diaTribe

TIME COALITION IN RANGE

August 28, 2025

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

Submitted via Regulations.gov

RE: 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]

Dear Administrator Oz:

On behalf of the Time in Range Coalition (TIRC), we appreciate the opportunity to comment on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) portion of the Calendar Year 2026 Home Health Prospective Payment System proposed rule [CMS-1828-P]. The TIRC applauds the Centers for Medicare and Medicaid Services (CMS) for seeking to provide beneficiaries more nimble access to the latest diabetes care products so their disease management can keep pace with technological advances, however, we have serious concerns about the untested approach for achieving this goal laid out in the proposed rule. Paying for continuous glucose monitors (CGMs) and insulin infusion pumps under the proposed DMEPOS Competitive Bidding Program (CBP) could instead cause negative, unintended consequences such as reducing beneficiaries' access to life-saving tools that are the standard of care for people with diabetes. We thank you in advance for your consideration of our concerns and recommendations and welcome the opportunity to work with you and your staff on this and other pressing diabetes care issues.

About the Time in Range Coalition (TIRC)

Spearheaded by The diaTribe Foundation, the TIRC is a diverse group of global diabetes stakeholders, including nonprofit organizations, professional societies, industry, and patient advocates working to drive awareness and adoption of time in range (TIR). Given the broad array of perspectives, collective reach, lived experience of people living with diabetes, and deep expertise in influencing the adoption of diabetes technology, the TIRC can offer CMS valuable insights with respect to evaluating coverage and payment policies for diabetes technology.

Reliable measurement of TIR, which is the percentage of time a person spends within a target glucose range and is reported alongside time above range (TAR) and time below range (TBR), is now possible through advancements in continuous glucose monitoring. This technology empowers individuals living with diabetes to be aware of their glucose levels every few minutes, such that they can make real-time adjustments to their diet, activity, and medication dosing to improve health outcomes.[1,2] Studies have

shown that as one's TIR increases, health complications from the disease–and associated healthcare costs—decrease.[3–13] To that end, ensuring unencumbered access to CGMs and other life-saving diabetes technology is a core focus for the TIRC.

Background

More than 11% of the U.S. population has diabetes – a staggering 38.4 million people.[14] Over the past decade, FDA approvals of safe and effective drugs and devices have transformed diabetes care. People with diabetes now have access to therapies and devices that not only improve glucose levels, but also support weight management, reduce hypoglycemia, and prevent some of the costly complications associated with diabetes, including cardiovascular and renal disease. Furthermore, advances in the accuracy and ease of use of CGM technology has increased the acceptability by clinicians and people with diabetes who are increasingly reliant on CGM metrics like TIR for the daily diabetes management. A growing body of evidence shows that TIR has added value in clinical, research, and regulatory settings.[15–18]

CGMs and Insulin Pumps as Rented DME from Suppliers Contracted through Competitive Bidding—Possible Unintended Consequences

In Section VII.G of the proposed rule, CMS states its intention to "reclassify all CGMs and infusion pumps under the frequent and substantial servicing payment category… CMS would pay for all CGMs and insulin infusion pumps on a monthly rental basis under both the DMEPOS CBP and in non-CBAs under the fee schedule payments. The monthly rental payments would include payment for any necessary supplies and accessories." While we appreciate that the intention of this approach is to allow beneficiaries to more nimbly switch to better-suited or upgraded devices than is possible under the current model (which only allows for changes in device five years after purchase of the previous device), we would like to highlight several anticipated unintended consequences:

1. *Life-Saving Devices Are Not Suited for Competitive Bidding or Rental*

CGMs and insulin pumps deliver timely, precise information and medication dosing that if interrupted or inaccurate, can have devastating consequences. These devices are technologically complex, life-saving, and vary greatly from model to model. People with diabetes depend on CGMs for current glucose levels as well as upward and downward trend information to avoid hyper- and hypoglycemic events. Automated insulin delivery (AID) systems, which require the combined use of insulin pumps and CGMs, adjust insulin delivery based on glucose levels and trends. These systems have become critical tools for people with diabetes, and are now the standard of care with respect to insulin delivery, especially for those with type 1 diabetes.[3] A few hours without them working properly can lead to catastrophic complications. For these reasons, insulin pumps and CGMs are profoundly different from other DME, which may be focused on supporting recovery from an acute injury, illness, or wound. We believe the fundamental nature of what these tools do for—and mean to—beneficiary health and well-being are inherently different from other products that are part of CBPs.

Under a rental model, beneficiaries will be required to return devices to suppliers. We are very concerned that the proposal does not include any provisions or protections that would require beneficiaries to have continuous access to the prescribed device. Suppliers must not be allowed to force a beneficiary to return the device currently in their possession before a replacement or upgraded device is provided, for example. Because these devices are used to titrate life-saving insulin and many patients

do not have the supplies or education to support a temporary switch to alternate methods, going without them for any period of time poses a significant disruption to their diabetes management and potentially deadly risks. Under a purchase model, such continuity of care is built in, while it is neither implied nor guaranteed under the proposed model.

Additionally, the proposed CBP does not appear to ensure that both retail and mail-order options are represented among the contracted suppliers. Mail-order businesses may have lower costs, making them more likely to be awarded a contract. However, many people with diabetes prefer the convenient, immediate access to their life-saving devices provided by retail suppliers, without possible disruptions and delays while waiting for shipments. Further, retail suppliers are essential for beneficiaries who may be transient or otherwise unable to reliably receive shipments. A finalized rule should preserve the supply delivery channel many people with diabetes depend on by ensuring retail suppliers remain available.

