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VIA ELECTRONIC SUBMISSION: http://www.regulations.gov

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

RE: The Diabetes Technology Access Coalition's Comments to the Calendar Year 2026 Home Health Prospective Payment System Proposed Rule (CMS-1828-P)

Dear Administrator Oz,

The Association of Diabetes Care & Education Specialists (ADCES) appreciates the opportunity to comment in response to the *Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies* (*CMS–1828–P*) as published in the *Federal Register* on July 2, 2025 (the "proposed rule"). Specifically, we are providing input on the section on *Payment for Glucose Monitors and Insulin Infusion Pumps*.

ADCES is an interdisciplinary professional membership organization dedicated to improving prediabetes, diabetes, and cardiometabolic care through innovative education, management, and support. With more than 11,000 professional members including nurses, dietitians, pharmacists, and others, ADCES has a vast and diverse network of practitioners working to optimize care and reduce complications. ADCES supports an integrated care model that lowers the cost of care, improves experiences, and helps its members lead so better outcomes follow.

Technology Choice

ADCES supports this proposal's desire to "eliminate the need to wait 5 years to replace equipment, allowing beneficiaries to use the latest technologically updated items." For beneficiaries who want the latest technologies, five years can be a substantial amount of time for certain produce classes that see advancements at a more rapid pace, and increasing choice—of devices, medications, and providers—for people with diabetes should be the primary goal of CMS's rulemaking. We are concerned, however, that this proposal has been created too quickly and without sufficient input from the diabetes stakeholder community to achieve an increase in choice without unintended consequences that threaten to outweigh the benefit of faster device switching.

Drawbacks for Technology Users of the Proposed Rule

As the association representing the diabetes care and education specialists (DCESs) and others who are helping patients navigate the complex landscape of diabetes management, we are primarily concerned with the logistical challenges that people with diabetes would face when taking advantage of the more frequent device switching offered under this proposal. Under the current rules, beneficiaries own their devices outright after 13 months and are eligible to switch after 60 months. Because they currently own their old device at the time they may decide to switch, they can continue using the device until the new one arrives and they feel adequately training to switch. This means no interruption in the use of their pump.

Under a perpetual rental model, beneficiaries will never own their devices, and it is concerningly unclear what would happen as they transition from one device to another. The proposed rule leaves open the possibility that beneficiaries would need to send their old device back before a new one is shipped to them, which could leave them without an insulin pump for days to weeks. Without a pump delivering their insulin, beneficiaries would need to receive a prescription for injectable insulin and supplies and would need to switch to manual insulin dosage calculations and insulin administration until their new pump arrives and is set up. It is reasonable to believe that some beneficiaries would be too worried about the consequences of temporarily switching from a pump to manual insulin delivery to take the risk of switching—which could leave beneficiaries accessing new technologies *less* frequently out of fear. For most individuals using insulin, the transition from one insulin pump to another is a process that requires planning and time. If not properly administered, this change will add to the burden of diabetes.

We are also concerned by the implementation of competitive bidding for diabetes technologies. Competitive bidding is intended to decrease costs to CMS, but it does so without concern for potential impacts to patient choice, which opposes the goal of the other portion of this rule. Unlike some other classes of DME, diabetes devices are not interchangeable. Particularly in the case of insulin infusion pumps, each device comes with different hardware, software, user interface, and integration potential with other devices and third-party software. If competitive bidding were to result in one or more device options being removed from the Medicare market, that would have significant impacts on all users of the removed devices who would need to re-learn a potentially very different piece of technology that they may or may not have as much success with. Self-management already represents a significant burden to people with diabetes. Periodically requiring a beneficiary to change from their technology of choice because a new round of supplier bids came in, leaving their current device no longer available, would harm beneficiaries' ability to self-manage their diabetes and could lead to increased comorbidities and healthcare costs that surpass any potential savings from competitive bidding.

