Analysis of Continuous Glucose Monitor (CGM) Supplier Costs and Market Dynamics

Examining the Impact of the Potential Expansion of Competitive Bidding to CGM Technology

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Introduction

The Centers for Medicare & Medicaid Services (CMS) has finalized substantial changes to the payment structure for CGMs in the CY 2026 Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) Final Rule (Federal Register Vol. 90, No. 229, December 2, 2025). Under the final rule, all Continuous Glucose Monitors (CGMs), regardless of classification as Class II or Class III devices, would be reclassified from "routinely purchased" durable medical equipment (DME) to the "frequent and substantial servicing" category, as defined under Section 1834(a)(3) of the Social Security Act and 42 CFR §414.222. As a result, CGMs will no longer be reimbursed as lump-sum purchases but instead paid exclusively on a monthly perpetual rental basis. The rule also introduces payment parity between Class II and Class III devices, along with detailed transition provisions and methodologies for calculating bidding amounts under the revised payment framework. Because Medicare did not begin covering CGMs until 2017, there are no 2015 fee schedule amounts available for use in the Competitive Bidding Program (CBP) pricing calculations. To address this, CMS will estimate 2015-equivalent rates by deflating the 2025 CGM fee schedule amounts using DMEPOS update factors from 2016 through 2025. This synthetic 2015 baseline is necessary to calculate non-lead item[1] ratios under 42 CFR §414.416(b) as part of CGM integration into a competitive bidding category.

Purpose

Given the backdrop of this rapidly shifting policy landscape for CGMs and insulin pumps, this study evaluates whether CMS's final regulation for CGMs is feasible and will achieve the desired results of the CBP: namely, producing cost savings to Medicare while maintaining beneficiary access to the medical equipment needed to promote positive health outcomes. The paper outlines the potential unforeseen consequences of the CGM CBP final regulation and how these unforeseen consequences could impact supplier sustainability and viability, potentially leading to negative patient outcomes. The study was commissioned by Dexcom, Inc. (Dexcom) to inform policy makers of the possible financial consequences of the CBP process to the Medicare CGM supplier community and ultimately, to the Medicare beneficiary.

[1] In the CMS Competitive Bidding Program (CBP) structure, lead items are the primary, high-cost items within a product category used to determine the single payment amounts for all products in that category, while non-lead items are the remaining related products whose payment rates are calculated as a fixed ratio to the lead item's bid amount.

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Methods

This study utilized a triangulated approach to determine the effectiveness of CMS achieving its dual CBP mandate of producing cost savings and safeguarding beneficiary access to life saving technologies. To begin, we conducted a literature review on the history of the Medicare CBP, including previous diabetes technologies, like insulin pumps, that had been subject to the CBP. The literature review also involved a thorough review of the CY 2026 DMEPOS Proposed Rule (Federal Register Vol. 90, No. 125, July 2, 2025) and its final version (Federal Register Vol. 90, No. 229, December 2, 2025), which included a substantial section on the proposal to implement CBP for CGMs and related supplies. Next, we conducted a preliminary survey of CGM suppliers to identify their FY 2024 Medicare volume (number of supplies and CGMs acquired) and their related costs. The results were analyzed and marked up based on the indirect and direct costs incurred as determined by substantiated literature.[2,3,4] Finally, we examined 8 comment letters on the proposed rule from significant CGM manufacturers and suppliers. These comment letters were thematically coded to identify relevant shared points of emphasis between these stakeholders.

History of the Competitive Bidding Program

The Medicare CBP, established under the 2003 Medicare Prescription Drug, Improvement, and Modernization Act (MMA), was designed to replace the fixed fee schedule for DMEPOS with a market-based pricing model. While the CBP has reduced Medicare expenditures through supplier bidding in designated geographic areas, it has faced significant criticism related to pricing accuracy, supplier eligibility, and long-term sustainability.[5] Despite subsequent reforms and CMS's plans to relaunch bidding following a 2024 program suspension, concerns persist over access, supplier participation, and payment adequacy.

Competitive Bidding for CGMs

The structure of the CBP becomes more challenging in categories with limited product or manufacturer diversity, such as Continuous Glucose Monitors (CGMs), a technology used in managing diabetes. Unlike typical CBP product categories, which might include 12 HCPCS codes covering over 700 products from more than 60 manufacturers, CGMs that could potentially be subject to CBP include only four products manufactured by two companies. The two Class III CGMs[6] currently on the market are statutorily exempt from CBP, which creates a problematic market dynamic when Class II CGMs become subject to CBP.

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[2] Dobson A, Heath S, DaVanzo J, Kilby D, Murray K. Analysis of the Cost of Providing Durable Medical Equipment to the Medicare Population: Measuring the Impact of Competitive Bidding. Dobson | DaVanzo; October 2016.

[3] U.S. Department of Health and Human Services, Office of Inspector General. *Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year.* OEI-04-20-00620. August 2022.

[4] US Department of Health and Human Services, Office of Inspector General. *Medicare Payments for Continuous Glucose Monitors Exceeded Supplier Acquisition Costs.* OEI-04-23-00430. November 2025.

[5] CRAMTON, Peter, ELLERMEYER, Sean, KATZMAN, Brett E., *Designed to fail : the Medicare auction for durable medical equipment*, Economic inquiry, 2015, Vol. 53, No. 1, pp. 469-485 - https://hdl.handle.net/1814/51965

[6] In the FDA framework, Class II devices are considered moderate-risk and typically cleared through the 510(k) pathway under "special controls" (in addition to general controls), whereas Class III devices are deemed high risk and require the more rigorous Premarket Approval (PMA) process.

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With CMS shifting to a continuous monthly rental model for CGMs, ensuring supplier viability becomes increasingly critical. The brand-specific nature of CGM supplies means that suppliers must maintain inventory and servicing capabilities across multiple product lines to ensure patients have access to their preferred technology. In the final rule, CMS requires suppliers to take on the responsibility of updating software, responding to recalls, and training patients on the use of CGM. In the perpetual rental model, CMS expects suppliers to take back used devices, refurbish them, and then rent them to subsequent patients. The rule also allows patients to swap out their CGM at any time—and for any reason except for intentional breakage—during the five years, meaning that suppliers are assuming the initial cost of purchasing the CGM and all risk involved during the five-year rental window. These changes will require suppliers to be able to validate the functionality of the used CGM receivers, appropriately remove individualized patient information from the devices, sterilize them, and repackage them before sending them to a new patient. All these duties have typically fallen to the manufacturers, and suppliers have historically had no experience or expertise with any of these functions. Without sufficient reimbursement or sustainable bid structures, smaller or specialized suppliers are likely to exit the market, potentially reducing competition and network adequacy. While beneficiary access remains important, the ability of suppliers to participate and operate effectively under the new payment model will ultimately determine whether the rental framework delivers on CMS's goals of cost savings and care continuity. Past experience with insulin pumps under the CBP illustrates how supplier attrition can lead to market disruption, even when coverage is maintained.[7]

Incompatibility of CBP with the Market Structure of CGMs

According to the final rule, CMS is setting a maximum monthly reimbursement rate of $272.69 (2025 amounts) to include both the CGM receiver and all related supplies over a five-year rental window.[8] Within the CBP, bids from interested suppliers must come in below the maximum payment threshold, thereby ensuring that the actual reimbursement will be lower than $272.69. Evidence from a limited sample of suppliers and a review of comment letters on the proposed rule from prominent CGM manufacturers and suppliers suggests that this maximum bid is set at an unsustainable level. The results of the HHS Office of Inspector General (OIG) study comparing supplier costs to Medicare payments adds strength to the argument that application of CBP to CGM is unlikely to produce meaningful savings, as OIG noted in the report that CMS savings when factoring in total costs was $70.4 million, with $46.2 million attributable to Class III supplies.[9] Already, with CMS reimbursement for FY 2025 currently at $295.36 for the CGM receiver (equated to $4.92 per month assuming a 60 month lifespan) and $267.92 for the monthly supplies, suppliers, when factoring in current direct and indirect costs, are experiencing reimbursement rates that leave very little margin to forfeit in a CBP process. The final rule adds additional cost burdens onto suppliers

[7] Puckrein GA, Nunlee-Bland G, Zangeneh F, Davidson JA, Vigersky RA, Xu L, Parkin CG, Marrero DG. Impact of CMS Competitive Bidding Program on Medicare Beneficiary Safety and Access to Diabetes Testing Supplies: A retrospective, longitudinal analysis. Diabetes Care. 2016;39(4):563-571. doi:10.2337/dc15-1264. PMID:26993148

[8] Centers for Medicare & Medicaid Services. Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Proposed Rule. Fed Reg. 2025 Jul 2;90(129):29108-29339. CMS–1828-P; RIN 0938-AV53

[9] US Department of Health and Human Services, Office of Inspector General**.** *Medicare Payments for Continuous Glucose Monitors Exceeded Supplier Acquisition Costs.* OEI-04-23-00430. November 2025.

due to the necessity for suppliers to perform software updates, device calibration, HIPAA compliant data security, and patient support, which are currently under the jurisdiction of the manufacturer. As of now, these additional costs associated with the final rule are unknown and have the potential to significantly increase supplier costs.

Suppliers also must wait five years to recoup the initial payment due to the continuous rental provisions. CMS has proposed a system under which patients would be strongly encouraged to switch devices much more frequently than once every five years, while basing reimbursement on the assumption that suppliers would be able to rent the devices for a full five-year period. Suppliers are almost certain to be put in a compromised position where they have expended capital to acquire CGM receivers yet are then unable to rent them for a full five-year period. To suppliers and manufacturers, this payment system could be unsustainable, especially for small regional companies without reserves. The lack of initial revenue generation for suppliers and manufacturers will mean that suppliers and manufacturers may be forced to cut costs, leading to lower quality products and the potential for regional suppliers to cease operations. Product quality affects patients, who are more likely to receive lower quality and less innovative products in future years, and fewer supplier options puts patient access to CGMs and supplies at risk, which in turn, could lead to negative health consequences for patients.

Commercial market studies have shown that the use of CGMs is associated with reductions in inpatient admissions and other costly services, generating monthly savings of $300 to $400 per patient.[10,11,12] Restricting access to CGMs through bidding-induced channel limitations may increase reliance on hospital care, ultimately negating any short-term financial gains achieved through lower DMEPOS reimbursement. Given that the quality and supply issues from the final rule could manifest, it is reasonable to assume that more patients with diabetes may seek emergency medical care because of the potential for device supply and quality issues experienced.

