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Aug. 28, 2025

The Honorable Dr. Mehmet Oz
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-1828-P
7500 Security Boulevard
Baltimore, MD 21244–1850

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]

Administrator Oz,

The National Community Pharmacists Association (NCPA) appreciates the opportunity to provide comments to CMS on its proposed rule *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* (HH DMEPOS proposed rule).

NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Almost half of all community pharmacies provide long-term care services and play a critical role in ensuring patients have immediate access to medications in both community and long-term care (LTC) settings. Together, our members employ 205,000 individuals, and provide an expanding set of healthcare services to millions of patients every day. Our members are small business owners who are among America's most accessible healthcare providers. NCPA submits these comments on behalf of both community and LTC independent pharmacies.

Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges (§ 424.57(c)(24))

CMS proposes requiring DMEPOS suppliers to be surveyed and reaccredited every year (as opposed to the current 3-year cycle). NCPA opposes this for several reasons:

Accreditation meant to safeguard quality, not prevent fraud. As CMS has recognized, accreditation serves to "confirm…that the supplier meets the DMEPOS *quality* standards" [NCPA

emphasis], and CMS is concerned that accrediting organizations (AOs) are accrediting DMEPOS suppliers that do not meet the quality standards, and that DMEPOS suppliers are falling out of compliance with the quality standards after becoming accredited.

However, in this proposed rule, CMS identifies multiple cases of criminal ***fraudulent*** billing practices and schemes where DMEPOS suppliers submitted false claims without even providing the DMEPOS product to the beneficiary. Among these multiple cases, none were pharmacies. Regardless, fraud, not quality, is at issue. So rather than allowing the AOs to ensure DMEPOS quality standards, under this proposal CMS is "deputizing" the accreditation organizations (AOs) with law enforcement powers, which is not appropriate to how AOs are meant to function. AOs are not intended to be investigators of fraud, nor do they understand the processes of detecting fraud. Therefore, the proposed rule will not protect the Medicare trust fund and beneficiaries as intended.

Pharmacies are already highly regulated. Pharmacies that are DME suppliers are already subject to rigorous regulatory oversight by state boards of pharmacy, the federal Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA). This state and federal oversight offers further assurances that the supplier pharmacy is operating in accordance with state and federal laws and regulations that govern the practice of pharmacy and the dispensing of prescription drugs, controlled substances, and DMEPOS supplies. In general, boards of pharmacy provide routine and for-cause inspections of pharmacies to ensure compliance with laws and rules and respond to consumer and patient complaints related to the practice of pharmacy, which may include unethical conduct, including fraudulent billing. Likewise, the DEA has the capability to enter a pharmacy and inspect records and inventory to ensure the pharmacy's compliance with the federal Controlled Substances Act (CSA).

Significant administrative and cost burden. NCPA strongly opposes this proposal given its significant administrative burden. This proposal is not feasible as larger DMEPOS suppliers would need to engage at least two surveyors every single business day of the year. In its Regulatory Impact statement, CMS significantly underestimates how costly this proposal will be to DME suppliers. DME suppliers will bear the direct costs of approximately $1,500 per location for the additional AO surveys; therefore, suppliers with multiple locations will incur more significant costs. DME suppliers will also incur additional indirect costs of additional workforce needed to ensure annual accreditation compliance.

Instead of annual accreditation, CMS could establish alternative, more effective ways to address fraud, waste, and abuse. For example, CMS could assess information that the AOs gather during their surveys related to suspicions of fraud, waste, or abuse.

Harms to patient access. NCPA is concerned that the increase in onsite surveys and the addition of ad-hoc surveys will cause an increased cost to DME suppliers, which in turn will negatively impact patient access to these products as pharmacies will reconsider participating in the program entirely. For example, diabetic test strips are often paid below cost in Medicare, so additional accreditation costs may cause pharmacies to decide to stop stocking these supplies.

For the above reasons, NCPA recommends that CMS maintain its current requirement for reaccreditation to occur every three years for state licensed pharmacies.

Revocation of enrollment in the Medicare program (§424.535)

(D) Items or services on claims that are not rendered or furnished. CMS proposes that the supplier's PTAN number can be revoked if the beneficiary attests that the item(s) or service(s) identified on the provider's or supplier's claim or claims was not or were not rendered or furnished. **NCPA opposes this proposal.** The beneficiary's testimony may be insufficient without corroborating information. Currently when a beneficiary contacts 1-800-Medicare to report this type of incident, the supplier is sent an additional documentation request (ADR) requesting information and proof of delivery, and other documentation. It is not appropriate to unilaterally revoke a PTAN based on a beneficiary's claim, especially given sporadic reliability of the United States Postal Service and other delivery services. In addition, beneficiaries may unintentionally provide incomplete or inaccurate information due to memory issues, confusion about delivery timelines, or lack of understanding about the services received. Revocation of billing privileges is overly punitive when there is a single claim of non-delivery from one beneficiary. Instead, CMS should consider revocation only after establishing a pattern of billing and non-delivery for the particular supplier.

