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Medicare Payments for Continuous Glucose Monitors and Supplies Exceeded Supplier Costs and Retail Market Prices, Indicating Medicare Can Save At Least Tens of Millions of Dollars in One Year

REPORT HIGHLIGHTS



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Medicare Payments for Continuous Glucose Monitors and Supplies Exceeded Supplier Costs and Retail Market Prices, Indicating Medicare Can Save At Least Tens of Millions of Dollars in One Year

Why OIG Did This Review

- Continuous glucose monitors (CGMs) are a wearable technology that can help patients manage diabetes by tracking glucose levels every few minutes. Low blood glucose levels can impact an individual's ability to think and function. High levels can damage organs over time.
- Medicare Part B payments for CGMs and supplies rose from \$109 million in 2018 to \$1.3 billion in 2023.
- This review compared Medicare payments for CGMs and associated supplies to the costs incurred by suppliers and retail prices to assess the potential for Medicare cost savings. Previous OIG work determined that Medicare was paying more than other payors for other types of durable medical equipment, other than CGMs, inflating Medicare's overall expenses and the enrollee copayments.

What OIG Found

Comparing Medicare payments to CGM suppliers' acquisitions costs; their total estimated costs; and, for supplies, retail prices, indicates that there are potential cost savings for Medicare and enrollees.



From July 2022 to June 2023, Medicare payments for CGMs and supplies exceeded suppliers' acquisition costs and suppliers' estimated total costs. Medicare payments for CGMs and supplies exceeded suppliers' acquisition costs by \$377 million (or 69 percent) in a year, and their total estimated costs by \$70 million (or 8 percent) in one year.

CGM supplies—the most common CGM-related Medicare billing—represent the largest potential number of dollars saved. Medicare payments exceeded suppliers' acquisition costs by \$359 million and their total estimated costs by \$61 million. Medicare payments for CGM supplies also exceeded retail market prices by \$290 million in one year.



Suppliers received \$7 million in potential overpayments based on improper coding of CGMs and supplies. Suppliers billed Medicare for CGMs and supplies that have higher payment rates but provided CGMs and supplies that should have had lower payment rates.

What OIG Recommends

- 1. CMS should pursue reductions to Medicare's payment rates for CGMs and supplies. In July 2025—during the course of this review—CMS issued a proposed rule to use the Competitive Bidding Program and CMS's inherent reasonableness authority for CGMs and supplies. CMS stated in the proposed rule that these actions would reduce Medicare payment rates.
- 2. CMS should take action to prevent overpayments caused by suppliers' improper use of billing codes for CGMs and supplies to achieve potentially millions of dollars of cost savings for Medicare and enrollees.

CMS concurred with both recommendations.

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BACKGROUND

OBJECTIVES

- 1. To compare Medicare payments for continuous glucose monitors (CGMs) and supplies to supplier costs.
- 2. To compare Medicare payments for CGM supplies to retail pharmacy prices for the same supplies.
- 3. To assess the accuracy of supplier coding for CGMs and supplies, as well as Medicare payments associated with improper coding.

Some individuals with diabetes need to monitor their blood glucose (sugar) levels to make sure the levels are not too high or too low. Low blood glucose levels can impact an individual's ability to think and function. High blood glucose levels can damage organs over time. Monitoring blood glucose levels has historically involved pricking a finger multiple times a day, which reflected levels at that specific point in time. CGMs and supplies are a more recent technology that can help enrollees manage diabetes through wearable technology that tracks glucose levels every few minutes, rather than through fingerstick checks.

Since January 2017, CMS has covered CGMs and supplies under Medicare Part B.² Billing for these items has increased dramatically since that time, with Medicare payments increasing from \$109 million in 2018 to \$1.3 billion in 2023. Typically, the Medicare program pays 80 percent of the cost, and the enrollee is responsible for the remaining 20 percent after paying the annual deductible.

Elevated billing for CGMs and supplies requires scrutiny to ensure Medicare is not overpaying for this equipment and supplies. CMS has previously sought to control costs for durable medical equipment through various authorities, including by lowering payment amounts when it determines current rates are too high, competitively bidding items, and reducing overpayments due to improper coding. When CMS acts on opportunities for savings, it benefits the Medicare program by ensuring that enrollees have continued access to these services at reasonable costs.

