

May 29, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-4207-NC
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare Program; Request for Information on Medicare Advantage Data (CMS-4207-NC)

Dear Administrator Brooks-LaSure:

The Diabetes Technology Access Coalition (DTAC) appreciates the opportunity to provide these comments to the *Medicare Program; Request for Information on Medicare Advantage Data* (the “RFI”).¹ DTAC is a cross-industry group of diabetes stakeholders. Collectively, the coalition members represent millions of Americans with diabetes, health care professionals who treat them, and major manufacturers that develop diabetes therapies, equipment, and supplies. Thus, our coalition represents those who manufacture and develop diabetes technology, the health care professionals who rely on this technology to best treat their patients, and the patients who benefit from the technologies.

The prevalence of both type 1 and type 2 diabetes has been rising over the last 20 years, largely driven by new cases of type 2 diabetes.² The prevalence of type 2 diabetes is only expected to grow in the coming years, as an estimated 54.9 million Americans will have diabetes in 2030,³ compared to the estimated 38.4 million individuals who currently have diabetes.⁴ Likewise, the prevalence of type 1 diabetes has increased in the last two decades, with a significant proportion of new cases occurring among our nation’s youth.⁵ Both type 1 and type 2 diabetes can have devastating effects on long term health, as it is associated with an increased risk of cancer, hospitalization, heart disease, chronic kidney disease, amputations, and other severe health consequences. Unfortunately, racial and ethnic communities have a higher prevalence of

¹ 89 Fed. Reg. 5907 (Jan. 30, 2024).

² *National Diabetes Statistics Report*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/diabetes/data/statistics-report/index.html>. According to the Centers for Disease Control and Prevention (CDC), their reports and estimates of diabetes typically do not differentiate between type 1 and type 2 diabetes, but that type 2 diabetes accounts for 90 to 95 percent of all diabetes cases, *see Methods: National Diabetes Statistics Report*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/diabetes/data/statistics-report/methods.html>.

³ William Rowley, et. al., *Diabetes 2030: Insights from Yesterday, Today, and Future Trends*, 20 Population Health Mgmt. 6 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5278808/>.

⁴ *National Diabetes Statistics Report*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/diabetes/data/statistics-report/index.html>.

⁵ Jasmine Divers, et. al., *Trends in Incidence of Type 1 and Type 2 Diabetes Among Youths — Selected Counties and Indian Reservations*, United States, 2002–2015, 69 Morbidity and Mortality Weekly Report 161 (2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6906a3.htm?s_cid=mm6906a3_w.

diabetes,⁶ are more likely to have diabetes related complications,⁷ and receive a lower quality of care compared to their White counterparts.⁸

Individuals with diabetes uniquely experience and therefore develop unique care plans as determined between the individual and health care professional. In turn, this means that all individuals with diabetes must have ready access to a comprehensive and flexible set of treatment options. This includes ensuring that individuals have access to all forms of life-sustaining diabetes technologies, as they all span different functions and do not necessarily have to be used in conjunction with each other. More must be done to improve access to diabetes care, as utilization of critical technologies such as continuous glucose monitors (CGMs) remains low despite being part of the standard of care for individuals with diabetes.⁹ Recent research of more than 1.3 million Medicare beneficiaries who used intensive insulin therapy produced disturbing results. Specifically, of these 1.3 million insulin-using beneficiaries, more than 38 percent have **no record** of glucose monitoring and only three percent of Medicare beneficiaries obtained a CGM.¹⁰ Of those beneficiaries, 90 percent were White, less than 8 percent were Black and less than 2 percent were Hispanic.¹¹ Depressed utilization of CGMs, especially among racial and ethnic minorities, indicates that more must be done to improve access to CGMs and other essential diabetes related interventions.

DTAC supports expanded and more flexible coverage of diabetes equipment and technology; our primary concern with respect to diabetes care is to ensure coverage and access to the diabetes technology that is most appropriate for each person with diabetes' unique circumstances. As part of this policy priority, DTAC supports ensuring equitable access to all forms of diabetes care, including for people with diabetes enrolled in a Medicare Advantage (MA) plan. Part of ensuring access to diabetes care in MA plans requires robust data collection, analysis, and reporting to ensure that MA plans are adhering to Medicare coverage requirements, to help policymakers identify gaps in care, and to provide prospective beneficiaries the chance to study data that could affect their choice of a MA plan. Robust collection of MA diabetes-related data is especially important as we continue to learn of MA enrollees facing onerous barriers to accessing diabetes care and technologies. For example, we were made aware of certain MA providers limiting access to covered diabetes technologies by inappropriately telling enrollees that they are not eligible for such technologies. Further, certain MA plans use utilization management (UM) techniques to force enrollees to use certain diabetes technologies first, limiting access to other technologies that the enrollee and care provider may have determined to be best for the enrollee's specific diabetes characteristics. Therefore, we urge the agency to consider the following recommendations and principles with respect to MA data collection.

