September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1807-P
P.O. Box 8016
Baltimore, MD 21244-8016

**Re: Calendar Year 2025 Medicare Physician Fee Schedule Proposed Rule (CMS-1807-P)**

Dear Administrator Brooks-LaSure:

The Diabetes Technology Access Coalition (DTAC) is pleased to provide comments to the Calendar Year (CY) 2025 Medicare Physician Fee Schedule (PFS) proposed rule. 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.

In general, we support 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's unique circumstances. Individuals with diabetes uniquely experience their disease and therefore greatly benefit from 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 and to improve utilization of critical technologies, such as continuous glucose monitors (CGMs), insulin pumps, and automated insulin delivery (AID) systems, since they are part of the standard of care for individuals with diabetes.[1]

All insulin pumps currently available in the U.S. pair with a CGM, and through the use of an algorithm, can control the flow of insulin provided. This combination of technologies, often called AID systems, can both improve overall glycemic control and reduce hypoglycemia, which numerous studies have shown to be common occurrences and a significant risk factor for hospitalizations and mortality among individuals with diabetes.[2] Underlying the AID system is the software/algorithm that continuously learns the user's behavior and physiological responses to meals, exercise, and insulin. Like CGMs and insulin pumps, both

[1] *Diabetes Technology: Standards of Care in Diabetes—2024*, 47 Diabetes Care S126 (2024), https://diabetesjournals.org/care/article/47/Supplement_1/S126/153939/7-Diabetes-Technology-Standards-of-Care-in; Lawrence Blonde, et. al., *American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan — 2022 Update*, 28 Endocrine Practice 923 (2022), https://www.endocrinepractice.org/action/showPdf?pii=S1530-891X%2822%2900576-6 [hereinafter *Clinical Guidelines*].
[2] *See, e.g.*, Richard Silbert, et. al., *Hypoglycemia among Patients with Type 2 Diabetes: Epidemiology, Risk Factors, and Prevention Strategies*, 18 Current Diabetes Reps. (2018), https://link.springer.com/article/10.1007/s11892-018-1018-0; Rozalina McCoy, et. al., *Increased Mortality of Patients With Diabetes Reporting Severe Hypoglycemia*, 35 Diabetes Care 1897 (2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3425008/;

the American Diabetes Association (ADA) and the American Association of Clinical Endocrinology (AACE) include the use of AID systems in their standards of care.[3]

Unfortunately, use of these essential diabetes technologies among both the general and Medicare populations is especially low among racial and ethnic minorities. Based on a 2022 study using 2018 data of more than 1.3 million Medicare beneficiaries using rapid-acting insulin, only three percent obtained a CGM,[4] and of those beneficiaries who did gain access, 90 percent were White, less than 8 percent were Black, and less than 2 percent were Hispanic.[5] Likewise, in a 2021 study of Medicare beneficiaries with type 1 diabetes, in 2019, 18 percent of White Medicare beneficiaries used insulin pumps compared to 5 percent of Black Medicare beneficiaries, and 4 percent of Asian, Hispanic, and North American Native Medicare beneficiaries.[6]

More recently, a 2023 study that examined CGM, insulin pump, and AID system use among individuals with type 1 diabetes showed that use of these life-sustaining technologies increased among all populations from 2016 to 2022.[7] However, this study confirms that significant disparities remain with respect to the use of diabetes technologies among racial and ethnic minorities. Specifically, this study found that in 2022 83 percent of White individuals used a CGM compared to 69 percent of Hispanic individuals and 57 percent of Black individuals; 70 percent of White individuals used an insulin pump compared to 50 percent of Hispanic individuals and 36 percent of Black individuals; and 36 percent of White individuals used an AID system, compared to 23 percent of Hispanic individuals and 15 percent of Black individuals. Past research confirms that these disparities also exist in the Medicare population.[8] These disturbing data underscore the need to improve access to essential diabetes related interventions, especially among racial and ethnic minorities.

DTAC supports efforts to remove unnecessary coverage and access barriers while ensuring more equitable access for those populations who are disproportionately impacted by diabetes. In keeping with our goal of ensuring that all Medicare beneficiaries can utilize the diabetes technologies that best fits their clinical needs, our comments to the CY 2025 PFS proposed rule address promoting access to innovative diabetes technologies and diabetes-related training and education, and the proposed inclusion of the glucose management indicator (GMI) in Medicare quality reporting measures.