Continuous Glucose Monitoring Systems

CGM monitoring systems are composed of both CGMs and supplies. The CGM (also called a reader or receiver) includes a software program that can display and save

information about glucose levels. The CGM is typically either a standalone receiver, integrated with an insulin pump worn on the body, or an application on a smartphone. Supplies are disposable and include a glucose sensor and transmitter, which may be separate or integrated.³ The sensor is inserted under the skin and measures glucose levels. The transmitter then sends the information from the sensor to the CGM. See Exhibit 1 below for a depiction of how CGMs and supplies work together.

Sensor/transmitter

Wireless monitor

Exhibit 1: CGMs and supplies can be used in a various configurations.

Source: National Institute of Diabetes and Digestive and Kidney Diseases, *Three people, each using a different type of wireless continuous glucose monitoring system*. Accessed at https://www.niddk.nih.gov/news/media-library/17824 on May 5, 2025.

Medicare Part B Coverage and Payment of CGMs and Supplies

Medicare Part B began covering therapeutic (non-adjunctive) CGMs and necessary supplies in January 2017, as a part of its coverage for Durable Medical Equipment, Prosthetic Devices, Prosthetics, Orthotics, & Supplies (DMEPOS). In February 2022, CMS expanded Medicare Part B DMEPOS coverage to include non-therapeutic (adjunctive) CGMs and necessary supplies.^{4, 5}

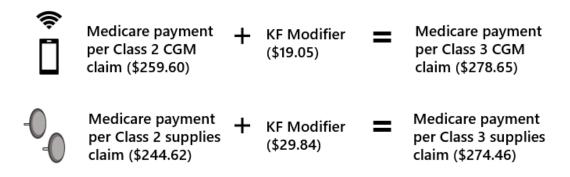
To be eligible for coverage, the enrollee must have diabetes and either use insulin or have a history of problematic low blood sugar levels and must have a prescription from a doctor or other health care provider. Medicare Part B covers CGMs that operate as a standalone receiver or are integrated into an insulin pump (i.e., it does not cover smartphone applications).⁶ Supplies (e.g., sensors) needed to operate the device are covered as a monthly supply allowance.⁷

In January 2017, CMS set fee schedule prices for CGMs and supplies based on supplier price lists and existing Medicare fee schedule prices for other items.⁸ The fee

schedule prices are the only CMS payments made to cover suppliers' total costs to provide these items (e.g., cost of equipment or supplies and other direct and indirect costs associated with furnishing CGMs and supplies), while adhering to CMS's DMEPOS Quality Standards.⁹ For every year since then, in accordance with the Social Security Act, CMS adjusts DMEPOS fee schedule prices for inflation, as measured by the Consumer Price Index for All Urban Consumers and adjusted by the change in the total productivity factor.¹⁰ CMS's payment is the lower of the fee schedule price or the reimbursement amount requested by the supplier. The CMS payment rate is the same for CGMs and supplies provided in a physical store or via mail order.

Medicare payments depend on the regulatory classification established by the Food and Drug Administration (FDA). FDA's classification is based on the level of risk to the user and the intended use of the device, which varies by make and model. 11 FDA classifies CGMs and supplies as either Class 2 (moderate to high risk) or Class 3 (high risk). CMS requires inclusion of the KF modifier on all claims for Class 3 CGMs and supplies billed to Medicare. Claims with this KF modifier result in a higher Medicare payment. 12 See Exhibit 2 for Medicare payments per item for Class 2 and 3 CGMs and supplies.

Exhibit 2: From July 2022 to June 2023, suppliers received \$19 more for Class 3 CGMs and \$30 more for Class 3 supplies when compared to Class 2 items.



Note: When submitting a claim for Medicare payment, suppliers must include the KF modifier when providing Class 3 items, which results in a higher payment by Medicare. CMS, Medicare Learning Network, MM11334 Revised. Source: OIG analysis of CMS claims data, July 2022 through June 2023.

From July 2022 through June 2023, the period of our review, the bulk of Medicare payments, 93 percent, was for monthly supplies. The other 7 percent was for CGMs, which require infrequent replacement.¹³

Medicare does not cover over-the-counter CGM supplies. In 2024, FDA began allowing the two primary CGM manufacturers to sell over-the-counter CGM supplies, which do not require a prescription.¹⁴

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CMS's Authorities to Reduce Payments

CMS has the authority to change the payment rates for DMEPOS items through two mechanisms. CMS can introduce an item into the Competitive Bidding Program (CBP), or it can adjust the payment rate through its inherent reasonableness authority.