Alternative Policy Prescriptions

Stakeholders noted that the market's limited manufacturer diversity, proprietary product design, and high supplier capital requirements make CGMs ill-suited for a rapid, nationwide CBP rollout.[13] The Diabetes Technology Access Coalition (DTAC) reported that CGM use reduces diabetes-related hospitalizations by

[10] Isaacson, B, Kaufusi, S, Sorensen, J, Joy, E, Jones, C, Ingram, V, Mark, N, Phillips, M, Briesacher, M. (2022). Demonstrating the Clinical Impact of Continuous Glucose Monitoring Within an Integrated Healthcare Delivery System. *Journal of Diabetes Science & Technology*, 16(2): 383-389.

[11] Norman, GJ, Paudel, ML, Parkin, CG, Bancroft, T, Lynch, PM (2022). Association between Real-Time Continuous Glucose Monitor Use and Diabetes-Related Medical Costs for Patients with Type 2 Diabetes. *Diabetes Technology & Therapeutics*. 24(7); 520-523.

[12] Hannah KL, Nemlekar PM, Green CR, Norman GJ. (2024). Reduction in Diabetes-Related Hospitalizations and Medical Costs After Dexcom G6 Continuous Glucose Monitor Initiation in People with Type 2 Diabetes Using Intensive Insulin Therapy. *Advances In Therapy*. https://doi.org/10.1007/s12325-024-02851-8

[13] AdaptHealth LLC. Comments on CMS–1828–P, "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." Submitted to the Centers for Medicare & Medicaid Services. Plymouth Meeting, PA: AdaptHealth; August 29, 2025

32%-57% and yields monthly cost savings in the commercial market of $329-$424 per patient due to fewer acute-care events.[14] Because each diabetes-related hospitalization costs Medicare approximately $9,000, even modest declines in device continuity could offset projected DMEPOS savings.[15,16] Abbott Laboratories similarly cautioned that restricting access under CBP "…could drive patients to rely on other Medicare Parts A, B, and D benefits, or lead to greater utilization of acute or alternative settings, with corresponding increases in Medicare expenditures".[17]

To minimize fiscal and operational risks, commenters across industry and patient groups recommended that CMS adopt a phased or pilot implementation within a limited number of Competitive Bidding Areas (CBAs) before expanding nationally. A pilot would enable CMS to validate program assumptions, assess supplier capacity, and monitor clinical outcomes under the new rental framework. In the final rule, the agency opted to move forward with a nationwide remote item delivery model instead of adopting a phased approach. The rule itself suggests that there will be no more than ten suppliers allowed to provide CGMs and related supplies to the entire Medicare fee-for-service population. Additional commentor recommendations included setting payment guardrails to prevent underbidding, ensuring transition provisions for beneficiaries with owned devices, incorporating outcome-based metrics, and reassessing the use of CMS's inherent reasonableness authority for Class III payment equalization. Collectively, these measures would allow CMS to modernize DMEPOS reimbursement while maintaining market stability, protecting beneficiary access, and safeguarding against unintended increases in total Medicare expenditures.[18,19,20]

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[14] Diabetes Technology Access Coalition (DTAC). Comments on CMS–1828–P, "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." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Diabetes Technology Access Coalition; August 29, 2025

[15] Agency for Healthcare Research and Quality. Diabetes-Related Inpatient Stays, 2018. HCUP Statistical Brief #279. Rockville, MD: AHRQ; July 2021. Accessed October 10, 2025. https://hcup-us.ahrq.gov/reports/statbriefs/sb279-Diabetes-Inpatient-Stays-2018.jsp

[16] Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. Chapter 3: Hospital Inpatient and Outpatient Services. Washington, DC: MedPAC; March 2023. Accessed October 10, 2025. https://www.medpac.gov/wp-content/uploads/2023/03/Ch3_Mar23_MedPAC_Report_To_Congress_SEC_v2.pdf

[17] Abbott Laboratories. Comments on CMS–1828–P, "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Abbott Laboratories; August 28, 2025

[18] American Association for Homecare. Comments on CMS–1828–P, "Medicare and Medicaid Programs; CY 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." Submitted to the Centers for Medicare & Medicaid Services. Arlington, VA: American Association for Homecare; August 27, 2025.

[19] Abbott Laboratories. Comments on CMS–1828–P, "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Abbott Laboratories; August 28, 2025

[20] Diabetes Technology Access Coalition (DTAC). Comments on CMS–1828–P, "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." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Diabetes Technology Access Coalition; August 29, 2025

Conclusion

Overall, the decision to move CGMs into the CBP is unlikely to achieve CMS's stated goals of reducing costs and improving efficiency. Instead, it could introduce significant market volatility, create barriers to beneficiary access, and impose unsustainable financial pressures on suppliers. With only a few manufacturers and non-interchangeable device platforms, the CGM market lacks the competitive diversity required for a stable bidding process. Reimbursement rates derived from imputed 2015 data and extended rental assumptions could drive suppliers out of the market, disrupt patient continuity of care, and ultimately increase overall Medicare spending through higher hospitalization and emergency utilization rates. Rather than producing the desired outcomes of the CBP program, this policy risks destabilizing the diabetes technology market and compromising access to critical devices for Medicare beneficiaries.

The OIG study predicts a 2% savings on CGMs and supplies,[21] and its analysis does not account for any profit margin for suppliers or potential new costs imposed by the final rule. When those factors are added into the OIG's analysis, the chance of CMS achieving savings is limited.

[21] US Department of Health and Human Services, Office of Inspector General. *Medicare Payments for Continuous Glucose Monitors Exceeded Supplier Acquisition Costs.* OEI-04-23-00430. November 2025.

Introduction

Overview of the Continuous Glucose Monitor (CGM) Competitive Bidding Program (CBP) Final Rule

The Centers for Medicare & Medicaid Services (CMS) has finalized a redesign of reimbursements for continuous glucose monitors (CGMs) in the CY 2026 Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) Final Rule (Federal Register Vol. 90, No. 229, December 2, 2025). Under the new policy, all Continuous Glucose Monitors (CGMs)—regardless of classification as Class II or Class III devices—would be reclassified from the "routinely purchased" durable medical equipment (DME) category to the "frequent and substantial servicing" payment tier under Section 1834(a)(3) of the Social Security Act and implementing regulation 42 CFR § 414.222. With that reclassification, CGMs will no longer be reimbursed via lump-sum purchase payments; instead, they would exclusively be paid on a monthly perpetual rental basis.

Under this rental model, suppliers—not beneficiaries—would retain ownership of the device and assume ongoing responsibility for maintenance, technical support, and cybersecurity compliance. Monthly bundled payments would encompass all device components, including sensors, transmitters, receivers, accessories, and software updates. CMS illustrates this by amortizing the CGM receiver—currently reimbursed at approximately $286.03—over 60 months (about $4.77 per month) and bundling it with monthly supply costs of roughly $267.92, resulting in a total capped rental payment of approximately $272.69. Suppliers will also be permitted to bill up to three months in advance under §414.229(b). While this framework seeks to modernize CGM payment policy and reflect ongoing service needs, a 60-month amortization period conflicts with CMS's stated goal of allowing beneficiaries to upgrade to newer models more frequently than every five years.

Moreover, the final rule establishes a path to payment parity between Class II and Class III devices, effectively removing any reimbursement premium tied to device class. For context, Class II devices are more technologically advanced and considered moderate-risk within the Food and Drug Administration (FDA) framework, requiring less stringent FDA oversight, whereas Class III devices are deemed high risk and require the more rigorous Premarket Approval (PMA) process. In practice, many CGMs are classified

as Class II under regulation 21 CFR § 862.1355, reflecting that their risk profile and intended use can be managed via performance standards and controls rather than the highest level of scrutiny.

CMS contends that equalizing payment rates between the two classes of CGMs will prevent perceived market distortions and misaligned supplier incentives. However, CMS's reliance on its "inherent reasonableness" authority to support this equalization appears procedurally incomplete, as the agency has not followed the statutorily required notice-and-comment process for invoking that authority and the pricing data that could be used as the basis of invoking the inherent reasonableness authority will not exist until after the application of CBP to CGM.

The rule also includes transition provisions to ensure continuity of care. Beneficiaries who currently own a CGM would continue to receive separate supply reimbursements until their existing device reaches the five-year useful lifetime, is lost or irreparably damaged, or until the beneficiary voluntarily transitions into the new rental-based model. Once transitioned, all payments would shift to the bundled rental rate, and standalone supply reimbursements would cease. CMS justifies these changes as necessary to (1) support timely upgrades to mitigate cybersecurity vulnerabilities, (2) ensure supplier accountability for device maintenance, and (3) align Medicare's DMEPOS framework with advancing CGM and insulin-pump technologies.

The rule further sets out transition provisions and explicit methodologies for how CGMs would be integrated into the competitive bidding architecture; that is, the method by which bid amounts would be calculated under the revised monthly rental framework. A central challenge is that Medicare did not cover CGMs until 2017, meaning there is no 2015 fee schedule benchmark available for competitive bidding pricing. To circumvent this absence, CMS will back-cast a "2015 equivalent" rate by deflating the 2025 CGM fee schedule amounts using DMEPOS update factors spanning from 2016 through 2025. This synthetic baseline allows CMS to compute non-lead item[22] ratios under 42 CFR § 414.416(b), facilitating integration of CGMs into a competitive bidding category despite the lack of historical pricing data.

In parallel, CMS has finalized a proposal to set up a Remote Item Delivery (RID) Competitive Bidding Program (CBP) structure for select high-volume DME items that are typically furnished via shipment rather than local distribution. Under this approach, components such as CGMs, supplies, and insulin pumps could be included in a national or regional RID CBP, in which a contract supplier would be responsible for shipping or delivering the product to any beneficiary regardless of geographic location. The final regulations define "remote item delivery items" under § 414.402, allowing these items to be shipped, delivered directly

[22] In the CMS Competitive Bidding Program (CBP) structure, lead items are the primary, high-cost items within a product category used to determine the single payment amounts for all products in that category, while non-lead items are the remaining related products whose payment rates are calculated as a fixed ratio to the lead item's bid amount.

to the beneficiary's home, or if the beneficiary or caregiver prefers, picked up at a local storefront, provided the outlet is a contracted supplier.

Purpose of the Study

Given the backdrop of this rapidly shifting policy landscape for CGMs and insulin pumps, this study critically assesses whether CMS's final regulation is not only administrable but also likely to meet the CBP's twin goals of generating savings for Medicare while safeguarding beneficiary access to medically necessary technology. We analyze whether the reclassification, rental payment model, and inclusion in RID CBP might produce unintended or underappreciated consequences, especially for the financial sustainability and viability of CGM suppliers, thereby impacting patient access and healthcare safety. The study was commissioned by Dexcom, Inc. ("Dexcom") to educate policymakers about the potential financial risks to the CGM supplier community and, by extension, to Medicare beneficiaries whose health outcomes depend on continuous access to CGM technology.