The TIRC is also concerned that the incentives under a rental model are generally misaligned when applied to CGMs and insulin pumps. Manufacturers' focus will shift to suppliers' needs, not patients' needs, as patients will no longer be the end purchaser. Suppliers will want to maximize the return on the investment they have made in the devices they rent out, incentivizing them to limit access to new emerging technologies. Additionally, suppliers, who are not required under the proposed rule to keep all commercially available devices in stock, may be incentivized to steer patients to items that are cheapest to source or to class III devices because they are excluded from competitive bidding.

Additionally, these devices contain private health information. Under a rental model, devices will be returned to suppliers, introducing the need to ensure contracted suppliers maintain rigorous systems to protect beneficiary data and privacy. Finally, suppliers would also be responsible for refurbishment, a process not currently undertaken by most manufacturers. Related, the proposed rule raises questions as to whether manufacturers of single-use devices would need to have the approved indication for use changed to multi-patient use, with potential implications for patient access during that process.[19–21]

2. Proposed Rule Fails to Ensure Timely Access to Rapidly Expanding Product Selection

While it is true that the proposed rule requires suppliers under the CBP "to furnish the CGM receiver or insulin pump ordered by the beneficiary's physician," that does not prevent suppliers from potentially limiting the universe of devices available in the first place. The proposed rule does not require suppliers to keep in stock or otherwise make available all commercially available devices that a health care professional might prescribe for a beneficiary with diabetes. Further, AID systems require the use of a specific combination of compatible CGMs and insulin pumps. Suppliers must be required to carry the full range of approved devices, allowing physicians to prescribe the most appropriate products for the individual beneficiary and beneficiaries to easily secure the prescribed devices from the supplier servicing their community.

The proposed rule sets pricing for a rental model based on "the purchase of a new, non-adjunctive CGM (HCPCS level II code E2103) with a reasonable useful lifetime of 5 years." Diabetes technology is evolving very rapidly, with multiple new CGMs and insulin pumps featuring distinct advancements in dosing algorithms, predictive alarm features, improved form factors, and more entering the market every year. Additionally, CGMs feature a single-use sensor, with various models utilizing a single-use or 3-month transmitter which communicate to a receiver, a smart phone, and/or an insulin pump. This construction means only the receiver, which is rarely utilized as most patients opt to use their smartphone, would be

part of the monthly rental option under the newly proposed rule. However, supplier reimbursement would then be locked based on the use of a single CGM system for five years, at a time when updated technology is being introduced frequently. Therefore, expecting the same device to be used for 5 years is not reasonable for these types of CGM technologies. Allocating funding to suppliers at a rate that assumes 5 years of use for each device is likely to disincentivize suppliers from stocking these new technologies as they emerge. Slow uptake of new products at the Medicare DME supplier level could have upstream effects as well, hindering viability for new manufacturers and stifling innovation. It is essential that CMS ensure beneficiaries have access to these quickly-evolving and outcome-changing tools as they become available.

3. *Competitive Bidding and the Use of Suppliers Interferes in Beneficiaries' Ability to Receive the Most Accurate, Appropriate, and Sufficient Device Training and Education*

In the proposed regulation, CMS classifies CGMs and insulin pumps as requiring "frequent and substantial servicing" and proposes that "the supplier of the rented equipment [would be] 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 equipment." Such a shift of responsibility from manufacturers to suppliers is not appropriate for such complex and rapidly advancing technologies. CGMs and insulin pumps rarely require 'servicing;'' when malfunctions occur, manufacturers provide troubleshooting assistance to users, and completely replace devices when issues cannot be resolved remotely. By moving to a CBP, CMS is introducing a less knowledgeable third-party into the equation. Suppliers are not prepared to respond to the highly device-specific nature of these beneficiary service requests, nor the software updates and patient training that are necessary to keep beneficiaries safe and healthy. Manufacturers are best suited for such important health and safety matters.

Of further concern is the potential for patients to exhaust their diabetes self-management training (DSMT) benefit when switching devices (as this proposed regulation intends to empower), since after the initial 10-hour (life-time limit) training period beneficiaries only qualify for up to two additional hours per calendar year. Since training is necessary to adapt to the unique features of a new or different device, use of multiple devices in the same year may require more than the allotted time for a beneficiary to learn how to use the new device. The proposed rule would ideally, to the maximum extent permitted by statute, include insulin pump training as explicitly eligible for reimbursement under the DSMT benefit and lift the time caps on the initial and annual DSMT benefits, so that beneficiaries can have access to the education and training they need to support safe and effective switching between devices. Without adequate training on how to use a new device, beneficiaries' health could be at risk.

Conclusion

The TIRC appreciates CMS' concern about ensuring beneficiary access to rapidly advancing diabetes technologies, but unfortunately the system outlined in the proposed rule falls short of improving access and instead presents a range of new concerns. It is essential that the voices, concerns, and perspectives of beneficiaries be considered before implementing a new system with significant impact on treatment access and health outcomes. As the issues we have outlined pose a series of unintended barriers to life-saving technologies, we urge CMS not to finalize this proposal until the nuances and potential implications of revising the system through which beneficiaries access these life-saving technologies can be discussed in detail with a working group of all stakeholders, including suppliers, manufacturers, prescribers, and people with diabetes.

The TIRC supports CMS' effort to modernize payment and coverage policy to facilitate more timely beneficiary access to diabetes technologies and we welcome the opportunity to be a part of a multi-stakeholder working group effort to inform changes that will allow beneficiaries to have improved access to new developments in CGMs and insulin pumps. At this time, we do not believe that CGMs and insulin pumps should be subject to competitive bidding; we stand ready to partner with you to craft an approach that will achieve CMS's laudable goal and address the issues we have raised herein. Should you have any questions, please do not hesitate to contact us, via julie.heverly@diaTribe.org, at any time.

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