In July 2025, CMS proposed regulatory changes to use both authorities to adjust payment methodologies and rates for CGMs and supplies. CMS proposed to include Class 2 CGMs and supplies in the CBP and proposed to adjust the fee schedule amount for Class 3 CGMs and supplies using its inherent reasonableness authority. CMS also proposed to cover both CGMs and supplies on a bundled monthly rental basis, meaning that one monthly payment would cover both the CGM device and the supplies.

Competitive Bidding Program. CMS has used the CBP to lower payment rates for DMEPOS. CMS has used the CBP to establish lower payment rates for hundreds of DMEPOS items within 15 different product categories.¹⁶

After implementing the first round of the CBP in 2011, CMS reported that the payment amounts resulting from supplier competition yielded average savings of 35 percent relative to the fee schedule prices.¹⁷ In 2021, CMS competed 15 product categories, including 13 product categories that had been in previous rounds of the CBP. However, CMS did not award new contracts in 2021 for any of the 13 previously competed product categories because those prices would not have achieved expected savings when compared to the prices based on prior CBP rounds. The remaining two product categories, off-the-shelf (OTS) back and knees braces, were new to the CBP.¹⁸ When CMS made contract offers for those two product categories, CMS expected to save an additional \$600 million for both the program and enrollees through 2023. It remains unclear when CMS will begin subsequent rounds of the CBP.¹⁹

When CMS introduces an item into the CBP, it can include it in a mail-order program. For example, CMS could establish a national mail-order program, and if there is a significant national mail-order market for the item, CMS must include rural areas in that CBP.^{20, 21}

Inherent Reasonableness Authority. CMS can implement payment rate adjustments for items of DMEPOS after following the process in regulations at 42 CFR 405.502(g) and (h). CMS may use this authority if it determines current rules for calculating payment amounts result in grossly deficient or excessive payments, which CMS defines as requiring an adjustment of at least 15 percent to produce a realistic and equitable payment.²² Generally, a payment limit set using this authority cannot vary by more than 15 percent from the payment amount established for the preceding year.²³ To implement payment adjustments greater than 15 percent, CMS must comply with additional requirements (42 CFR § 405.502 (h)). Factors that may result in a determination that Medicare is paying grossly deficient or excessive

payment amounts include, for example, grossly higher or lower payments made for the same category of items or services by other purchasers in the same locality.²⁴ CMS used this authority once, in 1995, when it reduced payment rates for blood glucose meters.²⁵

CMS's ability to adjust payment rates differs between Class 2 and Class 3 CGMs and supplies. CMS cannot competitively bid Class 3 items due to Federal statute.²⁶ To reduce payment rates for Class 3 DMEPOS items found to be grossly excessive, CMS can use its inherent reasonableness authority. CMS may use the CBP or use its inherent reasonableness authority to reduce payment rates for Class 2 items.

CMS Actions to Reduce Improper Payments

CMS requires DMEPOS suppliers that are responsible for providing CGMs and supplies to enroll in Medicare and to meet requirements, including that suppliers be responsive to audits and meet documentation requirements. CMS may revoke supplier enrollments if the supplier fails to meet requirements or demonstrates a pattern of abusive billing.

CMS also engages in efforts to support DMEPOS suppliers with guidance about correct coding and reviews portions of DMEPOS billing during regular audits. For example, a CMS contractor publishes a listing of products that may be provided under specific billing codes. Additionally, Medicare administrative contractors process claims from specific geographic areas and conduct audits for a portion of claims.

CMS also works to prevent DMEPOS fraud and protect Medicare enrollees from becoming victims of fraud. For example, in June 2025, the largest health care fraud takedown in history resulted from CMS's partnership with the Office of Inspector General (OIG) and others that, in part, alleges fraudulent billing for urinary catheters and other DMEPOS items by exploiting the stolen identities of over one million Americans.²⁷ On the basis of this takedown, the Department of Health and Human Services and CMS intend to seek to return the \$4.41 billion in escrow to the Medicare trust fund for needed medical care.