Methods

This study employed a triangulated research approach to balance quantitative cost analysis with qualitative insights from policy and stakeholder perspectives. By drawing on multiple lines of evidence, the study aims to provide a comprehensive assessment of the potential fiscal, operational, and access-related impacts of including CGMs in the CBP framework.

First, the study began with an extensive literature review of the history and implementation of the Medicare CBP, focusing particularly on DMEPOS categories that share clinical or operational similarities with CGMs. This review included the experiences of diabetes-related technologies, such as insulin pumps, that have previously been subject to competitive bidding or alternative pricing reforms. The literature review further incorporated a detailed examination of the CY 2026 DMEPOS Proposed Rule (Federal Register Vol. 90, No. 125, July 2, 2025) and its final version (Federal Register Vol. 90, No. 229, December 2, 2025), which contains CMS's policies to integrate CGMs and related supplies into the CBP. This regulatory review served to contextualize the reclassification of CGMs as "frequent and substantial servicing" equipment, the shift from lump-sum to rental-based reimbursement, and the accompanying introduction of payment parity between Class II and Class III devices.

Second, we conducted an exploratory supplier survey to quantify the financial and operational realities of the CGM market under Medicare. The survey was distributed to a representative sample of CGM suppliers and sought to capture their fiscal year (FY) 2024 Medicare volume (the number of CGMs and associated supplies provided to beneficiaries) and the corresponding acquisition costs. Responses were analyzed using a standardized cost markup framework derived from established literature on DME supplier cost structures, incorporating both direct costs and indirect costs.[23,24] In addition, we used the markup factor identified by the American Association for Homecare (AAHomecare) and used by the OIG in its recent report.[25] This empirical component was designed to illuminate the potential economic pressures suppliers may face under

[23] Dobson A, Heath S, DaVanzo J, Kilby D, Murray K. Analysis of the Cost of Providing Durable Medical Equipment to the Medicare Population: Measuring the Impact of Competitive Bidding. Dobson | DaVanzo; October 2016.

[24] U.S. Department of Health and Human Services, Office of Inspector General. *Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year.* OEI-04-20-00620. August 2022.

[25] US Department of Health and Human Services, Office of Inspector General**.** *Medicare Payments for Continuous Glucose Monitors Exceeded Supplier Acquisition Costs.* OEI-04-23-00430. November 2025.

a CBP model and to assess whether current reimbursement rates provide sufficient margins for financial sustainability once CGMs are incorporated into the competitive bidding process.

Finally, the study analyzed stakeholder feedback via comment letters to gain qualitative insight into industry perspectives on the proposed rule. Eight formal comment letters submitted to CMS by major CGM manufacturers and suppliers were reviewed in depth and thematically coded to identify recurring points of emphasis, areas of consensus, and key divergences in stakeholder positions. These letters were particularly valuable in revealing how the affected parties anticipate the proposed (and now final) changes will influence innovation, market participation, and beneficiary access. Common themes included concerns about the feasibility of establishing competitive bidding benchmarks without historical pricing data, the adequacy of monthly rental reimbursement rates, the potential administrative burden imposed by the Remote Item Delivery (RID) framework, and the impacts on beneficiary access to lifesaving CGM technology.

Taken together, these three components provide a holistic and balanced framework for evaluating CMS's integration of CGMs into the CBP. Through this triangulated methodology, the study not only measures potential fiscal outcomes but also assesses the broader implications for access and innovation in diabetes care under Medicare.

The Medicare Competitive Bidding Program

Overview of The Medicare Competitive Bidding Program

The DMEPOS CBP was implemented by CMS after the ratification of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003. Following demonstrations conducted between 1999 and 2002, the program was developed as a market-based reform strategy to replace the outdated fixed fee schedule system. The primary goals of the CBP are fourfold: 1) to reduce Medicare expenditures; 2) to lower beneficiary out-of-pocket costs; 3) to help limit fraud & abuse; and 4) to maintain access to high-quality items and services.[26] In essence, the CBP was responsible for reducing Medicare expenditures while maintaining beneficiary access to necessary medical equipment.[27] The CBP encompasses several major product categories, including enteral nutrition, hospital beds, commode chairs, nebulizers, negative pressure wound therapy, respiratory equipment (including oxygen and CPAP machines), walkers, wheelchairs, and transcutaneous electrical nerve stimulation (TENS) units.[28]

[26] Centers for Medicare & Medicaid Services. DMEPOS Competitive Bidding Program Overview. Updated 2024. Available at: https://www.cms.gov/medicare/payment/fee-schedules/dmepos-competitive-bidding. Accessed May 20, 2025.

[27] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub L No. 108-173, 117 Stat 2066.

[28] Centers for Medicare & Medicaid Services. Adjustments to Fee Schedule Amounts Using CBP Data. Fact Sheet. 2023. Available at: https://www.cms.gov/newsroom/fact-sheets/adjustments-fee-schedule-amounts-certain-dmepos-using-information-competitive-bidding-program. Accessed May 20, 2025.

The Medicare Competitive Bidding Program

Under this model, DMEPOS suppliers submit sealed bids to furnish selected items within defined Competitive Bidding Areas (CBAs), [29] and CMS awards contracts to those offering the lowest bids that meet licensing, financial, and quality standards. The bid amounts are used to calculate a Single Payment Amount (SPA) for each item initially based on the median of the winning bids.[30] In the most recent round of CBP, CMS arrayed bids from highest to lowest and cut off acceptance of bids at the point where they deemed sufficient capacity to serve beneficiaries in each CBA had been achieved. The SPA was then set at the high bid among those winning bidders. The SPAs for all other products in the category are calculated relative to the lead item using historical fee schedule ratios.[31] Suppliers who are awarded contracts must accept the SPA as full payment and agree to provide all items within the contracted category to any beneficiary who resides in or visits the CBA.

The CBP uses a composite bid structure in which the supplier's actual bid on lead items and imputed bids on non-lead items are weighted by estimated beneficiary demand. Bidders are evaluated based on eligibility, financial stability, and price. Notably, suppliers are required to furnish all items in the product category under contract and cannot discriminate against Medicare beneficiaries, but do not necessarily have to provide every brand of each item.[32] CMS selects the lowest composite bids until capacity needs in each CBA are met. To ensure that small suppliers are not excluded, CMS requires that at least 30% of contracts are awarded to suppliers with gross revenues of $3.5 million or less. If this threshold is not met through the initial selection, CMS adjusts the award pool to include more small suppliers, without altering the SPAs.[33]

On January 1, 2024, the CBP entered a temporary gap period following the expiration of Round 2021 contracts. During this time, any Medicare-enrolled supplier may furnish DMEPOS items, and reimbursement is based on the 2023 SPAs adjusted for inflation using the Consumer Price Index for All Urban Consumers (CPI-U).[34] CMS has announced its intention to initiate a new round of bidding following a formal rulemaking process, with the stated goal of ensuring sustainable prices while maintaining beneficiary access and limiting fraud.[35]

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[29] Centers for Medicare & Medicaid Services. Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment. Final Rule. 72 Fed Reg 18047. April 10, 2007.

[30] Centers for Medicare & Medicaid Services. Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment. Final Rule. 72 Fed Reg 18047. April 10, 2007.

[31] Centers for Medicare & Medicaid Services. Competitive Bidding Fact Sheet: Lead Item Pricing. Published November 2018. Available at: https://www.cms.gov/files/document/lead-item-pricing.pdf. Accessed May 20, 2025.

[32] Centers for Medicare & Medicaid Services. Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment. Final Rule. 72 Fed Reg 18047. April 10, 2007. 42 CFR 414.420(b)

[33] Centers for Medicare & Medicaid Services. CMS Awards Contracts for Round 2 Recompete. Press Release. 2016.

[34] Centers for Medicare & Medicaid Services. Competitive Bidding Gap Period Information. Updated January 2024. Available at: https://www.cms.gov/medicare/payment/fee-schedules/dmepos-competitive-bidding. Accessed May 20, 2025.

[35] Ibid.

Impact of Financial Pressures from CBP

Since its full implementation in 2011, Medicare's DMEPOS CBP initially targeted nine high-cost item categories, such as oxygen equipment, CPAP devices, hospital beds, wheelchairs, enteral nutrition, walkers, and urological supplies.[36] These product categories were selected based on their widespread use and budgetary impact.[37] The program's intent was to lower costs through supplier competition, but this came with significant consequences across product categories.[38] A 2016 report by Dobson | DaVanzo found that the average Medicare reimbursement covered only 88% of provider costs, and that for specific items like CPAPs and hospital beds, the ratio fell as low as 67–70%.[39] The report further concluded that cost-shifting to private payers is not feasible due to market-wide adoption of CBP pricing benchmarks, and that both small and rural suppliers face disproportionate financial pressure as a result of CBP.[40]

Following CBP's implementation in 2011, steep reductions in reimbursement rates forced many suppliers out of the market. Rental payments for oxygen concentrators dropped by 56% (from $180.92 to $78.74 per month), and hospital beds saw a 55% reduction (from $134.38 to $60.50) between 2015 and 2016 alone.[41] As prices fell, so did provider participation: the Government Accountability Office (GAO) found a 27% decline in high-volume suppliers in Round 1 (2011) competitive bidding areas (CBAs), compared to just a 5% drop in non-bid regions.[42] This market contraction translated into less supplier choice and uneven access for beneficiaries. During Round 2 (2014), 11% of product-area competitions had three or fewer suppliers, and 1% were dominated by a single supplier holding over 90% market share, indicating extremely limited competition.[43]

Although the DMEPOS CBP is designed to reduce out-of-pocket expenses and generate cost savings for the Medicare program, studies have highlighted its unintended consequences regarding beneficiaries' access to essential supplies, ultimately leading to negative health outcomes.[44] Research indicates that the implementation of competitive bidding has disrupted the supply chain for crucial devices, particularly for vulnerable populations. For instance, a 2016 study by Puckrein et al. found that a pilot program for diabetes

[36] National Home Infusion Association. Overview of the DMEPOS Competitive Bidding Program. Published ~2019. Accessed July 17, 2025. https://nhia.org/medicare_competive_bidding/

[37] Ibid.

[38] Ibid.

[39] Dobson A, Heath S, DaVanzo J, Kilby D, Murray K. Analysis of the Cost of Providing Durable Medical Equipment to the Medicare Population: Measuring the Impact of Competitive Bidding. Dobson | DaVanzo; October 2016.

[40] Ibid.