Unintended Consequences for Access to Education and Training

ADCES would also like to draw the administration's attention to the way this rule negatively intersects with the limited education and training made available to Medicare beneficiaries with diabetes to self-manage their condition, including training on the use of continuous glucose monitors and insulin infusion pumps. With the implementation of any policies that increase the rate at which beneficiaries can access new technologies, an increase in the need for training and education on these new devices will follow. The goal of training and education for new devices is to

improve patient success with integration of their new device into their diabetes self-management care plan. Inadequate access to education and training could result in beneficiaries switching technologies more often than they may otherwise choose to. This may impact management of diabetes which is key to maintaining health and reducing complications. Inadequate device education could also result in beneficiaries abandoning the use of diabetes technologies altogether, which then precludes them from reaping the myriad clinical benefits associated with the use of these devices.

Diabetes Self-Management Training Background
Medicare Part B has a long-standing benefit for beneficiaries with diabetes to receive training, education, and support for self-management of their disease. The Diabetes Self-Management Training (or DSMT) benefit has been largely unchanged since the early days of its creation 25 years ago and benefit design choices made by CMS contribute to the fact that fewer than 5% of newly diagnosed beneficiaries utilize DSMT within the first year after diagnosis.[1]

The DSMT benefit was conceptualized by CMS as something beneficiaries with diabetes receive a significant amount of upfront ("initial training" in the first year), with only what CMS calls "follow-up training" for the rest of their lives. As such, up to 10 hours of DSMT can be billed in the first 12 months after a beneficiary begins using the service. After the initial 10 hours are exhausted or after 12 months have passed (whichever comes first), only 2 hours per year are allotted by CMS. There is no pathway for beneficiaries who need additional education to receive additional hours of DSMT beyond the 2 allotted: not additional referrals, change in management plan, introduction of technologies or medications (that may not have even been invented yet when the beneficiary used their initial DSMT), hospitalizations, therapeutic inertia, or any other complications or comorbidities. Beneficiaries who need additional hours of DSMT beyond the 2 available must be charged full price by the program unless the patient meets conditions for sliding scale fees. Outside of that exception, programs are not allowed to provide the additional care for free as that is considered illegal beneficiary inducement.

The benefit also suffers from its design as a presumptive group service. In the first 12 months/10 hours of DSMT, CMS requires 9 of the 10 hours, to be conducted in a group setting unless one of three exceptions are met: 1) there are no group classes available within 2 months of when the referral was written, 2) the beneficiary has a special need ("such as severe vision impairment, hearing, or language limitations") that then allows the referring provider to specify individual-only initial training, or 3) the provider orders additional insulin training. CMS has refused repeated requests over many years to provide additional guidance on other qualifying exceptions, so programs are hesitant to accept exceptions outside this narrow list in the regulations. Fortunately, the 2 hours of follow-up training in the out-years are allowed to be conducted as individual education.

[1] Strawbridge LM, Lloyd JT, Meadow A, et al. Use of Medicare's diabetes self-management training benefit. *Health Education Behavior* 2015; 42: 530-8.

CGM Training Background
CMS pays for CGM placement and training via CPT code 95249. This code covers sensor placement, hook-up, calibration of the monitor, patient training, and a printout of the recording of 72+ hours of data from the worn device. The code can be billed once per device, meaning it can be used for initial training, but cannot be rebilled if a patient has additional questions or challenges later.

Pump Training Background
There are *no codes* in place to pay specifically for placement and training for a new pump. Currently, much of this device-specific training is provided by diabetes care and education specialists hired or contracted directly by pump manufacturers.

Intersection with Proposed Rule
The availability of education and training, especially for people receiving new pumps, is unclear, at best, and lacking, at worst, under the proposed rule. As there are no codes for providers to bill for training beneficiaries on new pumps, there is heavy reliance on manufacturer-provided training under the current system. With the shift of responsibilities to DME suppliers under the proposed rule, it is unclear who would provide device training moving forward. Suppliers have no experience with providing training, and any training networks they could hire out for would still need training themselves from the manufacturers on new devices.