Finally, each November, the Department publishes the improper payment rate in the Agency Financial Report. CMS later publishes more detailed improper payment rate information via annual Medicare Fee-for-Service Improper Payments Report and Appendices. In its most recent report, CMS identified a high rate of improper payments for CGMs and supplies.²⁸

Related Work

Several OIG reports have identified potential savings for the Medicare program and its enrollees by adjusting DMEPOS payment rates. For example, an August 2022 report found that Medicare payments for intermittent urinary catheters were substantially higher than supplier acquisition costs and other costs. OIG's

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recommendation to lower Medicare's payment rates for urinary catheters has not yet been implemented, and the financial incentive for wasteful utilization remains. However, CMS's July 2025 proposed regulatory changes also include proposals to introduce these items into the CBP, which would likely result in lower payment rates.

Additionally, OIG has reviewed the potential effects of competitive bidding on access to DMEPOS items on the basis of concerns raised by Congress. OIG issued three reports from 2017 through 2018 that generally found that Medicare enrollees continued to have access to DMEPOS items following price reductions after competitive bidding.³⁰

Methodology

To determine if there was potential for cost savings for Medicare and enrollees for CGMs and associated supplies from July 2022 to June 2023, we compared Medicare payment rates to a few different price points. We compared Medicare payments to an estimate of suppliers' total costs. We used the total estimated costs because suppliers incur additional costs beyond acquisition costs to provide these items while adhering to CMS quality standards. Since we could only estimate these total costs, we also compared Medicare payments to two other price points: suppliers' acquisition costs and, for supplies only, retail prices.

Key Terms

Total costs – All the expenses paid by a supplier to provide the item to the enrollee, including acquisition costs and other direct and indirect costs associated with furnishing CGMs and supplies.

Acquisition cost – The supplier's cost to purchase the item from a manufacturer or an intermediary, including any applicable discounts.

Other costs – All costs that are not acquisition costs. Examples are delivery fees; overhead costs, such as salaries for customer service personnel, rent, and utilities; and capital expenses.

Retail price – The prices available to consumers who obtain the items from pharmacies serving the retail market. This is a market price not dictated by CMS for Medicare.

Data Collection

We used the National Claims History data from the CMS Integrated Data Repository to obtain a stratified, random sample of 1,000 Medicare Part B claims for CGMs and supplies.

After identifying the suppliers for these claims, we collected acquisitions costs and supporting documentation from sampled suppliers for four strata: Class 2 CGMs, Class 2 supplies, Class 3 CGMs, and Class 3 supplies. The response rates varied by strata: 53 percent for Class 2 CGMs, 80 percent for Class 2 supplies, 11 percent for Class 3 CGMs, and 50 percent for Class 3 supplies.

We also requested and obtained an estimate of Medicare suppliers' other costs from the American Association for Homecare (AAH). AAH is a national association that represents providers and manufacturers of home medical equipment and services.³¹ To obtain this estimate, AAH surveyed its members that have a significant amount of business providing CGMs and supplies to Medicare enrollees. AAH reported that, on average, acquisition costs were 64 percent of total costs, and other costs represented 36 percent of total costs (21 percent for direct costs and 15 percent for indirect costs).

Finally, for the CGM supply models that our sampled suppliers reported providing, we obtained retail market prices for the same models. We obtained these prices by reviewing publicly available prices online. We focused this analysis on supplies instead of CGMs, because the majority of Medicare payments during our time period were for supplies. We limited our review to supply models in our sample.

Data Analysis

We compared suppliers' acquisition costs and their total estimated costs (i.e., acquisition costs plus other costs) to Medicare payments to identify and quantify differences. Our calculation of Medicare payments includes enrollee payments for coinsurance and the annual deductible. Using the supplier-provided data and AAH information, we determined the suppliers' total estimated costs for our sample of Class 2 CGMs, Class 2 supplies, and Class 3 supplies.

Using publicly available data, we determined the median prices available to consumers through retail pharmacies for a month's worth of supplies. We compared these median prices to the respective Medicare payment rates to calculate the cost differences.

We also reviewed supplier documentation to determine if suppliers appropriately used the KF modifier on Medicare claims to designate Class 3 CGMs and Class 3 supplies. We reviewed suppliers' invoices to determine which model was provided to enrollees and then determined whether the FDA classification matched how the supplier coded the claims when billing Medicare.