*a. Ensuring Access to Innovative Diabetes Technologies*

DTAC appreciates CMS's proposal to expand access to digital health devices and its recognition that these devices, which include software and algorithms, can be an essential piece of a beneficiary's treatment plan. As the agency begins to take steps to facilitate access to and beneficiary use of digital health devices, we want to emphasize to CMS that the software/algorithm that drives AID systems is as equally important as the other component parts of an AID system: the CGM and insulin pump. The Food and Drug Administration (FDA) has recognized the status of AID system algorithms as independent of CGMs and insulin pumps and has created the device category of "interoperable automated glycemic controller" specifically to describe AID system algorithms.[9] Insulin pumps and CGMs have been covered and paid by

[3] *Clinical Guidelines*, *supra* note 1.
[4] 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.
[5] *Id.*
[6] Kael Wherry, et. al., *Inequity in Adoption of Advanced Diabetes Technologies Among Medicare Fee-for-service Beneficiaries*, 107 *J. of Clinical Endocrinology & Metabolism*, e2177 (2021), https://doi.org/10.1210/clinem/dgab869.
[7] Osagie Ebekozien, et. al., *Longitudinal Trends in Glycemic Outcomes and Technology Use for Over 48,000 People with Type 1 Diabetes (2016-2022) from the T1D Exchange Quality Improvement Collaborative*, 25 Diabetes Technology and Therapeutics 765 (2023), https://www.liebertpub.com/doi/10.1089/dia.2023.0320?url.
[8] Puckerin, *supra* note 4; Wherry, *supra* note 6.
[9] 21 CFR 862.1356.

Medicare since 1999 and 2017 respectively, while the "brain" of the AID system is not separately reimbursed under Medicare. To promote innovation and patient access to AID systems, CMS must ensure there is a payment pathway for the software/algorithm in an AID system. Unlike other digital therapeutics or devices, software or algorithms in an AID system do not need a separate benefit category and instead should be appropriately categorized as a supply to durable medical equipment (DME). By doing so, CMS can promote access to AID systems as evidence becomes even more clear that AID systems improve diabetes care for insulin-dependent individuals. The Food and Drug Administration recently recognized this research and accordingly expanded the indication for Insulet's SmartAdjust technology, which enables an AID system, to include management of type 2 diabetes in individuals 18 years and older.[10]

Given the clinical evidence to support the use of AID systems, we believe that the algorithm or software that drives an AID system meets the threshold as a "reasonable and necessary" item "for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member"[11] to warrant Medicare coverage under the *Social Security Act* (SSA) for individuals with diabetes. Given that threshold requirement, DTAC believes that the software or algorithm that underlies the AID system can be considered a supply to DME. Regulation defines DME as an item that can withstand repeated use, has an expected life of at least three years, is primarily and customarily used for a medical purpose, is generally not useful to someone in the absence of an illness or injury, and is appropriate for use in the home.[12] Medicare currently covers both CGMs and insulin pumps as DME, meaning both components of an AID system, independently, are DME. The AID system, in totality, should also be categorized as DME. A supply to a DME is an item that is necessary for the effective use of DME.[13] The software/algorithm of an AID system is essential for the function of the entire AID system, as without it, the individual DME components do not operate together as part of the system. Under these criteria, nothing in statute or regulation would prevent the agency from classifying the software or algorithm of an AID system as a supply to a DME.

Without separate recognition for the costs and value of the software or algorithm in an AID system, future innovation may slow, thereby reducing patient access to an essential life-sustaining technology. By designating such software/algorithms as a supply to DME, CMS can provide stability and consistency to developers as they continue to innovate new and improved AID systems, which will support continued beneficiary access to AID systems. Finally, we reiterate that CMS must also enhance coverage for the other two critical components of AID systems, in part, by acting on the long pending National Coverage Determination (NCD) reconsideration request for Part B-covered insulin pumps.

*b. Promoting Expanded Access to Diabetes Related Education and Treatment*

Diabetes self-management training (DSMT) is a proven and effective intervention that teaches individuals how to use diabetes technologies, administer medications, and healthy lifestyle changes to improve diabetes management. DSMT has been shown to improve clinical outcomes and quality of life, while simultaneously reducing hospitalizations and healthcare spending.[14] As such, the ADA considers DSMT to be "a vital component of the full treatment for diabetes."[15] Given the proven clinical benefit of DSMT among individuals with diabetes, Medicare beneficiaries should have access to DSMT via the care modality that

[10] *FDA Clears First Device to Enable Automated Insulin Dosing for Individuals with Type 2 Diabetes*, Food & Drug Administration (Aug. 26, 2024), https://www.fda.gov/news-events/press-announcements/fda-clears-first-device-enable-automated-insulin-dosing-individuals-type-2-diabetes.
[11] 42 USC 1395y(a)(1)(A).
[12] 42 CFR 414.202.
[13] *Section 110.3 – Coverage of Supplies and Accessories, Chapter 15 – Covered Medical and Other Health Services – Medicare Benefit Policy Manual,* Centers for Medicare & Medicaid Services (June 13, 2024), https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.
[14] *See, e.g.*, Jody Davis, et. al., *2022 National Standards for Diabetes Self-Management Education and Support*, 45 Diabetes Care 484 (2022), https://diabetesjournals.org/care/article/45/2/484/140905/2022-National-Standards-for-Diabetes-Self.
[15] *Id.*

best fits their needs, including both in-person and telehealth services. As such, we align ourselves with comments submitted by the Association of Diabetes Care & Education Specialists (ADCES) in support of aligning coverage policies for telehealth DSMT under the Medicare Outpatient Prospective Payment System with those of the PFS.

