DIABETES LEADERSHIP COUNCIL

DIABETES PATIENT ADVOCACY COALITION

August 31, 2026

The Honorable Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Submitted via Regulations.gov

Re: Calendar Year 2027 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the Expanded HH Value-Based Purchasing Model; Medicare Provider Enrollment, Durable Medical Equipment (DME), and DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Policies [CMS-1844-P]

Dear Administrator Oz:

On behalf of the Diabetes Leadership Council (DLC) and the Diabetes Patient Advocacy Coalition (DPAC), we appreciate the opportunity to provide comments on the Calendar Year 2027 Home Health Prospective Payment System proposed rule.

We are extremely disappointed that the Agency has not responded to the multiple stakeholders, including patients and patient advocacy groups, that have raised concerns about the disruptions to Medicare beneficiary access that the competitive bidding program (CBP) for CGMs and insulin pumps will cause. DLC and DPAC, other leading diabetes patient and provider advocacy organizations, Members of Congress, durable medical equipment (DME) suppliers, and manufacturers have engaged with CMS leadership and staff over the last year to express our concerns and make recommendations on how to improve the regulations and supplier bid instructions governing the program to protect beneficiary access to the diabetes devices they need to survive. CMS still has not made changes to the program to protect patients.

CMS proposes in this rule to require winning suppliers under the CBP to disclose the country of origin of the lead items they furnish under the CBP. This proposed change acknowledges the issues that stakeholders have raised with the CBP without doing anything to actually address them. Under the CBP suppliers are incentivized to only provide beneficiaries with the products that are economically favorable to the supplier, leading to a potential for a race to the bottom of products and the potential for suppliers to favor products from countries of concern. Further, the rule ignores the other direct beneficiary access challenges the CBP presents as finalized.

We urge CMS to delay implementation of the CBP for CGMs and insulin pumps until it can make changes to the program to protect patients and ensure beneficiaries' access to their technology will not

be interrupted. If CMS insists on moving forward with a competitive bidding program for these products, we urge CMS to update the supplier bid instructions to address the challenges described below in order to protect patients.

About DLC and DPAC

DLC unites former leaders of national diabetes organizations, dedicated to securing effective, affordable health care for every person with diabetes. DPAC is an alliance of people with diabetes, caregivers, patient advocates, health professionals, and others working together to support public policy initiatives to improve the lives of all 38 million Americans with diabetes. As an organization run by and for people with diabetes, DPAC seeks to ensure quality of and access to care, medications, and devices for people living with diabetes.

DLC and DPAC Priorities to Protect Beneficiaries with Diabetes

Continuous Glucose Monitors (CGMs) and insulin pumps work through the use of an algorithm to control the delivery of insulin provided to a person with diabetes through the pump based on the glucose readings of the CGM. These systems are referred to as automated insulin delivery (AID) systems. Evidence shows the use of these systems improves clinical benchmarks in adults with type 1 diabetes[1] and adults with insulin-treated type 2 diabetes.[2] Based on current evidence, the American Diabetes Association (ADA)[3] and Association of Clinical Endocrinology (AACE)[4] include CGMs, insulin pumps, and AID systems as part of the standard of care for people with diabetes.

If CMS moves forward with competitive bidding of CGMs and insulin pumps, DLC and DPAC's priorities are threefold:

1. Ensure that there is no disruption in beneficiaries being able to access their CGM or insulin pump technology or supplies, which would negatively impact beneficiary health and safety.
2. Ensure beneficiaries can get the brand of CGM and insulin pump prescribed by their physician and that are interoperable to not disrupt use of Automated Insulin Delivery (AID) systems.
3. Ensure beneficiary access to training and education on how to use a new CGM, insulin pump, or AID system from a trained, certified, and appropriate healthcare professional.

