American Pharmacists Association

August 29, 2025

[Submitted electronically to www.regulations.gov]

The Honorable Mehmet Oz, MD
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)
Attention: CMS-1828-P
P.O. Box 8013
Baltimore, MD 21244-8013

RE: [Docket No. CMS-1828-P, RIN 0938-AV53] 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, Proposed Rule

Dear Administrator Oz,

The American Pharmacists Association (APhA) appreciates the opportunity to provide comments to HHS's 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." To prevent Medicare fraud, waste, and abuse, CMS and HHS are proposing to update the DMEPOS Competitive Bidding Program (CBP), the enrollment of providers and suppliers, and the accreditation of DMEPOS suppliers. APhA recognizes the importance of deterring fraud, waste, and abuse through audit and accreditation practices, but has concerns that the proposed change in the accreditation processes will disrupt pharmacy practice and amount to an unfunded mandate and administrative burden on pharmacists. Additionally, APhA is concerned that a nationwide competitive bidding program for continuous glucose monitors (CGMs) and insulin infusion pumps may limit patient access to these devices and close local brick-and-mortar DMEPOS suppliers, including trusted, local community pharmacies that seniors have come to rely on.

APhA is the only organization advancing the entire pharmacy profession. It represents pharmacists, student pharmacists, and pharmacy technicians in all practice settings, including— but not limited to—community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

Provider Enrollment, Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Accreditation (DMEPOS) Accreditation Policies, and DMEPOS Prior Authorization (FR 29190)

The HHS Secretary is required to establish processes and procedures for the enrollment of providers into the Medicare program under Section 1866(j)(1)(A) of the Social Security Act to ensure Medicare providers meet all applicable eligibility requirements and attempt to prevent fraudulent billing.[1] Currently, CMS surveys and reaccredits DMEPOS suppliers every three years.[2] CMS is proposing to change the accreditation process to require DMEPOS suppliers to be surveyed and reaccredited each year.[3]

HHS has concerns that not every supplier receives a survey as part of the DMEPOS accreditation process, explicitly listing large chain suppliers that operate twenty-five or more separately enrolled locations, like chain pharmacies.[4] HHS "believe[s] this is a potential vulnerability in our enforcement of the DMEPOS accreditation requirement."[5] APhA believes that the overwhelming majority of pharmacists and pharmacies providing DMEPOS are abiding by the accreditation standards. As such, the more frequent accreditation of chain pharmacies is likely not warranted and requires pharmacies to shift their focus from providing patient care to completing administrative paperwork, which is in contrast to the Secretary's goals under the "Unleashing Prosperity Through Deregulation of the Medicare Program, Request for Information."[6]

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[1] Medicare and Medicaid Program; 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, 90 Fed. Reg. 29108, 29190 (July 2, 2025). Available at: https://www.federalregister.gov/d/2025-12347/p-547.

[2] *Id.*

[3] *Id.*

[4] *Id.* at 29202. Available at: https://www.federalregister.gov/d/2025-12347/p-786.

[5] *Id.*

[6] Unleashing Prosperity Through Deregulation of the Medicare Program Request for Information, Centers for Medicare & Medicaid Services (Sept. 15, 2025). Available at: https://www.cms.gov/files/document/unleashing-prosperity-through-deregulation-medicare-program-request-information.pdf.

HHS spends substantial time in the proposed rule outlining several examples of fraud, waste, and abuse leading to criminal convictions related to the fraudulent billing of DMEPOS. However, the examples do not mention CGMs or insulin pumps as areas within DMEPOS fraud.[7] Accordingly, APhA encourages HHS and CMS not to overburden pharmacies with more frequent accreditation requirements. APhA recommends that HHS and CMS better utilize the increased resources spent on the proposed annual accreditation process on areas that are more prone to fraud, waste, and abuse.

DMEPOS Competitive Bidding Program (FR 29230)

The Secretary of HHS is required "to establish and implement CBPs in competitive bidding areas (CBAs) throughout the United States for contract award purposes for the furnishing of competitively priced DMEPOS items and services."[8] The proposed rule provides that "[t]he primary goal of the DMEPOS CBP is to reduce excessive Medicare payments for DMEPOS items and services by awarding contracts to a group of suppliers with the lowest bid amounts that have the capacity to furnish the items and services needed in each CBA."[9] The suppliers with the lowest bids still have to meet the established quality standards.[10]

Within this proposed rule, HHS is seeking to limit the number of contract suppliers to incentivize the bidding entities to make more competitive bids while also ensuring the selected suppliers can meet demand in a timely manner.[11] HHS notes that "awarding an excessive number of contracts can reduce the competitiveness of the program, which results in higher payment amounts – hurting potential savings."[12]