[41] Centers for Medicare & Medicaid Services. Adjustments to Fee Schedule Amounts for Certain DMEPOS Using Information from the Competitive Bidding Program. CMS Fact Sheet; June 23, 2016.

[42] Government Accountability Office. Medicare: CMS's Round 1 Durable Medical Equipment Competitive Bidding Program—Effects on Suppliers and Beneficiaries. GAO-14-156. December 2013.

[43] Government Accountability Office. Medicare: CMS's Round 2 Durable Medical Equipment and National Mail-Order Program. GAO-16-570. July 2016.

[44] Davidson JA, Parkin C. Diabetes and Medicare Competitive Bidding: The "Perfect Storm" for Patient Harm. *AJMC*. 2016;22. Accessed May 27, 2025. https://www.ajmc.com/view/diabetes-and-medicare-competitive-bidding-the-perfect-storm-for-patient-harm

supplies resulted in significant disruptions, compromising the acquisition of these supplies for beneficiaries.[45]

Device utilization rates have also dropped, suggesting access constraints. In a study of CPAP devices, Medicare spending fell by 47.2% after competitive bidding. But this was accompanied by a measurable 4.3% decline in the number of rentals—a decrease attributed not only to reduced inappropriate use, but also to suppliers leaving the market and tightening their eligibility protocols.[46] Mail-order diabetic testing supplies experienced an even steeper decline, with a 39% reduction in mail-order distribution following bidding implementation.[47] More broadly, the number of beneficiaries receiving any CBP-covered DME product declined by 17% in Round 2 areas (2012–2014), whereas such declines were only around 6% in non-CBP regions.[48] Academic and policy evaluations have found that while the CBP lowered costs, it may have unintentionally suppressed utilization. A National Bureau of Economic Research study found that, following bidding, overall Medicare expenditures for certain items dropped by 41.8%, but this was accompanied by a 9.3% decrease in the quantity of products supplied—suggesting constrained availability rather than improved efficiency alone.[49]

DMEPOS providers have few choices in how to respond to these less-than-cost reimbursement rates. A Congressional Budget Office (CBO) working paper analyzing hospital responses to Medicare payment reductions found that hospitals often mitigate revenue shortfalls by cross-subsidizing with higher commercial payer rates, thereby maintaining overall operating margins. However, DMEPOS suppliers generally lack this flexibility due to their narrow payer mix and already constrained margins. Sustained below-cost reimbursements under the CBP therefore increases the risk of reduced service availability, market exits, and consolidation, ultimately limiting beneficiary access to essential equipment.

The CBO analysis further highlights that providers facing persistent financial pressure may attempt to improve productivity to offset losses—delivering the same volume of services with fewer inputs such as labor, materials, and supplies. In the DMEPOS sector, such efficiency gains may temporarily mitigate negative margins, but opportunities for continued productivity growth are inherently limited. Over time, suppliers unable to achieve sufficient cost containment will incur financial losses, leading to market contraction and diminished capacity to serve Medicare beneficiaries.

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[45] Puckrein GA, Nunlee-Bland G, Zangeneh, F, et al. Impact of CMS Competitive Bidding Program on Medicare Beneficiary Safety and Access to Diabetes Testing Supplies: A Retrospective, Longitudinal Analysis. *Diabetes Care* 1 April 2016; 39 (4): 563–571. https://doi.org/10.2337/dc15-1264

[46] Ding H, Duggan M, Starc A. Getting the Price Right? The Impact of Competitive Bidding in the Medicare Program. NBER Working Paper No. 28457. National Bureau of Economic Research; 2021. Accessed July 17, 2025. https://www.nber.org/system/files/working_papers/w28457/w28457.pdf

[47] Government Accountability Office. Medicare: Preliminary Findings Suggest Improvements Made to Competitive Bidding Program, but Some Challenges Remain. GAO-15-63T. October 2014.

[48] GAO. Medicare: CMS's Round 2 Durable Medical Equipment and National Mail-Order Program (GAO-16-570). 2016.

[49] Ding H, Duggan M, Starc A. Getting the Price Right? The Impact of Competitive Bidding in the Medicare Program. NBER Working Paper No. 28457. National Bureau of Economic Research; 2021. Accessed July 17, 2025. https://www.nber.org/system/files/working_papers/w28457/w28457.pdf

As a result, providers may also need to find other means to either increase revenue or limit costs. Providers may be forced to raise prices, particularly for the privately insured. They may also reduce costs through reductions in staff, departments, and limits to capital improvements. Additionally, some providers may be forced to merge, close locations, or cease operations entirely. According to the CBO, while reductions such as these may maintain profit margins, they also may lead to a decrease in overall access to and quality of care.[50]

These risks could be further impacted by long-term fiscal pressures on Medicare. According to a 2022 CBO report, commercial insurers pay substantially more than Medicare for hospital and physician services, indicating a persistent gap that hospitals use to offset public payer shortfalls.[51] For DMEPOS providers, who do not benefit from similar reimbursement differentials, persistent underpayment poses a direct threat to financial viability. If statutory rules like PAYGO [52] trigger further Medicare reductions, estimated to total $500 billion from 2027 to 2034 as part of newly introduced legislation,[53] these vulnerabilities could be magnified.

In pre-implementation interviews, referral agents in rural parts of competitive bidding areas warned that eliminating local suppliers could place beneficiaries at risk.[54] Although access was deemed adequate at the time, they feared the removal of nearby vendors would destabilize fragile delivery networks in remote areas. The CMS-commissioned baseline case study reported that the availability of diverse DMEPOS options was already limited in sparsely populated zones, and that any disruption to the status quo might disproportionately impact rural patients.[55]

However, empirical evaluations of CBP suggest persistent flaws that undermine these objectives and impose disproportionate burdens on smaller and rural providers.[56] Structurally, bidder asymmetry remains a fundamental barrier to equitable participation. Suppliers differ significantly in their operational capacity, cost structure, and service quality, leading to distorted competition where entities with limited scale or higher overhead are systematically disadvantaged. Such asymmetry forces these suppliers to engage in

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[50] Ibid.

[51] Congressional Budget Office. The Prices That Commercial Health Insurers and Medicare Pay for Hospitals' and Physicians' Services. January 2022. Accessed May 22, 2025. https://www.cbo.gov/system/files/2022-01/57422-medical-prices.pdf

[52] The Statutory Pay-As-You-Go (PAYGO) Act of 2010 requires that new legislation affecting mandatory spending or revenues must not increase the federal deficit. If such legislation is not offset, the Office of Management and Budget (OMB) is required to implement automatic, across-the-board spending cuts (sequestration) to certain mandatory programs, including Medicare (capped at 4% annually). **Source**: Congressional Research Service. *The Statutory Pay-As-You-Go Act: A Brief Overview*. CRS Report R41157. Updated February 9, 2023. Accessed May 22, 2025.

[53] Tankersley J. Trump-backed tax plan could trigger $490 billion in Medicare cuts, CBO says. *The Washington Post*. May 21, 2025. Accessed May 22, 2025. https://www.washingtonpost.com/opinions/2025/05/21/trump-tax-spending-deficit-debt/

[54] Abt Associates Inc; Centers for Medicare & Medicaid Services. Baseline Case Study Report: Evaluation of the National DMEPOS Competitive Bidding Program. October 2010. Accessed July 17, 2025. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/ABT_Case_Study_Report_October_2010.pdf

[55] Ibid.

[56] Ibid.

aggressive pricing behavior, often resulting in financially unsustainable contracts or market exit.[57] Compounding this issue is the complexity inherent in bid management under regulated conditions. Effective submissions require seamless coordination across clinical, regulatory, and administrative domains, yet many providers lack integrated systems capable of supporting this level of sophistication.[58]

Also, payment amounts are not recalculated when unqualified or non-participating suppliers affect SPAs, leaving reimbursement rates potentially based on flawed data.[59] These concerns continue to raise questions about the program's long-term sustainability and effectiveness. A 2016 OIG report identified that 34% of suppliers awarded contracts in Round 2 were not properly licensed to supply items in their designated CBAs.[60] Because states are not required to submit licensure data to CMS or its contractors, discrepancies can go undetected, allowing unqualified providers to shape final payment rates.[61] Independent oversight by the Government Accountability Office (GAO) has also documented risks related to ineligible contract awards, weak incentives for compliance, and threats to market sustainability in rural regions.[62]

Suicide Bidding

Additional concerns have focused on the program's pricing methodology, especially the use of non-binding bids in earlier rounds, which enabled suppliers to submit unrealistically low offers without a contractual obligation to accept awards.[63] Initially, the CBP permitted non-binding bids, meaning that suppliers could decline contracts after winning without facing any penalties. This encouraged what researchers have termed "suicide bidding," wherein suppliers would submit extremely low bids to win contracts and later drop out if they determined the SPA was unsustainable.[64] This practice may have contributed to artificially suppressed prices that did not reflect actual costs, particularly for small or rural suppliers with higher operational burdens.[65] This bidding strategy also exploited the use of median pricing. Because SPAs are determined at the median of winning bids, half of all winners are automatically awarded contracts at prices above their own bids. That dynamic was in part addressed when CMS moved to using the high bid among winning bidders to set SPAs. Suppliers could also lower their composite bids by bidding unreasonably low on less critical products, knowing they may not be obligated to supply them.[66]

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[57] Lorentziadis PL. Competitive bidding in asymmetric multidimensional public procurement. *Eur J Oper Res*. 2020;284(1):304–314.

[58] Aaltio A, Toppinen A, Ollikainen M. Managing bids at the engineering–commercial interface: a systems, integration and contingency perspective. *Int J Ind Organ*. 2024;92:102847.

[59] Cramton P, Katzman B. Reforming Medicare's Bidding System for Durable Medical Equipment. Am Econ Rev. 2018;108(5):1314–1317.

[60] Office of Inspector General. Incomplete and Inaccurate Licensure Data Allowed Some Providers in Round 2 of the DMEPOS Competitive Bidding Program That Did Not Have Required Licenses. HHS OIG; 2016. Report OEI-05-13-00047.

[61] Ibid.

[62] Government Accountability Office. *Medicare: CMS Should Monitor Efforts to Recoup Improper Payments Related to the Competitive Bidding Program*. GAO-18-88. November 2017. Accessed May 22, 2025. https://www.gao.gov/products/gao-18-88

[63] Cramton P, Ellermeyer S, Katzman B. Designed to Fail: The Medicare Auction for Durable Medical Equipment. *Econ Inq*. 2015;53(1):469-485.

[64] Ibid.

[65] Cramton P, Katzman B. Reforming Medicare's Bidding System for Durable Medical Equipment. *Am Econ Rev*. 2018;108(5):1314–1317.