(ix) False or misleading information on the enrollment application. CMS proposes that false or misleading information on the enrollment application would result in the DME supplier having a revocation of enrollment in the Medicare program, effective on the date the application's certification statement was signed. **NCPA opposes this proposal as unreasonably harsh.** For example, a DME supplier that provides information that is not intended as false or misleading, and that is not otherwise disqualifying, should not be grounds for retroactive deactivation. At the very least, CMS should clearly define what is "false or misleading," which should include a requirement of evidence of intent. The supplier should be allowed the opportunity to timely address the issue to avoid retroactive revocation. Moreover, this situation would previously have been handled under a SACU (Supplier Audit & Compliance Unit) investigation, and it should continue to do so.

(x) Change of ownership. CMS proposes that failure to timely report a change of ownership would result in the DME supplier having a revocation of enrollment in the Medicare program, effective the day after the date by which the supplier was required to report to CMS. **NCPA opposes this proposal.** CMS should allow for a stay of enrollment to give the DME supplier an opportunity to correct the issue. If the supplier cannot timely correct the issue, then revocation may be appropriate, but not on a retroactive basis.

When a pharmacy that is a DME supplier has a change of ownership, often the pharmacy must obtain a new state license, and through this process experience a delay in obtaining the license. Under CMS' proposal, this may result in a failure to timely report a change in ownership, as submitting an 855S without the licensure will result in a revocation. This delay would have occurred in a normal series of events that occur when change of ownership occurs, and through

no fault of the supplier. Additionally, a formal name may result in delays in the DME supplier receiving new CP575 documentation showing the legal name change and tax identification number, through no fault of the supplier.

Competitive Bidding: Continuous Glucose Monitors and Insulin Infusion Pumps

Overview. CMS proposes to reclassify all continuous glucose monitors (CGMs) and insulin infusion pumps under the frequent and substantial servicing payment category under § 414.222(a) and to pay for these on a monthly rental basis under the DMEPOS competitive bidding program (DMEPOS CBP) and in non-competitive bidding areas (CBAs) under the fee schedule payments. The monthly rental payment would include payment for the base DME item and associated supplies and accessories. CMS would allow contract suppliers to bill for up to 3 months of rental for these items in advance. In contrast, CGMs and insulin pumps are currently paid under the Medicare Part B DME benefit, where Medicare beneficiaries receive a replacement CGM receiver or insulin pump once every 5 years, unless their equipment is lost, stolen or irreparably damaged.

§ 414.408 Payment rules. - *Special temporary transition rules for payment for supplies and accessories necessary for the effective use of beneficiary owned continuous glucose monitors and insulin infusion pumps*. CMS proposes to continue, as applicable, to make separate payments under the DMEPOS CBP for supplies and accessories for class II continuous glucose monitors or insulin infusion pumps owned by the beneficiary at the time a competitive bidding program is phased in for class II continuous glucose monitors or insulin infusion pumps for the first time in a competitive bidding area (CBA) where the beneficiary resides until coverage for the beneficiary-owned equipment ends, the equipment is no longer used, or at any point when the equipment has been replaced with rented equipment under the DMEPOS Competitive Bidding Program (DMEPOS CBP). **NCPA argues that CMS should not place these supplies in the DMEPOS CBP. However, if CMS does place these supplies in the DMEPOS CBP, NCPA supports this transitional coverage.**

§ 414.412 Submission of bids under a competitive bidding program.

Continuous glucose monitors. CMS proposes that the bid amount submitted for rental of class II continuous glucose monitors included as a lead item in a product category in a remote item delivery competitive bidding program (CBP) for the first time must not exceed the payment amount that would otherwise apply to the monthly fee schedule amount for the supplies for the class II continuous glucose monitor under subpart D of this part plus the average of the purchase fee schedule amounts that would otherwise apply to the class II continuous glucose monitor for the areas included in the remote item delivery CBP divided by 60.

Insulin infusion pumps. CMS proposes that the bids amount submitted for rental of insulin infusion pumps included as a lead item in a product category in a remote item delivery CBP for the first time must not exceed the nonrural payment amount that would otherwise apply to the

supplies and accessories for the insulin infusion pump under subpart D of this part, with the application of § 414.210(g), for a 1-month period plus the total nonrural rental fee schedule amounts that would otherwise apply to rental of the insulin pump for 13 months of continuous under subpart D of this part, with the application of § 414.210(g), divided by 60.