In addition, CMS has yet to act on requests for updates to the coverage policies for both of these technologies, which would allow Medicare beneficiaries to access these technologies aligned with scientific evidence and clinical guidelines.[5] This presents yet another barrier to care that Medicare

[1] Mercedes J. Burnside, et. al., Open-Source Automated Insulin Delivery in Type 1 Diabetes, 387 New England J. of Med.869 (2022), https://www.nejm.org/doi/full/10.1056/NEJMoa2203913.
[2] Yogish Kudva, et. al., A Randomized Trial of Automated Insulin Delivery in Type 2 Diabetes, 392 New England J. of Med.1801 (2025), https://www.nejm.org/doi/full/10.1056/NEJMoa2415948.
[3] Standards of Care in Diabetes – 2025, 48 Diabetes Care S1 (2025), https://diabetesjournals.org/care/issue/48/Supplement_1
[4] 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.
[5] NCD 280.14; LCD L33822

beneficiaries with diabetes face when entering the program, which will likely be worsened under the CBP when beneficiaries will have to switch suppliers and could need to be recertified to meet the coverage requirements to maintain access to their technologies.

Ensure Access to Prescribed Device

CGMs, insulin pumps, and AID systems have different FDA indications, physical features, supply features (infusion sets, wear times), clinical features (basal and bolus ranges, extended bolus options), software capabilities and algorithms, and languages offered. Devices also have different interoperability – not all CGMs and pumps talk to each other. The devices a beneficiary needs are unique based on clinical needs, lifestyle needs, and physiology. Patients and providers work together to determine what diabetes device a person with diabetes needs. Patients need choice in which devices they use and need access to the device their provider prescribes for them.

The supplier bid instructions released by CMS state, "If the contract supplier does not ordinarily furnish the specific brand or mode of delivery and cannot obtain a revised prescription or locate another contract supplier that will furnish the needed item, the contract supplier MUST furnish the item as prescribed."[6] However, regulations under 42 CFR 414.420 are insufficient to prevent suppliers from steering beneficiaries toward a diabetes device that is most economically favorable to the supplier. If CMS does not have a way to enforce suppliers to carry all of the devices, there could be no suppliers that offer the device a beneficiary needs.

This also leads to the potential for suppliers to steer beneficiaries toward technologies that come from countries of concern. Diabetes technologies contain critical patient health data, and this data is used to deliver insulin through insulin pumps, which is extremely dangerous to the patient if not secure. The GAO and FBI have cited insulin pumps as medical devices susceptible to cyber attacks.[7] CMS should ensure that any devices that are provided by suppliers do not compromise the security of patient data. The proposed disclosure requirement is insufficient to do so, and does not address the key concern of patients not being able to get access to the device they are prescribed because suppliers are steering them toward the device that is the most economically favorable or the only device the supplier is willing to carry.

To ensure beneficiary access to their prescribed device, CMS should:

- Require and monitor that suppliers, except those suppliers that also are the manufacturers of their own diabetes technologies, carry all brands of CGMs and durable insulin pumps subject to the CBP prior to the start of the CBP to ensure beneficiary access to the full range of diabetes technologies and interoperable AID systems.

Prevent Other Access Disruptions

To prevent disruptions to beneficiary access to these critical technologies, CMS should:

[6] https://dmeposcompetitivebid.cms.gov/2028-fact-sheets
[7] United State Government Accountability Office. Report to Congressional Committees. Medical Device Cybersecurity. December 2023. https://www.gao.gov/assets/gao-24-106683.pdf