Without manufacturer-provided device training for pumps, the alternative would be to use the DSMT benefit. It is critical to understand that this benefit was not designed to accommodate significant changes to the beneficiary's management plan beyond the first year of diagnosis, let alone to absorb all device training needs within Medicare. As discussed above, a beneficiary receiving a new pump who has never used any of their DSMT benefit would have access to 10 hours over the first year, but this training would likely need to occur in a group setting due to CMS regulations at §410.141(c), which can pose challenges for new device training. If the beneficiary had used DSMT services before, they would be left with a maximum of 2 hours available during the calendar year, with no ability for additional hours. This is insufficient time to train the average beneficiary on a new insulin infusion pump. Compounding these challenges are our additional concerns that not all providers prescribing diabetes technology are aware of DSMT, know how to refer for it, or know how to locate a program to refer to. For beneficiaries seeing a provider with this awareness gap, their access to device training could be even further reduced.

We are highly concerned that this rule's shift of responsibilities to suppliers could have the unintended consequence of leaving beneficiaries without access to adequate education and training. Leaving beneficiaries to self-teach the use of a new insulin infusion pump or relying on insufficiently training office staff could have devastating consequences.

Education and Training Solutions
For patients with access to DSMT, two main changes to the regulations governing the structure of the benefit (42 CFR §410.141(c)) would make it easier for this subset of patients to use the benefit to accommodate the increased frequency of education expected to be necessary under this proposal.

First is to allow all 10 hours of initial DSMT to be done individually if the referring provider specifies that need, without limiting this access to people with specific disabilities or circumstances as is currently the case. This is achieved through small tweaks to the current regulation: 1) Amend 42 CFR §410.141(c)(1)(i)(D) to read, "(D) Is furnished on an individual basis or in a group setting consisting of 2 to 20 individuals who need not all be Medicare beneficiaries," 2) delete 42 CFR §410.141(c)(1)(i)(F), and 3) Delete 42 CFR §410.141(c)(1)(ii).

Second is to remove or increase the 2-hour limit on follow-up DSMT and allow referring providers to refer for additional hours, as needed. This could be achieved by increasing the specified hours available at 42 CFR §410.141(c)(2)(i) from 2 hours to 10 hours, so that 10 hours are available in all years. Ideally, CMS would also write a new section (at 42 CFR §410.141(c)(3)) to create a new category of "additional hours" under which hours are made available based on a referring provider's certification of medical necessity so that beneficiaries can have access to as much education and training as is medically necessary.

In addition to these changes, CMS should also create and pay for a code for startup/training for insulin pumps to allow prescribing providers to provide this training within their offices rather than relying on the DSMT benefit that needs to be available to cover all aspects of diabetes self-management. This new code could be loosely based on 95249 for personal CGM startup/training. However, due to the more intensive nature of pump startup/training, the new code should either be assigned a greater value to reflect the additional work involved, or the code should be time-based rather than the one-size-fits-all, once-per-device billing limit inherent to an intensity-based code.

Conclusion

Despite the laudable goal of increasing patient access to the latest technologies, ADCES is concerned that unintended consequences of the proposed rule will outweigh the positives. This is compounded by the rule's fast-paced timeline. We strongly encourage the administration to forego finalizing this portion of the rule for CY26 and to instead engage in a dialogue with the diabetes community on how to achieve these goals in a beneficiary-centric way. When and if CMS moves forward with finalizing any version of a rule to increase access to diabetes devices more often, we implore the administration to simultaneously make the changes outlined above to education and training benefits to minimize the impact that lack of access to these services would have.

ADCES appreciates the opportunity to comment on this proposed rule. Please contact ADCES director of advocacy Hannah Martin at hmartin@adces.org should you have any questions regarding ADCES' comments.

Sincerely,

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Chief Executive Officer

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Director of Advocacy