While we appreciate the agency's commitment to allowing DSMT providers to provide services via telehealth, many individuals continue to face barriers in accessing diabetes related education and treatment. This is due to two issues we believe CMS can address: (1) clinically inappropriate caps on DSMT services; and (2) lack of recognition of insulin pump set-up and training. Currently, individuals with diabetes have a limit on the volume of DSMT services they can receive. The current benefit allowing ten hours of DSMT in the initial year and only two hours in years thereafter implies that diabetes management is unlikely to change over the course of the beneficiary's life. Not only is this highly misaligned with the nature of diabetes as a progressive disease, but it does not recognize the astounding technological and pharmacological advancements that have and are expected to continue to occur in diabetes management, which, by definition, will lead to many beneficiaries managing myriad different treatment plans over the course of their lifetimes all while only having access to two hours per year of DSMT.

We believe it is inappropriate to limit the education and training available to beneficiaries with this lifelong disease. It is also inappropriate for beneficiaries newly diagnosed with diabetes as they must learn to use new technology and potentially switch technologies because either the original diabetes technologies are not producing ideal clinical outcomes or Medicare forces beneficiaries to switch diabetes technologies when they "age" into Medicare. For example, the current insulin pump NCD was last updated in 2004 and as we have requested, must be updated to reflect current clinical evidence. As a result, Medicare beneficiaries have to change insulin administration technologies if they are unable to meet the outdated coverage criteria associated with Part B-covered insulin pumps (e.g., laboratory assessments of C-peptide and beta cell autoantibody levels).[16]

Further, while there is a payment mechanism for CGM set-up and training, there is no separate acknowledgement or reimbursement for providers who perform insulin pump set-up and training. Thus, individuals with diabetes must use their limited DSMT hours to obtain insulin pump training or providers must provide this training without reimbursement. Eventually, as AID systems become more prevalent, similar codes for set-up and training will be needed for the algorithm component of these advanced systems, which is separate from and in addition to the use of the underlying CGM and pump technologies alone. To support beneficiary access and to ensure appropriate use of diabetes technologies, DTAC urges the agency to ensure that DSMT and other diabetes care and education services are accessible for a wide array of diabetes-related training and educational services spanning the multiple technologies available today and in the future.

c. *Inclusion of Additional Glycemic Control Metrics in Quality Reporting Measures*

CMS proposes changes to the reporting measure currently entitled "Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)," which is used in multiple programs such as the Merit-based Incentive Payment System (MIPS) and in multiple MIPS Value Pathways (MVPs). Among other changes, CMS proposes to include the use of GMI, in addition to HbA1c, to assess individuals' glycemic status. CMS identifies that GMI is used by clinicians to ensure proper management of individuals using CGMs and DTAC supports efforts to be inclusive and encompassing of the evidence-based metrics that quantify and measure glycemic control. This is especially true as more beneficiaries adopt CGMs. GMI, which is a CGM derived measure

[16] Grazia Aleppo, et. al., *Lost in Translation: A Disconnect Between the Science and Medicare Coverage Criteria for Continuous Subcutaneous Insulin Infusion*, 23 Diabetes Technology and Therapeutics 715 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8573795/.

that estimates laboratory A1c, can complement other measures of glycemic control, such as HbA1c.[17] As previously noted, diabetes is a highly personalized disease. We agree with CMS's rationale that this would appropriately broaden the acceptable methods for monitoring glycemic status of individuals with diabetes. Finally, we appreciate that CMS is proposing to update the denominator exclusion by removing the requirement that individuals had at least one or two outpatient encounters to recognize a diagnosis of advanced illness. Individuals with diabetes may have multiple care providers who assist in the monitoring and management of diabetes and this change will remove unnecessary administrative burdens.

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Thank you for the opportunity to provide comments to the CY 2025 PFS proposed rule. Please feel free to contact Brian Lee at brian.lee@alston.com should you have any questions or if there are more details we can provide.

Sincerely,

Timothy P. Trysla
Executive Director
Diabetes Technology Access Coalition

[17] Michael Monostra, *Glucose management indicator, time in range can be valuable tools in diabetes care*, Healio (Oct. 22, 2021), https://www.healio.com/news/endocrinology/20211022/glucose-management-indicator-time-in-range-can-be-valuable-tools-in-diabetes-care.