For additional information, see the Detailed Methodology.

Limitations

Our calculation of potential cost savings is not exact because we did not collect data on other supplier costs from our sampled suppliers. In lieu of collecting this data from suppliers, we used estimates of this data (provided by AAH) to perform an illustrative analysis of potential cost savings. That estimate uses the AAH data to approximate the percentage of acquisition costs and other total costs. This approximation does not reflect verified supplier costs and did not determine if supplier's other total costs were reasonable or necessary.

The supplier response rate for Class 3 CGMs (i.e., the lowest Medicare billing category for all CGMs and supplies in this review) was insufficient to produce estimates; thus, we eliminated it from our analysis of acquisition costs and estimated total costs. For the other three strata, the report understates the potential cost differences and savings because our estimates are proportional to the response rates.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued in 2020 by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

In one year, Medicare payments for CGMs and supplies exceeded suppliers' acquisition costs by \$377 million and suppliers' estimated total costs by \$70 million

From July 2022 to June 2023, there were potential costs savings for Medicare and enrollees for CGMs and supplies based on the difference in Medicare payment rates when compared to suppliers' costs. When comparing annual costs, we found that Medicare paid an estimated \$70 million (8 percent) more than suppliers' estimated total costs (i.e., acquisition costs plus an industry estimate of other costs). On the other end of the spectrum, Medicare paid \$377 million more (69 percent)—over the course of a year—than suppliers' acquisition costs. These figures indicate that there are potential cost savings for Medicare and enrollees due to the difference between Medicare payments and suppliers' costs.

Medicare payments exceeded suppliers' acquisition costs by \$377 million in one year

We determined that Medicare payment rates exceeded suppliers' acquisition costs by \$377 million for the three billing items in one year. Supplies are a recurring need and account for the bulk (\$359 million) of this difference. See Appendix A for details.

Medicare payments varied in how much they exceeded the suppliers' acquisition costs per item billed.³² For Class 2 CGMs and Class 3 supplies, per claim, Medicare's payments exceeded acquisition costs by an average of roughly \$140. For Class 2 supplies, the difference was lower (\$92).

Over the course of a year, the impact of these price differences for supplies becomes significant when we factor in monthly billing. For 12 months of supplies, Exhibit 3 shows that average Medicare payments would exceed the suppliers' acquisition costs by approximately \$1,100 for Class 2 supplies and by nearly \$1,700 for Class 3 supplies. Individual enrollees, who are responsible for 20 percent of Medicare payments, would be responsible for roughly \$220 or \$337, respectively, of this cost difference each year.

Exhibit 3: Annual differences between Medicare payments and supplier acquisition costs for CGM supplies.

	Class 2 Supplies	Class 3 Supplies
Monthly Medicare payment per item	\$245.67 X 12	\$278.98 X 12
Annual Medicare payments per item	\$2,948.04	\$3,347.76
Monthly supplier acquisition cost	\$153.84 X 12	\$138.36 X 12
Annual supplier acquisition cost	\$1,846.08	\$1,660.32
Difference between annual payments per item and acquisition cost	\$2,948.04 - \$1,846.08 \$1,101.96	\$3,347.76 - \$1,660.32 \$1,687.44

Source: OIG analysis of CMS claims data and suppliers' reported acquisition costs from suppliers in our sample.

Medicare payments exceeded supplier estimated total costs by \$70 million in one year

Medicare payments were also more than suppliers' estimated total costs, though the amount varied by item. During our 1-year period of review, Medicare payments for these three billing items exceeded suppliers' estimated total costs by \$70.4 million. The largest difference was for Class 3 supplies, at \$46.2 million. The difference between suppliers' estimated total costs and Medicare payments for Class 2 supplies was \$14.7 million. The smallest difference was for Class 2 CGMs, with a difference of \$9.4 million. See Appendix B for details.



This comparison may underestimate the difference between Medicare payment rates and suppliers' estimated total costs, in part, because mail-order suppliers can obtain savings in total costs relative to "brick and mortar" businesses, such as pharmacies.³³ Our sample of suppliers shows that the vast majority (98 percent) of CGMs and supplies were provided to enrollees via mail order (see Appendix C). However, AAH's estimate of Medicare suppliers' other costs did not distinguish between mail-order and non-mail-order items.