Remote Item Delivery (RID) CBP (FR 29254)

The Government Accountability Office (GAO) previously "recommended that [HHS] consider using mail delivery for items that can be provided directly to beneficiaries in the home as a way to implement DMEPOS competitive bidding strategy."[13] This recommendation went as far as to provide that "[b]ecause MMA [Medicare Prescription Drug Improvement, and Modernization Act of 2003] authorizes CMS to designate the geographic areas for competition

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[7] Medicare and Medicaid Program; 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, 90 Fed. Reg. 29108, 29199-201 (July 2, 2025). Available at: https://www.federalregister.gov/d/2025-12347/p-721.

[8] *Id.* at 29230. Available at: https://www.federalregister.gov/d/2025-12347/p-1294.

[9] *Id.* Available at: https://www.federalregister.gov/d/2025-12347/p-1300

[10] *Id.*

[11] *Id.* at 29235. Available at: https://www.federalregister.gov/d/2025-12347/p-1332.

[12] *Id.* at 29237. Available at: https://www.federalregister.gov/d/2025-12347/p-1364.

[13] *Id.* at 29254. Available at: https://www.federalregister.gov/d/2025-12347/p-1474.

for different items, designating the entire country as the competitive area for selected items is a possibility."[14] GAO also noted that areas "that have low population density should not be excluded from competition if a significant national market exists through mail order for a particular item or service."[15] Since the GAO has published these statements, HHS has explored providing items through mail order under the DMEPOS CBP, including a national mail order CBP for diabetes testing supplies.[16] Currently, "Medicare claims data shows that several high-volume categories of items subject to the DMEPOS CBP are furnished to beneficiaries throughout the nation from remote supplier locations" and that "the national average distance between the beneficiary address and supplier location is several hundred miles for the lead items in seven[] high-volume categories of items."[17] Taking this into account, HHS is proposing to include these seven categories of items, including Class II CGMs and insulin infusion pumps, in a single nationwide RID CBP or regional RID CBPs.[18]

Under § 414.402, a RID CBP would mean "a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under the product category primarily to all Medicare beneficiaries regardless of where they live in the CBA."[19] It further provides that "[t]he CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country."[20] The proposed rule provides that "[c]ontract suppliers serving a nationwide or regional RID CBP would be responsible for furnishing the items on either a mail order or non-mail order basis under the product category to all Medicare beneficiaries, regardless of where they live in the CBA."[21] While CMS chooses the items to be included in the CBP, the definition of "remote item delivery item" "means an item falling under a remote item delivery competitive bidding program that may be shipped or delivered to a beneficiary's home, regardless of the method of delivery or picked up at a local pharmacy or supplier storefront if the beneficiary or caregiver for the beneficiary chooses to pick the item up in person."[22]

Within the proposed rule, HHS notes that "the bid items would be delivered by the contract supplier to the beneficiary from a remote location, for example, through the mail."[23] In addition,"[i]tems may be furnished to beneficiaries who come into the local storefront of a contract supplier, but we believe that most contract suppliers would have a limited number of local storefronts and therefore these occurrences would be rare."[24] As such, patients receiving

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[14] *Id.*
[15] *Id.*
[16] *Id.* Available at: https://www.federalregister.gov/d/2025-12347/p-1476.
[17] *Id.* Available at: https://www.federalregister.gov/d/2025-12347/p-1479.
[18] *Id.* at 29261. Available at: https://www.federalregister.gov/d/2025-12347/p-1486.
[19] *Id.*
[20] *Id.*
[21] *Id.*
[22] *Id.*
[23] *Id.* at 29260. Available at: https://www.federalregister.gov/d/2025-12347/p-1484.
[24] *Id.*

bid items would likely receive them through the mail and have limited access to a local storefront that could provide additional assistance with the items they receive. As HHS is proposing to include CGMs and insulin infusion pumps, patients using these devices may be unfamiliar with this new process for acquiring them. Further, because this would be a new way of providing these items to beneficiaries nationwide, HHS and CMS may be unaware of the potential implications of implementing this change. Accordingly, APhA has concerns that without further research or pilot studies, patient access may be compromised due to the inability of the selected supplier to meet demand or fully understand all the ins and outs of a nationwide CBA. APhA is also concerned that the inclusion of more items in nationwide RID CBPs may push brick-and-mortar DMEPOS suppliers, including DME pharmacies that supply DMEPOS products, to close, which could lead to access issues now and in the future. In addition, these efforts would be in contrast to the Administration's support for keeping local, small businesses open as well as expanding these opportunities throughout the country, particularly in our nation's rural areas. Thus, APhA encourages HHS and CMS to consider the value to patients that brick-and-mortar DMEPOS suppliers, including pharmacies, provide to Medicare beneficiaries and Americans, particularly in rural areas, in terms of their health care. Paying particular attention to CGMs and insulin infusion pumps, APhA recommends that HHS and CMS consider implementing pilot programs to ensure that patient access issues and other problems will not arise by including them in a nationwide RID CBP.