[66] Merlob B, Plott CR, Zhang Y. The CMS Auction: Experimental Studies of a Median-Bid Procurement Auction with Non-Binding Bids. Q J Econ. 2012;127(2):793–827.

The Medicare Competitive Bidding Program

As a result of the concerns surrounding "suicide bidding", the overall design of the CBP auction itself has come under substantial criticism. Peter Cramton, a prominent auction theorist has argued that the use of non-binding bids and median pricing introduced distorted price signals and encouraged strategic underbidding.[67] Furthermore, a 2020 publication by Ding, Duggan, and Starc found that this auction structure led to substantial inefficiencies, including lower-than-optimal prices, supplier withdrawal, and reduced access to critical equipment.[68] The authors estimate that the CBP led to a 6% reduction in prices below competitive market levels, which in turn decreased supply availability and patient utilization. They emphasize that the program's design, particularly the lack of bid commitment requirements, contributed to strategic underbidding by suppliers who later declined to fulfill contracts.

In response to growing criticism of the auction design, the Bipartisan Budget Act of 2018 mandated the use of binding bids for all future rounds of bidding, although implementation of this reform was delayed and will not be fully enforced until CMS finalizes new program rules.[69] Even with this change, however, CMS has historically only verified the cost of goods (based on manufacturer invoices) when assessing whether a bid is "bona fide." It does not factor in indirect costs such as warehousing, delivery, staffing, regulatory compliance, and patient education—substantial costs that should be considered when calculating the total expense of furnishing DMEPOS items.[70]

[67] Cramton P. *Medicare Competitive Bidding: A Market Design Problem*. University of Maryland; 2011.

[68] Ding L, Duggan M, Starc A. *Inefficiencies in the Pricing of Medical Equipment: Evidence from the Medicare Competitive Bidding Program*. National Bureau of Economic Research Working Paper No. 27150. May 2020. Available at: https://www.nber.org/papers/w27150. Accessed May 20, 2025.

[69] Bipartisan Budget Act of 2018, Pub L No. 115-123, § 16008.

[70] Centers for Medicare & Medicaid Services. DMEPOS Competitive Bidding Program. CMS.gov. Updated January 2024. Accessed May 22, 2025. https://www.cms.gov/medicare/payment/fee-schedules/dmepos-competitive-bidding

Incompatibility of CBP for CGMs

The structure of the CBP presents heightened risks in product categories with limited manufacturer diversity and non-interchangeable technologies, such as CGMs. Unlike the broader DMEPOS categories—some of which include over 60 manufacturers and hundreds of HCPCS-coded products—CGMs currently include only six distinct models produced by three manufacturers. Of those six models, four are Class II and two are Class III. Statutorily, only Class II CGMs are subject to CBP consideration. Class III devices are statutorily excluded from CBP.[71]

However, under the CY 2026 Final Rule, CMS seeks to equalize reimbursement across Class II and Class III CGMs. The agency is invoking its inherent reasonableness authority to revise reimbursement for Class III CGMs such that it is equivalent to the pricing of Class II CGMs resulting from the CB process. This approach raises both procedural and policy concerns. The inherent reasonableness authority includes specific statutory and regulatory prerequisites, such as transparent data analysis, stakeholder notice, and demonstration of a payment distortion. It is not clear whether CMS has met the standard required by these statutory and regulatory provisions since the Class II CBP-based payment rate does not yet exist. While the reclassification and rental-based payment model aim to standardize CGM reimbursement, the limited number of manufacturers and the non-interchangeable nature of current CGM systems could create significant risk of market disruption under a CBP framework. CBP, in a product category with only two manufacturers, could result in reduced competition, supply instability, and access barriers if one manufacturer or supplier fails to participate or is unable to meet demand. Because CGMs are tightly integrated with insulin pumps and individualized treatment regimens, disruptions in product availability or supplier continuity could directly affect patient safety and clinical outcomes. In combination, the equalization of payment, reclassification under the frequent and substantial servicing category, and

[71] Social Security Act Section 1847(a)(2)(A)

application of CBP in such a concentrated market may undermine program stability, limit patient choice, and hinder continued technological advancement in diabetes care.

CBP Potential to Impact CGM Market Viability

The viability of suppliers under the CGM rental and competitive bidding model is central to the success of CMS's reclassification policy. Under 42 CFR §414.222(a) and Section 1834(a)(3) of the Social Security Act, CGMs will be reclassified as items requiring frequent and substantial servicing and thus be reimbursed on a continuous monthly rental basis. Contract suppliers would be responsible for furnishing the device, associated supplies and accessories, and all required servicing, including maintenance, technical support, recalls, patient education, and device cybersecurity updates. Unlike more commoditized DMEPOS categories, the CGM market is highly consolidated, with only three manufacturers (only two of which manufacturer Class II CGMs) and no cross-brand interoperability. Suppliers must therefore maintain brand-specific inventory and build parallel logistical systems to support multiple proprietary platforms, which would increase fixed overhead costs and elevate the capital intensity needed for participation.

These operational demands could be further amplified by the rapid pace of CGM software updates and product iteration, which may require ongoing training, system integration, and compliance monitoring beyond the scope of traditional DMEPOS servicing. The model would shift these obligations to suppliers without corresponding reimbursement adjustments, introducing financial strain and potentially discouraging participation. In response to CMS's proposal to include CGMs and insulin pumps in the RID CBP, a prominent health organization indicated that they oppose a national RID CBP for Class II CGMs and insulin pumps as it would result in beneficiary access issues, noting that "reducing hundreds of DME suppliers to fewer than ten contractors would require each to ramp up capacity by 35 to 40 times virtually overnight".[72] These comments directly address CMS's proposal to limit contract suppliers under the RID CBP structure.

Consistent with 42 CFR §414.416(b), the SPA for non-lead items would be calculated based on the ratio of 2015 unadjusted fee schedule amounts for the non-lead item and lead item. However, because Medicare did not begin covering CGMs until 2017, CMS proposes to impute synthetic 2015-equivalent rates by deflating the 2025 fee schedule amounts using DMEPOS update factors from 2016 through 2025, as described in the final rule.[73]

To support future integration of CGMs into a national or regional CBP, CMS will designate CGM supplies as the lead item within a new product category using imputed 2015 rates. CMS incorporates this

[72] American Association for Homecare. Comments on CMS–1828–P, "Medicare and Medicaid Programs; CY 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." Submitted to the Centers for Medicare & Medicaid Services. Arlington, VA: American Association for Homecare; August 27, 2025.

[73] Centers for Medicare & Medicaid Services. Medicare program; end-stage renal disease prospective payment system, payment for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); issues related to coverage of dental services; proposed rule. 90 Fed Reg 29266. July 2, 2025.

methodology into new paragraph §414.416(b)(4) to support SPA calculations under Remote Item Delivery (RID) CBPs. While imputing historical rates satisfies regulatory consistency requirements, the resulting bid ceilings may not reflect current acquisition, servicing, and distribution costs, particularly considering the increased operational responsibilities suppliers would bear under the new payment model. In response to this use of imputed 2015 rates, AdaptHealth warned that "outdated 2015 pricing data could have unintended consequences … risk creating insufficient supplier capacity in Competitive Bidding Areas and potentially compromising Medicare beneficiary access to essential durable medical equipment categories, items, and services."[74]

If reimbursement ceilings are based on imputed 2015 rates rather than contemporary market realities, suppliers, especially smaller, regional, or specialty entities, may find it financially infeasible to submit sustainable bids. To further complicate the potential for inadequate reimbursement, CMS will also establish SPAs using the 75th percentile of winning bids, meaning that one quarter of winning bids would be forced to accept lower reimbursement rates than those for which they bid. Abbott Laboratories, commenting on CMS's bid-price methodology to pay CGMs at the 75th percentile of winning bids, stated that "paying CGMs at only the 75th percentile of winning bids will cause payment rates to fall below a sustainable level … risking withdrawal of some advanced products from the market and disruption of patient access."[75] This may force some suppliers to carry one brand of product instead of another to offset their potential revenue losses.

Because CGM systems are highly specialized and non-interchangeable, suppliers cannot readily substitute between brands to offset cost pressures. The finalized structure could therefore limit participation to larger national entities capable of absorbing financial and logistical risk, reducing competition and increasing the market's vulnerability to disruption if a major manufacturer or distributor withdraws. Given that only two manufacturers produce Class II CGMs, the potential for a manufacturer monopoly with a winning supplier in a CBA is a very distinct possibility.

Prior CBP rounds have shown that similar CBP structural misalignments contributed to supplier attrition and diminished geographic access, even when target program savings were achieved.[76] A poorly calibrated CGM CBP could yield comparable results, with adverse consequences for both patient access and supplier market stability. CMS must reconcile the technical requirements of §414.416(b) with the economic realities

[74] AdaptHealth LLC. Comments on CMS–1828–P, "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." Submitted to the Centers for Medicare & Medicaid Services. Plymouth Meeting, PA: AdaptHealth; August 29, 2025

[75] Abbott Laboratories. Comments on CMS–1828–P, "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Abbott Laboratories; August 28, 2025

[76] U.S. Government Accountability Office. CMS's Round 2 Durable Medical Equipment and National Mail-order Diabetes Testing Supplies Competitive Bidding Programs. GAO-16-570. September 2016. Available at: https://www.gao.gov/assets/690/689690.pdf

of CGM provisioning to ensure a robust, competitive, and resilient supplier network capable of meeting national demand.

The perpetual rental model could pose its own stability concerns for the CGM market. An important aspect of the perpetual rental model adopted by CMS is the establishment of a monthly rental amount based on the assumption that suppliers will be able to rent CGM receivers for 60 months. CMS's current regulations permit replacement of a DME item no more frequently than once every 5 years. To create a payment ceiling for their perpetual rental arrangement, CMS divided the current payment for a CGM receiver by 60 and added that amount to the current payment for monthly supplies. In the final rule, CMS notes that the payment cap in 2025 dollars will be $272.69. In the context of CBP, bids will not be accepted unless they are below this amount so that CMS can satisfy a statutory requirement that CBP only be implemented if the agency can achieve savings relative to what otherwise would have been spent.

CMS has adopted the perpetual rental arrangement with the intention of allowing beneficiaries to switch devices at any time, rather than having to wait five years between being able to access a new device. The justification behind this model is based on the historic, rapid pace of innovation in the CGM space and the agency's assertion that they want beneficiaries to be able to use the latest technology.

