ENDOCRINE SOCIETY
Hormone Science to Health

August 28, 2025

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1832-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare and Medicaid Programs; Calendar Year 2026 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates

Submitted via Regulations.gov.

Dear Administrator Oz,

On behalf of the Endocrine Society, thank you for the opportunity to submit these comments on the Calendar Year (CY) 2026 Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates proposed rule. We are submitting comments specifically on the proposal to add continuous glucose monitors (CGMs) and insulin pumps to the DME competitive bidding program (CBP).

Founded in 1916, the Endocrine Society represents approximately 18,000 physicians and scientists engaged in the treatment and research of endocrine disorders, such as diabetes, hypertension, obesity, osteoporosis, endocrine cancers (i.e., thyroid, adrenal, ovarian, pituitary) and thyroid disease. Our members are leaders in the treatment of diabetes and have authored clinical practice guidelines in diabetes technology, diabetes and pregnancy, and the treatment of diabetes in older adults. As such, our members are knowledgeable about the challenges patients with diabetes face controlling their condition and have found that diverse types of diabetes technology have significantly improved their health outcomes and quality of life.

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Payment for Continuous Glucose Monitors and Insulin Infusion Pumps:

The Endocrine Society appreciates the agency's efforts to address the rapid pace of technological advancement in CGMs, and insulin pumps and shares the Agency's goal of ensuring that beneficiaries have access to the most current technology available. As you know, diabetes technology has seen rapid advancements in recent years, and our members want to ensure that their patients have the most appropriate technology to manage their chronic disease. However, we are concerned that this proposal could result in unintended consequences which may hinder patient access and affordability. Given our concerns, we urge the agency not to finalize this proposal for these devices because of the impact this could have on prescribing decisions, patient choice, and physician administrative burden, which are outlined below.

CMS has proposed a major change to the continuous glucose monitor (CGM) and insulin pump access and reimbursement model, by proposing to reclassify CGMs and insulin infusion pumps to the durable medical equipment (DME) *frequent and substantial servicing* payment category. Under this reclassification, CGMs and insulin pumps would be subject to the DME Competitive Bidding Program (CBP). The Society is concerned about the unintended consequences that could result from these proposed changes. For example, CMS has proposed using a national remote delivery model for CGM, which would limit the number of suppliers the agency contracts with under the competitive bidding program. Consequently, this proposal would significantly decrease the number of CGM suppliers, which could result in reduced patient choice limiting the types of devices that providers may prescribe to their patients. Each patient has varying needs and preferences, and it is paramount that freedom to choose or prescribe the right device, for the right patient and at the right time, is preserved. There are differences between the devices which can have a major impact on patient outcomes and satisfaction. Prescribing decisions for both insulin pumps and CGMs often depend on medical, functional, and lifestyle factors. Examples of these factors include diabetes related complications, cognitive and self-management ability, and lifestyle factors. For CGMs, there are also differences between devices that may influence patient choice including the amount of time a patient can wear the device, device accuracy, how the device is inserted, and pump integration. There are also differences in

insulin pumps that influence patient choice including automation levels, CGM compatibility, insulin requirements, and wearability of the pump.

We are also concerned that these proposed changes will result in increased administrative burden associated with this program. As we detailed in comments on June 6 responding to the agency's RFI on "Unleashing Prosperity Through Deregulation of the Medicare Program", our members are already burdened by duplicative requirements within the Medicare program. Navigating DME supplier procedures, increases in the amount of paperwork, and differing payment structures, to ensure that patients are receiving the devices they need may lead to less time spent in patient care, and increase physician burnout, which continues to be an issue for our members.

Another unintended consequence is that the CBP may lead to supplier consolidation because smaller or local suppliers may leave the market after being unable to compete with large suppliers, leading to fewer suppliers over time. Products and supplier services may also suffer due to price constraints and competition. We are concerned that these changes may hinder patient access and affordability of these devices. Given the concerns we have outlined and the impact this could have on prescribing decisions, patient choice, and physician administrative burden, we recommend that you do not implement this proposal for these devices. However, if the agency chooses to finalize this, then we strongly urge you to publish sub-regulatory guidance to provide all stakeholders with a clear definition of the program; outline the responsibilities of each entity (i.e., manufactures, suppliers, patients, providers) involved in the program; address software updates, technology roll-outs/malfunctions, and device programming; and ensure a simple process for all entities to be able to serve the patient at a minimal cost.

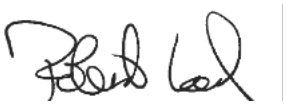
Software Updates and Supply Upgrades:

Under this new model contracted suppliers will be responsible for required software updates, ongoing maintenance, addressing product recalls, and replacing any recalled devices. The agency states in the rule "*If beneficiaries are using rented CGM and/or insulin pump equipment, **then the supplier of the rented equipment is responsible** for making sure*

*the equipment has the latest software updates and that the beneficiary is educated on how to use any updated software or features on the rented equipmen*t." The Endocrine Society is concerned that DME suppliers will not have the infrastructure and other required capabilities to push out software updates as required under this proposed model. Since suppliers do not have experience in this highly technical area, this could result in beneficiaries not having access to the most updated software available. This will also create confusion because CGM updates are released as needed based on software improvements, safety, and compatibility. Given these concerns, we recommend that any software updates from these devices come from the manufacturer. This will ensure that patients receive the latest updates regardless of what device they currently have.

Thank you again for the opportunity to provide feedback on this critical issue. If you have any questions or we can be of further assistance, please contact Rob Goldsmith, Director of Advocacy and Policy at rgoldsmith@endocrine.org.

Sincerely,



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