Congress of the United States

Washington, DC 20515

October 24, 2025

The Honorable Mehmet Oz Administrator Centers for Medicare & Medicaid Services U.S. Department of Health and Human Services 200 Independence Avenue SW Washington, DC 20510

Dear Administrator Oz:

As Co-Chairs of the House and Senate Diabetes Caucuses, we write to express our concerns about the Centers for Medicare & Medicaid Services' (CMS) proposals regarding the Medicare Competitive Bidding Program included in the Calendar Year (CY) 2026 Home Health Prospective Payment System (HH PPS) proposed rule. Specifically, we are concerned that the agency's proposals will reduce and complicate patient access to continuous glucose monitors (CGMs) and durable insulin pumps.

As you know, diabetes is one of the most common and costliest chronic diseases among Americans.¹ Despite the prevalence and costly nature of this disease, many Medicare beneficiaries have difficulty accessing effective tools to manage their diabetes, such as CGMs and insulin pumps, both of which are part of the American Diabetes Association's and the American Association of Clinical Endocrinology's standards of care for individuals with diabetes.² These tools are also cost-effective, as research has shown that their use has yielded billions of dollars of savings to federal health care programs, namely due to reduced hospitalization and utilization of emergency department visits.³ Federal policies should support access to these technologies.

In the CY 2026 HH PPS proposed rule, CMS proposes a new and untested payment model for CGMs and durable insulin pumps while also proposing to include these devices in the competitive bidding program. We are concerned that by shifting responsibilities for maintenance, education and training from CGM and insulin pump manufacturers to suppliers, CMS' proposal

 $\underline{https://advisory.avalerehealth.com/wp-content/uploads/2025/07/White-Paper_Estimated-federal-cost-savings-from-the-Special-Diabetes-Program.pdf.}$

¹ National Diabetes Statistics Report, Centers for Disease Control and Prevention (May 15, 2024), https://www.cdc.gov/diabetes/php/data-research/index.html; https://www.cdc.gov/diabetes/php/data-research/index.html; https://advisory.avalerehealth.com/special-Diabetes Program, Avalere Health (July 7, 2025), https://advisory.avalerehealth.com/special-Diabetes Program, Avalere Health (July 7, 2025), https://advisory.avalerehealth.com/special-Diabetes Program, Avalere Health (July 7, 2025), https://advisory.avalerehealth.com/special-Diabetes Program, Avalere Health (July 7, 2025), https://advisory.avalerehealth.com/special-Diabetes Program, Avalere Health (July 7, 2025), https://advisory.avalerehealth.com/special-Diabetes Program, Avalere Health (July 7, 2025), https://advisory.avalerehealth.com/special-Diabetes Program, Avalere Health (July 7, 2025), https://advisory.avalerehealth.com/special-Diabetes Program, https://advisory.avalerehealth.com/special-Diabetes Program, https://advisory.avalerehealth.com/special-Diabetes Program, https://advisory.avalerehealth.com/special-Diab

Diabetes-Program.pdf.

² Standards of Care in Diabetes – 2025, 48 Diabetes Care S1 (2025), https://diabetesjournals.org/care/issue/48/Supplement_1; George Grunberger, et. al., American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus, 27 Endocrine Practice 505 (2021), https://www.endocrinepractice.org/action/showPdf?pii=S1530-891X%2821%2900165-8; Lawrence Blonde, et. al., American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan—2022 Update, 28 Endocrine Practice P923 (2022), https://www.endocrinepractice.org/article/S1530-891X(22)00576-6/fulltext.

³ Estimated federal cost savings from the Special Diabetes Program, Avalere Health (July 7, 2025),

would both decrease patient access and choice to this critical technology and hinder technological innovation.

Under the proposed rule, just a few suppliers nationwide would be responsible for furnishing durable insulin pumps and CGMs to beneficiaries, in addition to the maintenance, software updates, and recalls of these technologies, creating a new and unnecessary layer of bureaucracy. This is in contrast to the current system in which medical providers prescribe insulin pumps and CGMs and manufacturers are directly responsible for support. We also are concerned that these proposed policies will have the unintended consequence of reducing choices for CGM or durable insulin pump beneficiaries. Suppliers would not be required to carry all types and combinations of CGMs and durable insulin pumps under this proposal, which would push beneficiaries closer to a one size fits all model that would not meet their needs. Indeed, these technologies are not universally interchangeable, and each beneficiary uses a specific device based on their clinical needs and physiology after consulting with their medical provider. Previous rounds of competitive bidding have been associated with a decline in technological innovation, including a 25% reduction in new product entries and a 75% decrease in medical device patenting, which raises serious concerns for the diabetes community where ongoing device advancements are essential to patient care.⁴

On top of these concerns, the new tasks suppliers will have to undertake as winning bidders under competitive bidding would further disrupt beneficiary access. As you know, suppliers are generally not legally authorized under Food & Drug Administration regulations to perform tasks such as software updates, or address device malfunctions, recall management and insulin pump refurbishment. Imposing substantial new requirements on suppliers is especially concerning given the importance and technical nature of maintaining and educating beneficiaries on appropriately using devices as sophisticated as CGMs and insulin pumps.

Given these concerns, we urge CMS to not finalize these proposals. As we have stated in past communications to the agency, we believe it is more appropriate for CMS to reform coverage policies for these technologies in alignment with the latest clinical evidence and support streamlined access. We note that there is currently a National Coverage Determination reconsideration request to align Medicare insulin pump coverage with current standards of care and evidence pending at CMS, and we encourage the agency to act expeditiously on that request. Additionally, while we support the overarching goal of the agency's proposal to allow beneficiaries to switch to newer technologies more often than every five years, we believe there are other mechanisms for CMS to effectuate the same goal and stand ready to work with the agency to improve access to insulin pumps and CGMs.

We acknowledge and share CMS's concerns and goals to address fraud and the bad actors who take advantage of the Medicare program. However, we ask the agency to ensure that whatever approach it takes appropriately balances and protects beneficiary access to these life-sustaining technologies.

⁴ i, Y., & Rogers, P. (2024). *The long-run impacts of regulated price cuts: Evidence from Medicare* (NBER Working Paper No. 33083). National Bureau of Economic Research. https://doi.org/10.3386/w33083

Thank you for your attention to this matter and we look forward to working with you to achieve our shared goal of ensuring that all Medicare beneficiaries have access to appropriate high quality diabetes care.

Sincerely,

Jeanne Shaheen

United States Senator

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Diana DeGette

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Susan M. Collins United States Senator

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