The inherent conflict in CMS' approach is that they are setting reimbursement and the bid ceiling based on the assumption that suppliers will be able to rent the CGM receiver for a full 60 months, while at the same time encouraging beneficiaries to switch in much shorter time frames. CMS asserts that suppliers will be able to re-rent CGM receivers to subsequent beneficiaries; however, a beneficiary may not want to use either a previously operated receiver or one that corresponds to an older CGM model. Thus, suppliers will likely make substantial upfront investments in CGM receivers that may never be recouped. This cost must be factored into their bids, making it less likely that they will be able to bid under the reimbursement cap to achieve savings for the Medicare program. CMS intends to use this same approach with insulin pumps, but that device category contains much larger up-front cost for durable insulin pumps and the pump costs are a much larger portion of overall costs across a five-year horizon.

SUICIDE BIDDING AND MARKET INSTABILITY

The CBP introduces the risk of "suicide bidding", where suppliers submit unrealistically low bids in an effort to secure contracts, often at the expense of long-term financial sustainability. This phenomenon has been documented in past CBP rounds and is associated with downstream consequences such as supplier attrition, contract non-fulfillment, and diminished service quality.[77] A 2016 GAO report found that, following Round 2 of the CBP, the number of beneficiaries receiving covered items in CBP areas declined by 17%, compared to 6% in non-CBP areas, suggesting that supplier exits and bid-related disruptions

[77] Ibid.

affected access despite cost savings (GAO-16-570).[78] In past rounds of CBP, CMS required bidding suppliers to provide an estimate of the number of beneficiaries they could serve, which CMS validated by checking the claims history for existing suppliers. In addition, the agency required bidders to submit a tax return extract, income statement, balance sheet, or statement of cash flows. Under the final rule, CMS has removed these requirements in favor of a credit report submission. CMS argues that its requirement that bidders submit a $50,000 surety bond for each area in which they bid will discourage suicide bidding, but obtaining these bonds is relatively inexpensive, with an average price of $300-$400.[79] These new measures implemented by CMS in the final rule could make it easier for suppliers without capacity to service a large number of beneficiaries to bid while simultaneously removing the safeguards historically in place to ensure the suppliers can actually fulfill their obligations to beneficiaries.

According to the OIGs report, during their July 2022–June 2023 study period, there were 750,000 CGM users in the Medicare FFS population. This figure has been growing steadily as more people adopt this technology to help manage their diabetes. It would be reasonable to assume that by the time the CBP is implemented in 2028, there could be more than a million CGM users in the Medicare program, particularly given the recent increasing trends of obesity and diabetes diagnoses in the United States. Since CMS has indicated they will contract with no more than 9-10 suppliers in their nationwide remote item delivery model, each contracted supplier would need to be able to service at least 100,000 beneficiaries a month—a feat which would likely be difficult for all but a small handful of existing suppliers. Given that previously used safeguards, like supplier capacity attestations and various financial documents, are no longer a part of the CBP for CGMs, it would appear the only potential barrier to a small supplier submitting an unrealistically low bid in a national competition is CMS's requirement that suppliers maintain an applicable license in every state they intend to serve. The structure that CMS has finalized could incentivize "suicide bidding," and it is unclear how that possibility will be addressed in bid solicitation instructions or contractual requirements.

CMS'S PROPOSED 15% REDUCTION

In 2017, CMS set the monthly reimbursement for CGM supplies at $248.38, approximately 36% of Dexcom's wholesale acquisition cost at the time ($683.73).[80] Since then, rates have increased by only 7.9% over eight years, reaching $267.92.[81] These modest increases are dictated by statute, not by manufacturers, and occur regardless of improvements in device functionality.

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[78] Ibid.

[79] *Medicare Durable Medical Equipment: Effect of New Bid Surety Bond Requirement on Small Supplier Participation in the Competitive Bidding Program*, Government Accountability Office (Aug. 2021), https://www.gao.gov/assets/gao-21-602.pdf.

[80] Centers for Medicare & Medicaid Services. HCPCS Public Meeting Agenda for External and Internal Requests. May 2017. https://www.cms.gov/medicare-coverage-database

[81] CGS Medicare. Continuous Glucose Monitor (CGM) Supply Allowance Billing. https://www.cgsmedicare.com/jc/pubs/news/2021/05/cope21817.html. Published May 2021.

Incompatibility of CBP for CGMs

CMS has previously been concerned with manufacturer price manipulations and their potential effect on Medicare reimbursement rates. However, it is reasonable to assume that concerns that CGM reimbursement under Medicare has increased due to pricing manipulation are unfounded. CGM payment rates were established by CMS using standard statutory mechanisms. Payment for the CGM receiver was set via "crosswalking" to blood glucose monitors, while monthly supply payments were "gap filled" using publicly available pricing data.[82] Increases in reimbursement after CMS set the initial rate has been dictated by statute, essentially Consumer Price Index for all Urban Consumers (CPI-U) minus a small productivity adjuster.[83] After initial rates are set, manufacturer price changes have no effect whatsoever on Medicare DME reimbursement.

Since Medicare began covering CGMs, significant advancements have been made to device safety, user experience, accuracy, and integration with health systems. Features now include improved accuracy, reduced sensor warm-up times, longer communication ranges, integrated wearables, enhanced interoperability with electronic health records (EHRs), and data-sharing capabilities with consumer health platforms. Despite these innovations, CMS does not adjust reimbursement rates to reflect increased clinical value, placing pressure on manufacturers to sustain innovation within static or declining margins. Medicare patients have been able to benefit from these product enhancements while experiencing price increases that are less than inflation. Reductions in reimbursement based on a CBP program that incentivizes inappropriately low bids would materially impact manufacturer ability to continue such investment in research and development. As Abbott explained, "if rates are set too low, manufacturers may be forced to reduce investment in future CGM technology, risking withdrawal of some advanced products from the market and disruption of patient access".[84]

CBP Potential to Impact Beneficiary Access

CGMs and their associated supplies are device-specific: sensors, transmitters, and receivers are uniquely paired by brand and model, limiting therapeutic substitution. Transitioning between devices may necessitate new prescriptions, patient retraining, and clinical oversight, particularly for beneficiaries using integrated technologies such as Automated Insulin Delivery (AID) systems. Under current policy at 42 CFR §414.210(e)(6), Medicare prohibits payment for a replacement CGM receiver within five years unless it is lost, stolen, or irreparably damaged. Without targeted transition provisions or clinical exceptions, CBP participation could create pressure for some beneficiaries to switch from a clinically stabilized device platform, potentially disrupting care continuity.

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[82] Centers for Medicare & Medicaid Services. Medicare Coverage of Diabetes Supplies. MLN Fact Sheet. https://www.cms.gov/files/document/mln7674574-medicare-coverage-diabetes-supplies.pdf. Published February 2025.

[83] Social Security Act, Section 1834(a)(14)

[84] Abbott Laboratories. Comments on CMS–1828–P, "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Abbott Laboratories; August 28, 2025

Incompatibility of CBP for CGMs

As discussed previously, the use of imputed 2015 rates to calculate SPAs may indirectly affect beneficiary access by discouraging supplier participation or limiting product availability. Under a CBP model that rewards the lowest-cost bids, smaller or regional suppliers may be unable to sustain operations, increasing the likelihood of reduced device choice and regional service gaps. Experience from previous CBP rounds involving insulin pumps underscores the importance of carefully structuring CBP for technologically specialized categories. Restricting access to preferred CGM models could erode demonstrated clinical and economic benefits, offsetting any short-term savings achieved through lower reimbursement. A prominent health organization similarly warned that "…forcing beneficiaries to change from one CGM brand to another would cause patient confusion, increase provider burden, and jeopardize continuity of care for individuals who have achieved stable glycemic control".[85]

Although the DMEPOS CBP is designed to reduce out-of-pocket expenses and generate cost savings for the Medicare program, studies have highlighted its unintended consequences on beneficiaries' access to essential supplies, leading to negative health outcomes.[86] Low-income and indigent patients, who are at heightened risk if competitive bidding reduces the pool of willing suppliers, particularly for CGMs, are at the most risk. A 2016 study by Puckrein et al. found that a pilot program for diabetes supplies resulted in significant supply chain disruptions, compromising the acquisition of these supplies for vulnerable beneficiaries.[87] Inconsistent coverage and stringent requirements for both initial and ongoing CGM access often impede patients' ability to manage their diabetes effectively.[88] The Diabetes Technology Access Coalition (DTAC) cautioned that "…a CGM competitive bidding program with only two eligible manufacturers could concentrate access risk, leaving patients vulnerable to supply disruptions if one producer fails to deliver".[89]

To address these challenges, some suppliers offer Patient Assistance Programs (PAPs) to make diabetes supplies more affordable. For example, Dexcom, a leading manufacturer of G6 and G7 CGMs, provides a PAP for type 1 diabetic patients who are not covered by government programs and whose income is below

[85] American Association for Homecare. Comments on CMS–1828–P, "Medicare and Medicaid Programs; CY 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." Submitted to the Centers for Medicare & Medicaid Services. Arlington, VA: American Association for Homecare; August 27, 2025.

[86] Davidson JA, Parkin C. Diabetes and Medicare Competitive Bidding: The "Perfect Storm" for Patient Harm. *AJMC*. 2016;22. Accessed May 27, 2025. https://www.ajmc.com/view/diabetes-and-medicare-competitive-bidding-the-perfect-storm-for-patient-harm

[87] DiGrande S, Caffrey M. Three Years After Advocates Report Flaws, Medicare Diabetes Test Strip Bidding Program Nears Collapse. *AJMC*. 2019;25(4). Accessed May 27, 2025. https://www.ajmc.com/view/three-years-after-advocates-report-flaws-medicare-diabetes-test-strip-bidding-program-nears-collapse

[88] Howe G, Chavis J. *Expanding Medicaid Access to Continuous Glucose Monitors*. Center for Health Care Strategies ; 2022. Accessed May 27, 2025. https://www.chcs.org/media/Expanding-Medicaid-Access-to-Continuous-Glucose-Monitors_011222.pdf

[89] Diabetes Technology Access Coalition (DTAC). Comments on CMS–1828–P, "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." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Diabetes Technology Access Coalition; August 29, 2025

400% of the federal poverty level.[90] However, the role of PAPs in DMEPOS is limited. While PAPs can provide medications to low-income or uninsured individuals, DMEPOS lacks similar comprehensive support for devices like CGMs. This gap in patient assistance means that Medicare beneficiaries have fewer financial avenues for acquiring CGMs, potentially hindering device adoption and adherence.