- **Extend the transition period** for beneficiaries to switch to contract suppliers from six months to at least one year to account for wait times to see a provider and getting beneficiaries, suppliers, and providers equipped to operate under the new system. Significant transition time will be required to go from hundreds of suppliers of these technologies to ten. Beneficiaries will have to find a new supplier who offers their device. Suppliers will have to ensure that beneficiaries qualify for technology. Providers will have to recertify that beneficiaries meet coverage requirements, potentially requiring a patient visit, lab tests, and more.
- **Prohibit policies that would allow suppliers to withhold new diabetes devices from beneficiaries.** Suppliers will be incentivized to require beneficiaries to return their old device before getting a new one, because under the new CBP for these devices the supplier owns the device and the beneficiary is renting it. This would apply whenever a beneficiary is switching a device or supplier. This is a significant threat to patient safety and health. CMS should include in bid instructions specific prohibitions on policies that would jeopardize beneficiaries' 24/7 access to diabetes technologies, including any practice that involves withholding devices until the supplier receives the beneficiary's previous device.
- **Ensure suppliers are equipped to provide CGMs and pumps to the anticipated number of beneficiaries on day one.** The supplier standards state that "if you win a DMEPOS CBP contract, you must be ready to provide items and services for the entire CBA on the first day of the contract performance period." Our understanding is that today very limited suppliers have expertise in providing both CGMs and pumps. CMS should implement specific requirements to ensure suppliers can provide both devices. CMS should require suppliers to demonstrate that at the time of bid submission, they have the capacity, both physically and logistically, to ship CGMs and durable insulin pumps to the number of individuals equal to their projected market share under CBP.
- **Implement a system for monitoring patient disruption** as CBP is implemented. This could include in-person audits, site visits, the use of secret shoppers, and maintaining open communication with beneficiaries and patient advocacy groups. CMS should monitor for patient disruption through an independent arbiter studying Medicare beneficiaries longitudinally for adverse impact.
- **Clarify how suppliers are supposed to rent equipment to multiple beneficiaries when these devices are approved by the FDA for single-use.**

Ensure Access to Appropriate Training and Education

Under the CBP and monthly rental program for CGMs and insulin pumps, suppliers are required to take on the responsibility for training beneficiaries on the diabetes devices. Because the beneficiary previously owned the device for five years and therefore had a relationship with the manufacturer of the device, manufacturers often provided education on how to use the devices. However, there is no guarantee nor requirement that manufacturers continue to do so, even through contracts with the supplier, if the supplier owns the device and the beneficiary's relationship is direct with the supplier, not the manufacturer.

The supplier instructions issued by CMS state that the "supplier must … ensure beneficiaries receive proper instructions on how to use Medicare-covered items safely and effectively." However, CMS does

not include specific requirements to ensure that DME suppliers contract with qualified diabetes educators or other trained, certified, and appropriate healthcare professionals to educate beneficiaries on how to use the technology. Under the CBP, CMS stated that additional flexibility will be provided to beneficiaries to switch technologies/devices more often. If that is the case, beneficiaries will need even more education than they currently do to learn the new devices if they switch. The training required to use a CGM or insulin pump is much more extensive than "instructions for use," that may be required for other categories typically competitively bid. If a person with diabetes does not know how to correctly use their insulin pump or CGM, it disrupts patient safety and could lead to a medical emergency, hospitalization, or worse.

The supplier standards also state that the bid made by the supplier should "consider all anticipated costs (including overhead) and desired profit associated with furnishing both the lead item and non-lead items in the product category throughout the CBA."

To ensure beneficiaries have access to appropriate training and education on how to use their diabetes devices, CMS should:

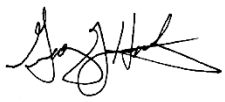
- **Require suppliers to document that they employ trained, certified, and appropriate healthcare professionals who can educate, provide device set up and training, and otherwise assist beneficiaries in using their CGM and insulin pump.**
- **Ensure supplier bids include costs for education, customer service, and fulfilling the duties described in the rule that suppliers must fulfill on behalf of beneficiaries.**

Conclusion

We strongly urge CMS to delay implementation of the CBP for CGMs and insulin pumps to make changes to the program to prevent beneficiary harm. Much more time is needed for suppliers to prepare for the program. At a minimum, CMS needs to add safeguards to the supplier instructions as soon as possible to prevent disruptions to beneficiary access to these innovative, lifesaving devices and to protect patients from harm.

Thank you for your consideration of these comments.

Sincerely,



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