Until the completion of such a pilot program, to ensure uninterrupted access and maintain patient choice, CMS should consider exempting community pharmacies from the CBP. This recommendation aligns with CMS's previous policy under the National Mail Order program for blood glucose monitors, where retail pharmacies were not subject to competitive bidding for walk-in patients, and reimbursement was based on rates established through the bidding process. Given the complexity of CGMs and the essential role pharmacists and pharmacies play in treating patients with diabetes, the rationale for following a similar approach as it relates to CGMs makes sense. A hybrid model that provides one category for patients using CGMs used alone, and one for patients who utilize a CGM in combination with an insulin infusion pump, would also ensure that patient access to both their devices and pharmacists is not compromised.

Payment for Continuous Glucose Monitors and Insulin Infusion Pumps (FR 29261)

The proposed rule seeks to reclassify all CGMs and insulin infusion pumps within the frequent and substantial servicing payment category at section 1834(a)(3) of the Social Security Act.[25] HHS cites the rapid technological change and frequent and substantial servicing of CGMs and insulin infusion pumps as the reasons for this reclassification.[26] Accordingly, "CMS would pay for all CGMs and insulin infusion pumps on a monthly rental basis under both the

[25] *Id.* at 29261. Available at: https://www.federalregister.gov/d/2025-12347/p-1488.
[26] *Id.*

DMEPOS CBP and in non-CBAs under the fee schedule payments" rather than the current payment structure.[27] Currently, CGMs are paid for as routinely purchased equipment, and insulin pumps are paid for on a capped rental basis, where the beneficiary owns the pump after thirteen months of continuous use.[28]

HHS notes that the current classification of CGMs and insulin infusion pumps "limit[s] beneficiary choice and access to newer technology, thereby limiting options for beneficiaries to improve their health and [does] not account[] for the frequent and substantial servicing these devices require."[29] However, APhA disagrees with these findings and has concerns regarding this reclassification. APhA is deeply concerned that, if implemented as proposed, the CGM CBP could inadvertently hinder Medicare beneficiaries' access to appropriate CGM technologies. Such limitations may not only disrupt patient care but also pose a threat to ongoing innovation in diabetes management and conflict with the Administration's broader objectives of enhancing chronic disease outcomes and supporting healthy aging.

By classifying CGMs and insulin infusion pumps as items requiring frequent and substantial servicing, beneficiary ownership of these devices is eliminated.[30] HHS provides that this would be a benefit to the patient because the patient would not be locked into the same device for five years and would be able to utilize newer technology more easily.[31] APhA supports patients having access to CGMs and insulin pumps that fit their particular needs as personalized health care solutions are another goal of this Administration. APhA also encourages patient and caregiver education of such devices, with appropriate reimbursement for these services, which could be provided by a pharmacist, as pharmacists are our nation's medication experts and can provide in-depth knowledge about the appropriate use of the device and corresponding medications. In addition, there are benefits for patients in owning rather than renting their CGMs and insulin pumps.

Regarding insulin pumps, the selection of these devices for each patient is most often highly personalized, considering many factors of a patient's lifestyle and health care needs. As such, many patients, after thorough education on proper use and care for their insulin pump, are anecdotally satisfied with their insulin pump and see improvements in health. In addition to any cost savings associated with owning the device outright after a certain amount of time, patients also know that once they own their device, they are not subject to fluctuating rental costs or coverage issues with insurance. Additionally, patients utilizing these devices often use them long term, and during that tenure, the devices may need to be customized to fit the patient's needs. As such, there may be restrictions on such customization in the rental

[27] *Id.*
[28] *Id.*
[29] *Id.* Available at: https://www.federalregister.gov/d/2025-12347/p-1491.
[30] *Id.* at 29263. Available at: https://www.federalregister.gov/d/2025-12347/p-1508.
[31] *Id.*

contracts, which may prevent providers and patients from making these needed changes. Further, many patients have success with the same device that they have used for years and do not wish to change devices regularly. This is especially true for older Americans, who want to continue to use the simple, yet effective, device that they have become accustomed to.