Commenters responding to the proposed regulation universally cautioned of potential disruptions in patient care that could stem from the application of CBP to CGMs and insulin pumps, which are likely to occur for two reasons. First, despite the assertion that suppliers will be required to provide the brand of device as prescribed, suppliers are in fact free to refuse to carry all brands of devices subject to CBP. The applicable regulatory text at 42 CFR 414.420(b) states that contract suppliers must fill the order with the specific brand on the order, however if they do not possess it, they can call the prescriber back to request a different brand be put on the order, or they can send the beneficiary to a supplier that carries the ordered item. Furthermore, not all orders include a specific brand, and suppliers could encourage beneficiaries to take the brand that they find most profitable, enabling them to carry only the specific brand they find most financially rewarding. This scenario would create a manufacturer monopoly with a given supplier, meaning that beneficiaries would lack the ability to use the product of choice. Ironically, the unintended consequences of CBP for CGMs could end up negating the ability for beneficiaries to change CGMs whenever they choose—a core tentpole of CMS's continuous monthly rental model.

The second reason that continuity issues in patient care could occur is the perpetual rental payment arrangement. A scenario could arise where beneficiaries fail to return the older device, which would make it impossible for suppliers to re-rent the device to any other beneficiary, resulting in a loss of their capital investment. Under this approach suppliers could require beneficiaries to return their old device before shipping a new one. The break in care, between the time when the old device is shipped and the new one is received, even one that encompasses a relatively short time frame, could have negative impacts to patient safety.

CBP Potential to Impact CMS Spending

For a limited sample of suppliers, we tabulated the FY 2024 weighted acquisition cost of goods and applied a 67%, 72%, and 56.25% markup based on the results of our previous true cost study that was utilized by Health and Human Services (HHS) Office of Inspectors General (OIG) to identify the average markup for urinary catheters subject to CBP[91,92] and the additional cost factor used by the OIG in its recent report to

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[90] Association of Diabetes Care & Education Specialists. *CGM and Insulin Pump Cost Savings Resource Manufacturer Specific Programs for CGM.*; 2023. Accessed May 27, 2025. https://www.adces.org/docs/default-source/handouts/costsavingsresources/ehandout_hcp_costsaving_cgminsulinpump2023.pdf?sfvrsn=be56359_17

[91] Dobson DaVanzo & Associates, LLC; American Association for Homecare. Analysis of the Cost of Providing Durable Medical Equipment to the Medicare Population: Measuring the Impact of Competitive Bidding [final report]. Vienna, VA: Dobson DaVanzo & Assoc; 2016. October 18, 2016.

[92] U.S. Department of Health and Human Services, Office of Inspector General. *Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year.* OEI-04-20-00620. August 2022

account for supplier costs other than device acquisition.[93] Applying these validated markup methodologies to key CGM components shows a pronounced misalignment between supplier costs and CMS's proposed payment. Based on supplier-provided data, the monthly weighted acquisition cost for CGM receivers under HCPC E2103, plus estimated supplier costs of doing business ranged from $3.95 to $4.36, while the monthly supply allowance for CGMs billed using HCPC A4239 ranged from $268 to $296 under the same parameters. Therefore, the actual cost of providing a CGM receiver and related supplies would likely range from $272 to $300 per month.

Table 1: FY 2024 Survey Reported Acquisition and Marked Up Cost in Comparison to Current and Proposed Medicare Reimbursement

HCPCS Code	Monthly Reported Acquisition Cost	Monthly Acquisition, marked up by 56.25%	Monthly Acquisition, marked up by 67%	Monthly Acquisition, marked up by 72%	Monthly 2024 Medicare Reimbursement Rates	Monthly 2025 Medicare Reimbursement Rates	CMS Proposed Bid Ceiling for Monthly Rental
E2103 (CGM receiver)††	$2.53	$3.95	$4.23	$4.36	$4.81	$4.92	$4.77
A4239 (CGM monthly supplies)	$171.27	$267.61	$286.03	$295.59	$261.64	$267.92	$267.92
Total	**$173.80**	**$271.56**	**$290.26**	**$299.95**	**$266.45**	**$272.84**	**$272.69**

††When conducting our survey, suppliers reported acquisition costs as a lump sum cost because that is how they currently pay for the devices. Similarly, CMS's 2024 and 2025 reimbursement rates are lump-sum payments. Given that CMS is proposing moving to a monthly rental model for the CGM receiver, to arrive at monthly costs and reimbursement rates, we divided the current E2103 CGM receiver numbers, provided as a lump-sum, by 60 to account for the typical 5-year life of the CGM receiver. Therefore, to arrive at the current CGM receiver lump-sum costs and Medicare reimbursement rates, simply multiply each column in the E2103 CGM receiver row by 60.

This cost estimate, however, does not include any costs associated with software updates, device calibration, HIPAA compliant data security, patient support, and continuous shipping costs associated with the continuous rental model, nor does it account for bad debt that will be incurred when patients do not return used devices, or the losses associated with the inability to rent CGM receivers for a full 60-month period before new models emerge. All these additional costs, and potentially more, need to be accounted for to calculate an accurate monthly cost estimate that suppliers would incur under CMS's bundle rental. Furthermore, the markup factor used by the OIG in its report on CGMs (56.25%) does not include any allowance for a profit margin. It is therefore very likely that an appropriate markup of acquisition costs would exceed the 56.25% markup figures used to model total costs by the OIG in its report on CGMs. It is notable that the OIG itself concluded that there is only a 2% difference between supplier total costs and Medicare's payment for CGMs, before considering any of the new costs noted above or the need for profit.

[93] US Department of Health and Human Services, Office of Inspector General. *Medicare Payments for Continuous Glucose Monitors Exceeded Supplier Acquisition Costs.* OEI-04-23-00430. November 2025.

Given these realities, suppliers are highly unlikely to be able to bid under the maximum ceiling of $272.69 set by CMS, and applying CBP to CGM will not be able to produce any meaningful savings.

Furthermore, CMS's proposed bundled rental rate of $272.69 would prove fiscally unsustainable to suppliers. The differential of 2% found by OIG, before application of additional costs or need for profit, suggests that suppliers would operate at a substantial loss under the proposed methodology. In response to CMS's proposed rental model and expanded supplier servicing obligations, CCS Medical stated that "…the proposed remote item delivery competitive bidding program is not a sustainable reimbursement model for CGMs and insulin pumps".[94] Additionally, Byram Healthcare explained that "Suppliers would be required to assume long-term ownership and responsibility for devices … managed directly by manufacturers … This creates a conflict in responsibilities and introduces inefficiencies that could disrupt patient care".[95]

While CMS's stated intent in reclassifying CGMs and incorporating them into a competitive bidding framework is to achieve budgetary savings, the proposed approach could paradoxically increase total Medicare spending over time. The DMEPOS account may realize very slight short-term reductions, but these savings are likely to be offset by higher costs across Medicare Parts A and B due to worsened clinical outcomes, increased acute-care utilization, and new administrative demands. Several studies have found that CGM use is associated with monthly savings of $300 to $400 in the commercial market, primarily due to reduced hospitalizations and other inpatient costs.[96,97,98] These savings can meaningfully offset the costs of CGM coverage, suggesting that limiting access could lead to increased downstream Medicare expenditures through avoidable acute care utilization. Similarly, DTAC reported that CGM adoption reduces diabetes-related hospitalizations by 32% to 57% and generates average monthly cost savings of $329 to $424 per patient, primarily through fewer emergency department visits and inpatient admissions.[99] Therefore, providing reimbursement rates that do not adequately cover the cost of supplying CGMs and related supplies could cost Medicare significant money in the long-term.

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[94] Byram Healthcare Centers, Inc. Comments on CMS–1828–P… Section 3: National CBP for CGMs and Insulin Pumps. White Plains, NY: Byram Healthcare Centers, Inc.; August 28, 2025

[95] Byram Healthcare Centers, Inc. Comments on CMS–1828–P, "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." Submitted to the Centers for Medicare & Medicaid Services. White Plains, NY: Byram Healthcare Centers, Inc.; August 28, 2025

[96] Isaacson B, Kaufusi S, Sorensen J, et al. Demonstrating the Clinical Impact of Continuous Glucose Monitoring Within an Integrated Healthcare Delivery System. J Diabetes Sci Technol. 2022;16(2):383-389. doi:10.1177/1932296821998614

[97] Norman GJ, Paudel ML, Parkin CG, et al. Association between Real-Time Continuous Glucose Monitor Use and Diabetes-Related Medical Costs for Patients with Type 2 Diabetes. Diabetes Technol Ther. 2022;24(7):520-523. doi:10.1089/dia.2022.0116

[98] Hannah KL, Nemlekar PM, Green CR, Norman GJ. Reduction in Diabetes-Related Hospitalizations and Medical Costs After Dexcom G6 Continuous Glucose Monitor Initiation in People with Type 2 Diabetes Using Intensive Insulin Therapy. Adv Ther. 2024. doi:10.1007/s12325-024-02851-8

[99] Diabetes Technology Access Coalition (DTAC). Comments on CMS–1828–P, "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." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Diabetes Technology Access Coalition; August 29, 2025

The fiscal implications of even small disruptions are significant. For context, Medicare spends approximately $9,000 per diabetes-related hospitalization, based on national estimates from the Agency for Healthcare Research and Quality (AHRQ) and the Medicare Payment Advisory Commission (MedPAC).[100] [101] If only 5% of CGM users experiences one hospitalization or emergency visit that otherwise would have been avoided through continuous device use, the aggregate cost to Medicare would surpass the DMEPOS savings projected under the final policy.

CMS's reliance on imputed 2015 fee schedule data and an extended 60-month rental assumption also risks setting Single Payment Amounts (SPAs) that do not reflect the actual cost of provisioning or maintaining CGMs under the frequent and substantial servicing classification. As AdaptHealth cautioned, "outdated 2015 pricing data could have unintended consequences… risk creating insufficient supplier capacity… and potentially compromising Medicare beneficiary access to essential durable medical equipment," resulting in system inefficiencies that ultimately increase costs through delayed replacements, reissued claims, and expanded oversight responsibilities. [102] Administrative expenses associated with supplier turnover, contract management, appeals, and compliance audits would add further indirect costs to CMS's operations.

A prominent health organization noted that across prior DMEPOS categories, "short-term rate reductions were accompanied by significant increases in long-term costs due to reduced innovation and supplier attrition".[103] If innovation slows, Medicare will lose future efficiency gains that come from better technology and more stable glucose control.

Evidence suggests that CMS's final CBP structure may increase aggregate Medicare spending through higher hospitalization rates, emergency visits, administrative overhead, and lost downstream savings from innovation. If the finalized payment reductions limit availability or continuity of CGM use, these savings would be lost, reversing the trend of cost savings that CGMs have produced since their introduction into Medicare coverage in 2017. A more calibrated payment policy anchored in current cost data and accompanied by outcome monitoring would better align with the program's long-term fiscal interests.