First, DTAC recommends that the Centers for Medicare & Medicaid Services (CMS) implement a regular data collection process that includes diabetes care-related information. Specifically, we recommend that more data be collected to: (1) monitor the extent to which UM and prior authorization (PA) requirements are utilized for diabetes items and services; and (2) ensure enrollees with diabetes have access to diabetes

⁶ *Id.*

⁷ J. Sonya Haw, et. al., *Diabetes Complications in Racial and Ethnic Minority Populations in the USA*, 21 *Diabetes Epidemiology* 2 (2021), <https://link.springer.com/article/10.1007/s11892-020-01369-x>.

⁸ Juan Canedo, et. al., *Racial/Ethnic Disparities in Diabetes Quality of Care: The Role of Healthcare Access and Socioeconomic Status*, 5 *J. of Racial and Ethnic Health Disparities*, 7 (2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5505804/>.

⁹ Nuha A. ElSayed, et. al., *Diabetes Technology: Standards of Care in Diabetes—2023*, 46 *Diabetes Care* S111 (2023), https://diabetesjournals.org/care/article/46/Supplement_1/S111/148041/7-Diabetes-Technology-Standards-of-Care-in.

¹⁰ Gary Puckerin, et. al., *Assessment of Glucose Monitoring Adherence in Medicare Beneficiaries with Insulin-Treated Diabetes*, 25 *Diabetes Tech. & Therapeutics* 1 (2022), <https://www.liebertpub.com/doi/abs/10.1089/dia.2022.0377?j>.

¹¹ *Id.*

self-management training (DSMT) and medical nutrition therapy (MNT) services at the minimum required level under Medicare fee-for-service. At a minimum, the agency should collect data that captures how many PA requests are approved or denied at each step of the PA process, the timing between PA submission and a decision, and the reasoning why the PA was denied for each item or service related to diabetes care. This should be conducted by diabetes care-related item (e.g., continuous glucose monitor, insulin pump) and service (e.g., DSMT or MNT service), including the number and rate of denials and number and rate of approvals following a denial. To provide context for this data, CMS should compare UM data among MA plans and how access to diabetes care, considering plans' UM techniques, compares to access in traditional Medicare. We also recommend the published data reflect the benefit plan (e.g., medical, pharmacy) under which the UM or PA is applied. This would provide useful information for beneficiaries with diabetes regarding the availability of medically necessary diabetes items and services, the channels through which they are offered by MA plans, and the application and results of UM/PA.

Second, we suggest that CMS collect data on MA plans' network adequacy, including how many suppliers are enrolled to provide the diverse array of diabetes care and products across different treatment modalities. This is especially true for DSMT and MNT services, while the shortage of primary care and endocrinology practitioners is a challenge we fully recognize. CMS should use existing data to closely monitor MA plan network adequacy in diabetes care, including with respect to different modalities (e.g., access to both in-person and telehealth services) and a sufficiently diverse array of providers (e.g., MA plans contracting with one telehealth company that employs numerous providers).

Finally, we urge CMS and MA plans to be transparent regarding coverage and access to diabetes care. People with diabetes uniquely experience and require special treatment plans. Publishing the results of these data collection and monitoring efforts will provide policymakers and stakeholders with needed information to develop evidence-based policy solutions to improve access to care for people with diabetes. Further, this information will better inform individuals aging into Medicare regarding the type of MA plans that are available to best meet their specific needs.

We thank the agency for the opportunity to submit these comments and appreciate your continued support for our shared mission of increasing access to medically necessary and appropriate diabetes care for Medicare beneficiaries. Please do not hesitate to contact Brian Lee at brian.lee@alston.com with any questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read 'Timothy P. Trysla', with a long horizontal flourish extending to the right.

Timothy P. Trysla
Executive Director
Diabetes Technology Access Coalition