§ 414.416 Determination of competitive bidding payment amounts - Payment for Continuous Glucose Monitors and Insulin Infusion Pumps

CMS is proposing to make payment under the DMEPOS Competitive Bidding Program (CBP) for certain continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories on a bundled monthly rental basis. CMS asserts that the technology of products used by beneficiaries to help manage diabetes continues to change rapidly, and without frequent and substantial servicing to ensure that the devices continue to function correctly, the beneficiary might not receive information they need to make correct diabetes treatment decisions or the dosage of insulin administered by the insulin pump could be incorrect, putting the beneficiary in imminent danger. CMS' proposal would eliminate the need to wait 5 years to replace equipment, allowing beneficiaries to use the latest technologically updated items. Payment for continuous glucose monitors and insulin infusion pumps and all necessary supplies and accessories that are not furnished under the DMEPOS CBP would also be made on a bundled monthly rental basis in the same amounts established for continuous glucose monitors and insulin infusion pumps under the DMEPOS CBP.

NCPA Concerns

NCPA is concerned that this proposed CGM Competitive Bidding Program could inadvertently hinder Medicare beneficiaries' access to appropriate CGM technologies, which would reduce access to patient care and threaten diabetes management.

Pharmacist's role in CGM. Diabetes management is a necessary and growing service provided by community pharmacists, which is made possible by continuous glucose monitoring (CGM). CGM devices allow patients and providers to monitor glucose levels in real time and optimize medication usage and wellness practices. Diabetes management is a necessary and growing service provided by community pharmacy as pharmacy is the true gateway to care in the community. Patient access to CGM allows pharmacists to better coach and counsel their patients with diabetes. It illuminates patient adherence to their medications and allows for high personalization of recommendations.

While pharmacies are unable to facilitate maintenance of rented equipment, and required processes outlined in the proposed rule, pharmacists are integral in providing education and support. The proposed rule offers limited opportunity for patients to ask face-to-face questions and get in-person support for their devices in a timely manner, which will negatively impact seniors with low health literacy and digital literacy. Patients who have relied on their pharmacies for years for CGMs, related supplies, and pharmacist expertise on these products will likely continue returning to their pharmacies for information and education, but without the necessary infrastructure for pharmacies to accommodate CGM access and wraparound support.

Additionally, physicians and other prescribers will likely continue to send prescriptions for CGMs to pharmacies, creating confusion and delayed access for patients.

Pharmacists likely excluded under these proposals. There is particular concern that pharmacies will be excluded from becoming contract suppliers under the CBP, causing beneficiaries with diabetes to lose access to pharmacies that provide them with both diabetes-related and other health care services. Beneficiaries living in rural areas may be impacted the most by the exclusion of pharmacies from becoming contract suppliers, as pharmacies are often seen as the place for in-person acquisition, education, and support. A nationwide CBP would prevent patients from picking up their CGMs from their local community pharmacy, which jeopardizes patient access to the devices and pharmacist-provided services.

Beneficiaries should own, not rent CGMs and insulin pumps. Patients can benefit from owning rather than renting their CGMs and insulin pumps. The selection of insulin pumps for each patient is most often highly personalized, considering many factors of a patient's health care needs. In addition to any cost savings associated with owning the device outright after a certain amount of time, patients that own their devices are not subject to fluctuating rental costs or coverage issues with insurance. Additionally, patients using these devices often use them long term, which often necessitates customization of those devices. In contrast, there may be restrictions on such customization in rental contracts, which may negatively impact patient care.

CGMs should not be reclassified under frequent and substantial servicing. While HHS's comments imply that CGMs need frequent and substantial service, this is not a reflection of the current marketplace. Most CGMs use a sensor that is attached under the patient's skin and a transmitter to send blood glucose data back to a receiver. Depending on the device, the sensors are replaced by the patient every seven to fourteen days, but the receiver usually does not have to be routinely changed. When handheld devices or other smart devices (i.e., smart watches, mobile applications) are used as the receiver or transmitter of information, updates may be required over the product's life but should not be routine. **As such, NCPA advises that CMS should not reclassify CGMs within the frequent and substantial servicing payment category, which would require payment on a rental basis.** Broadening this classification to include items like CGMs may exceed Congressional authority.

Pharmacists should be able to bill for CGM. It is important that CMS set a precedent for allowing pharmacists to bill for the device unit and the corresponding counseling of continuous glucose monitoring (CGM) in Medicare. We are aware of a number of private plans that cover the CGM device unit under the prescription benefit, while others cover it under the medical benefit. We are not aware of private plans that cover and reimburse for the counseling component. **NCPA urges CMS to expand access to needed diabetes services, specifically by covering CGM that is delivered by pharmacists and other qualified practitioners under direct or general (preferable) supervision. NCPA encourages CMS to consider pilot programs, especially for CGMs and insulin infusion pumps, to use and reimburse pharmacists to remotely monitor patients' blood glucose values to provide coordinated care and adjust medication regimens to achieve better patient outcomes, driving down health care costs over time.**

Given our above concerns, NCPA urges CMS to not adopt the proposed revisions to the CGM Competitive Bidding Program.

Conclusion

NCPA appreciates the opportunity to share with CMS our comments and suggestions on the HH DMEPOS proposed rule. Please let us know how we can assist further, and should you have any questions or concerns, please feel free to contact me at steve.postal@ncpa.org or (703) 600-1178.

Sincerely,

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National Community Pharmacists Association