CGMs are vastly different than insulin pumps. HHS's comments imply that CGMs need frequent and substantial service, which is not a reflection of currently available products. 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, reclassifying CGMs within the frequent and substantial servicing payment category, which would require payment on a rental basis, is not the best approach for HHS to take.

Additionally, CGMs likely do not meet the statutory definition of items that need "frequent and substantial servicing," as the need for this type of servicing and maintenance is not required. Broadening this classification to include items like CGMs may exceed congressional authority. Thus, APhA asks HHS to reconsider this reclassification and consult with Congress.

Pharmacists are also well-positioned to provide advice to Medicare seniors on application updates and the interpretation of information from CGMs to improve patient outcomes and adoption of these technologies if incentivized by CMS with appropriate reimbursement for providing these services. With nearly 90% of Americans living within 5 miles of a community pharmacy, pharmacies are the perfect hubs for delivering health care through pharmacists to help fight and prevent chronic diseases, like diabetes.[32] This could also lead to cost savings. For example, improved medication adherence was associated with a 13% reduction in the risk of hospitalizations and ER visits, which is projected to save $4.7 billion annually[33] and could be enhanced by the incorporation of pharmacists' involvement in remote patient monitoring of CGM.

Additionally, HHS is "proposing to establish a nationwide or regional CBP(s) for items such as CGMs and insulin pumps that may be phased in under future competitions … with

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[32] Lucas A. Berenbrok, et al., *Access to Community Pharmacies: A Nationwide Geographic Information Systems Cross-Sectional Analysis*, 62 Journal of the American Pharmacists Association 1816 (2022). Available at: https://www.japha.org/article/S1544-3191(22)00233-3/fulltext.

[33] William H. Polonsky and Robert R. Henry, *Poor Medication Adherence in Type 2 Diabetes: Recognizing the Scope of the Problem and Its Key Contributors*, 10 Patient Preference and Adherence 1299, 1301 (2016). Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC4966497/pdf/ppa-10-1299.pdf.

payment on a monthly rental basis … under the DMEPOS CBP."[34] As stated above, APhA is concerned that the use of nationwide CBPs for CGMs and insulin infusion pumps will lead to patient access issues. 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. This change would impact all patients accessing CGMs, as patients with commercial insurance, Medicare Advantage, or Medicaid may face new barriers and challenges in accessing these devices if access is limited at the pharmacy for Medicare beneficiaries. 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.

APhA encourages HHS to utilize pilot programs, especially for CGMs and insulin infusion pumps, to ensure that patient access is not interrupted. As part of these pilot programs, APhA strongly recommends that HHS and CMS utilize 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. Currently, pharmacists play a crucial role in managing a patient's diabetes through medication management, promoting healthy lifestyle choices, and providing education on both the disease state and the patient's current medication regimen. Whether educating patients on how to use the monitor, troubleshooting device or patient problems, or adjusting therapy based on trends in the patient's blood glucose levels, the pharmacists' role in continuous glucose monitoring is continually growing. In addition to the education pharmacists are providing patients utilizing these devices, studies have shown that pharmacist-driven continuous glucose monitoring is associated with absolute mean reductions in A1C between -0.47% and -1.8%, more patients meeting their glycemic goals, increased time spent within their glycemic range, and improved health behaviors.[35]

APhA appreciates the opportunity to provide HHS with comments regarding this proposed rule. APhA reemphasizes that HHS should not overburden pharmacies with unfunded mandates by changing the current accreditation process. Additionally, APhA encourages HHS

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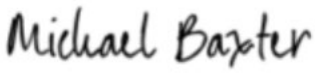
[34] Medicare and Medicaid Program; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies, 90 Fed. Reg. 29108, 29264 (July 2, 2025). Available at: https://www.federalregister.gov/d/2025-12347/p-1509.

[35] Angelina Vascimini, et al., *Pharmacist-Driven Continuous Glucose Monitoring in Community and Ambulatory Care Pharmacy Practice: A Scoping Review*, 63 Journal of the American Pharmacists Association 1660 (2023). Available at: https://www.japha.org/action/showPdf?pii=S1544-3191%2823%2900251-0.

and CMS to conduct additional research or pilot studies that utilize our nation's pharmacists before launching a nationwide CBP for CGMs and insulin infusion pumps. If you have any questions or would like to meet with APhA to discuss our comments, please contact Corey Whetzel, APhA's Senior Manager, Regulatory Affairs, at cwhetzel@aphanet.org.

Sincerely,



Michael Baxter
Vice President, Government Affairs

cc: The Honorable Robert F. Kennedy, Jr., Secretary, HHS