Manage Their Diabetes.")

Many of the 26 members of the DAA have expertise in policy related to the use of technologies to address diabetes, prediabetes, and obesity. The DAA has an ongoing Digital Health Workgroup comprised of representatives of DAA member organizations who are experienced advocates, and who could provide insights and advice to OASH staff about federal policies that currently limit the capacity to deploy and scale technology-driven solutions for aging populations. The DAA also has a Health Disparities & Health Equity Workgroup that looks broadly at these issues as they relate to prediabetes, diabetes, and obesity. If you are interested in connecting with the DAA and any of its members, please feel free to contact one of our two DAA co-chairs:

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We thank you for the opportunity to submit our comments in response to your Request for Information.

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