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[100] Fingar KR, Reid LD. Diabetes-Related Inpatient Stays, 2018. HCUP Statistical Brief #279. Rockville, MD: Agency for Healthcare Research and Quality; July 2021. Accessed October 10, 2025. https://hcup-us.ahrq.gov/reports/statbriefs/sb279-Diabetes-Inpatient-Stays-2018.jsp

[101] Medicare Payment Advisory Commission (MedPAC). Report to the Congress: Medicare Payment Policy. Chapter 3: Hospital inpatient and outpatient services. Washington, DC: MedPAC; March 2023. Accessed October 10, 2025. https://www.medpac.gov/wp-content/uploads/2023/03/Ch3_Mar23_MedPAC_Report_To_Congress_SEC_v2.pdf

[102] AdaptHealth LLC. Comments on CMS–1828–P, "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." Submitted to the Centers for Medicare & Medicaid Services. Plymouth Meeting, PA: AdaptHealth; August 29, 2025

[103] American Association for Homecare. Comments on CMS–1828–P, "Medicare and Medicaid Programs; CY 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." Submitted to the Centers for Medicare & Medicaid Services. Arlington, VA: American Association for Homecare; August 27, 2025.

Alternative Policy Proposal

The reclassification of CGMs and introduction of a rental-based CBP mark a significant departure from the current DMEPOS payment framework. While the policy is intended to modernize reimbursement and align with the clinical realities of continuous monitoring technology, the collective evidence from prior CBP experience and stakeholder analysis suggests this approach carries substantial operational and fiscal risks. The findings of this review point to a misalignment between the structure of the CGM market and the assumptions underpinning CMS's proposed payment methodology, which, if implemented nationally without modification, could undermine both cost-effectiveness and beneficiary outcomes.

Across multiple comment letters, stakeholders consistently questioned the readiness of the CGM market for CBP application. The market's limited manufacturer diversity, lack of product interchangeability, and high capital requirements for suppliers introduce volatility that differs materially from other DMEPOS categories. These characteristics make CGMs uniquely vulnerable to distorted bidding dynamics and pricing errors, particularly when payment ceilings are based on imputed 2015 data that do not reflect current acquisition or servicing costs. If realized, these pressures would likely drive consolidation and supplier exits, diminishing both competition and CMS's leverage in future pricing cycles.

Our analysis suggests that CMS's proposed bid ceiling is significantly below the current cost structure of suppliers. Considering the acquisition cost markups associated with the inclusion of direct and indirect costs, the need for a realistic profit margin, and the increasing cost burden suppliers are likely to incur with the final rule, there is little probability CMS will achieve the savings it desires. In fact, CMS's proposed rule is likely to have adverse consequences for supplier financial sustainability and significantly disrupt an industry and market with a limited number of manufacturers and products. These adverse consequences will likely impact beneficiary access to CGMs, potentially increasing hospitalizations and other adverse outcomes.

The fiscal implications of these structural risks are equally significant. DTAC reported that CGM use reduces diabetes-related hospitalizations by 32%–57% and yields monthly commercial market savings of $329–$424 per patient, primarily through reduced emergency and inpatient utilization.[104] These savings

[104] Diabetes Technology Access Coalition (DTAC). Comments on CMS–1828–P, "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-

directly contribute to net program efficiency. Under a pricing model that disincentivizes participation or interrupts beneficiary access, Medicare could forfeit some of these savings. Considering that each diabetes-related hospitalization costs approximately $9,000,[105,106] even small increases in acute utilization would negate the minimal projected DMEPOS savings. Together, these data illustrate how a payment policy designed to reduce costs could, in practice, elevate total spending through care disruptions, administrative overhead, and diminished innovation.

To mitigate these risks and align implementation with CMS's program integrity goals, commenters across the CGM industry, supplier associations, and patient coalitions recommended a phased or pilot-based approach. Abbott, AdaptHealth, and DTAC each urged CMS to test the proposed payment model in one or a small number of CBAs before national rollout, emphasizing that a pilot would provide valuable empirical evidence to validate program assumptions, ensure adequate supplier capacity, and safeguard beneficiary access prior to national expansion. Establishing such a pilot would allow CMS to validate its cost assumptions, monitor supplier participation, and assess real-world patient outcomes under the new rental and servicing framework before broader adoption.

In addition to piloting, several commenters proposed complementary measures to strengthen fiscal and operational feasibility. AdaptHealth recommended payment floors or bid guardrails to prevent underbidding that could destabilize supplier markets. For example, since the OIG's estimate of savings amounts to no more than 2% on CGM supplies, if CMS receives bids below that amount, CMS should require such bidders to demonstrate capacity to serve at least 100,000 beneficiaries. Furthermore, before signing contracts with selected final bidders, CMS should conduct in-person site visits, financial reviews, and/or claims history analyses to verify capacity to meet expected demand.

Abbott stressed the importance of transition provisions to protect beneficiaries currently using owned CGM devices, avoiding care disruptions during the policy shift. DTAC and Abbott also encouraged CMS to incorporate outcome-based performance measures—including adherence, device uptime, and hospitalization rates—to ensure that program success is defined not solely by unit price but also by sustained improvements in patient outcomes and system efficiency. Finally, Abbott called for CMS to reexamine its use of inherent

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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." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Diabetes Technology Access Coalition; August 29, 2025

[105] Fingar KR, Reid LD. Diabetes-Related Inpatient Stays, 2018. HCUP Statistical Brief #279. Rockville, MD: Agency for Healthcare Research and Quality; July 2021. Accessed October 10, 2025. https://hcup-us.ahrq.gov/reports/statbriefs/sb279-Diabetes-Inpatient-Stays-2018.jsp

[106] Medicare Payment Advisory Commission (MedPAC). Report to the Congress: Medicare Payment Policy. Chapter 3: Hospital inpatient and outpatient services. Washington, DC: MedPAC; March 2023. Accessed October 10, 2025. https://www.medpac.gov/wp-content/uploads/2023/03/Ch3_Mar23_MedPAC_Report_To_Congress_SEC_v2.pdf

reasonableness authority in equalizing Class II and Class III payment rates to ensure compliance with statutory prerequisites and avoid disincentivizing technology.[107,108,109,110]

CMS should also be prepared to educate beneficiaries that suppliers will not be required to carry every brand, nor are they categorically required to provide beneficiaries the brand their prescriber orders. Therefore, the beneficiary must be deliberate about which supplier they contact to fill their CGM or pump prescription. An alternative to this extensive beneficiary education would be to include a contractual requirement that winning bidders arrange to carry all models of CGM and pumps. This mandate should not be overly burdensome given the limited number of brands available.

When beneficiaries opt to return their old device to obtain a new one, suppliers should ship the new device upon request and allow beneficiaries a reasonable time to return the old device. If the beneficiary fails to do so, suppliers should be permitted to bill the beneficiary for the entire new purchase price of the older device. In this scenario, it is plausible that the beneficiary may not ever pay the entirety of the purchase price of the CGM, resulting in bad debt to the supplier. Bidding instructions should include a clear explanation of this approach and encourage bidders to estimate the amount of bad debt they will incur under this scenario and include that in their bid calculations.

Finally, to help discourage suicide bidding, CMS should include a contractual requirement that winning suppliers cannot sell themselves or have a change of ownership for a reasonable amount of time after the beginning of the contract period (i.e., one calendar year). Potential bidders should be educated about this requirement.

Taken together, these recommendations represent a pragmatic path forward. A phased pilot program, supported by payment guardrails, transition protections, and outcome monitoring, would enable CMS to test and refine its methodology while maintaining market stability and beneficiary access. This approach would generate empirical data on supplier solvency, patient outcomes, and program costs, ensuring that future expansion is guided by measurable evidence rather than modeled assumptions. By adopting a deliberate,

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[107] American Association for Homecare. Comments on CMS–1828–P, "Medicare and Medicaid Programs; CY 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." Submitted to the Centers for Medicare & Medicaid Services. Arlington, VA: American Association for Homecare; August 27, 2025.

[108] Abbott Laboratories. Comments on CMS–1828–P, "Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Abbott Laboratories; August 28, 2025

[109] AdaptHealth LLC. Comments on CMS–1828–P, "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." Submitted to the Centers for Medicare & Medicaid Services. Plymouth Meeting, PA: AdaptHealth; August 29, 2025

[110] Diabetes Technology Access Coalition (DTAC). Comments on CMS–1828–P, "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." Submitted to the Centers for Medicare & Medicaid Services. Washington, DC: Diabetes Technology Access Coalition; August 29, 2025

data-driven implementation strategy, CMS can fulfill its intent to modernize DMEPOS reimbursement while preserving the fiscal and clinical integrity of the Medicare program.

Conclusion

The incorporation of CGMs into the CBP represents a fundamental misalignment between CMS's intended policy objectives and the practical realities of the diabetes technology market. While the program is designed to reduce spending and promote efficiency, applying CBP to a category as concentrated and clinically integrated as CGMs would instead introduce volatility, limit access, and yield minimal savings relative to the risks imposed.

The CGM market is characterized by two Class II manufacturers, non-interchangeable product platforms, and high fixed costs for inventory and technical servicing. These structural features make the category uniquely vulnerable to the distortions inherent in competitive bidding. A national bidding process based on imputed 2015 rates and unrealistic rental assumptions would push reimbursement well below suppliers' actual costs, discouraging participation and triggering market consolidation. Fewer participating suppliers would reduce competition, weaken supply chain stability, and increase the likelihood of localized shortages. These precise conditions have historically undermined beneficiary access in prior CB rounds.

From a fiscal perspective, these risks are not justified by the potential savings. The OIG's report, when combined with new supplier costs required by the final rule and the requirement for at least a modest profit, demonstrate that the opportunity for savings on CGM through CBP is minimal. Were there to be any reductions in DMEPOS spending, they would be so small as to be easily offset by higher costs across Medicare Parts A and B, driven by increased hospitalizations and emergency utilization among beneficiaries who lose access to continuous monitoring. Prior analyses have shown that consistent CGM use lowers acute-care spending by hundreds of dollars per patient per month; and disrupting that continuity could reverse these gains. CMS would also face additional administrative burden associated with supplier turnover, contract oversight, and appeals, further eroding any budgetary benefit. In sum, moving CGMs into CBP would create market instability, threaten patient access, and fail to deliver meaningful savings for the Medicare program. The final rule, as written, risks compromising the very outcomes the CBP was designed to achieve: sustainability, quality, and access. CMS might consider pursuing a more deliberate, data-driven approach that reflects the operational realities of CGM supply, preserves beneficiary continuity, and ensures that payment policy aligns with both market viability and program integrity.