Medicare payments for CGM supplies exceeded retail prices by \$290 million in one year, reinforcing that an opportunity exists for savings

We calculated that Medicare payment rates for CGM supplies exceeded retail prices by \$290 million in one year. For an enrollee receiving 12 months of CGM supplies, Medicare payments exceeded retail prices by \$1,524 (84 percent) according to the model with the greatest cost difference (Model 1-A) and by \$572 (24 percent) according to the model with the smallest cost difference (Model 2-D). See Exhibit 4. Enrollees were responsible for \$305 and \$114, respectively, of this cost difference each year. For more details, see Appendix D. Two models from the same brand (Model 1-A and Model 1-B) showed a greater potential for savings compared to the other two models from a different brand.

Exhibit 4: Medicare payment rates are high compared to retail prices for the models of CGM supplies in our review.



Source: OIG analysis of sampled suppliers' acquisition costs and the median prices from Internet pharmacies.

Suppliers received at least \$7 million in potential overpayments based on improper coding

We identified occurrences in which suppliers billed Medicare for higher-cost items than they supplied to enrollees. There were 27 claims in our sample that billed Medicare for Class 3 CGMs and for which we received documentation from responsive suppliers. All of these 27 claims were billed as Class 3 CGMs, but instead, suppliers actually provided Class 2 CGMs to Medicare enrollees. We could only make that determination on the basis of the documentation suppliers submitted to us. Due to that limitation, there may be more claims for Class 3 CGMs that have a similar issue that we were unable to identify because we did not receive documentation from those suppliers. Similarly, among the responsive suppliers that billed Medicare for Class 3 supplies, 17 percent of these items should have been billed as Class 2 supplies.

As a result, Medicare and enrollees paid an additional amount for these CGMs and supplies. We calculated a potential Medicare overpayment of \$2.3 million, based on the fact that all Class 3 CGMs in our review were actually Class 2 CGMs, which have lower Medicare payment amounts.³⁴ Medicare made additional overpayments of \$5

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million for supplies that were incorrectly billed as Class 3 supplies. Taken together, potential overpayments associated with items improperly coded as Class 3 items during our review period are nearly \$7.4 million.³⁵ Enrollees would be responsible for nearly \$1.5 million of these payments due to their cost-sharing obligations.

CONCLUSION AND RECOMMENDATIONS

During our review period, Medicare helped over 750,000 enrollees monitor their diabetes by paying DMEPOS companies for these enrollees to use CGMs and supplies. However, differences between Medicare payments and suppliers' costs indicate there are potential cost savings for Medicare and enrollees.

We found that Medicare's payment per item exceeded suppliers' acquisition costs and estimated total costs for CGMs and supplies, as well as retail market prices for supplies. We also identified potential Medicare overpayments due to suppliers improperly coding claims. Addressing these overpayments through improved oversight could result in additional Medicare savings.

In July 2025, CMS issued a proposed rule lowering payment rates using its existing authorities (i.e., competitive bidding and the inherent reasonableness authority) and covering both CGMs and supplies as a single, monthly rental payment. As stated in the proposed rule, CMS expects these changes to reduce Medicare payments for both Class 2 CGMs and supplies through the Competitive Bidding Program (CBP) and Class 3 CGMs and supplies through the inherent reasonableness authority. Additionally, CMS proposed equalizing payments between Class 2 and Class 3 items.

We recommend that CMS:

Pursue reductions to Medicare's payment rates for CGMs and supplies

CMS should pursue reductions to Medicare's payment rates for CGMs and supplies. Based on the difference between Medicare payments and CGM suppliers' acquisition costs, estimated total costs, and comparable retail prices, there is a potential for substantial savings. CMS's proposed rule uses the CBP and CMS's inherent reasonableness authority for CGMs and supplies. CMS expects these actions to reduce Medicare payment rates.

Take action to prevent overpayments caused by suppliers' improper use of billing codes for CGMs and supplies to achieve potentially millions of dollars of cost savings for Medicare and enrollees

> CMS should increase efforts to prevent overpayments for CGMs and supplies that are improperly coded as Class 3 items.

> For example, CMS could consider whether its program integrity contractors should expand their reviews to ensure that the Class 3 modifier is being used appropriately. CMS's contractors conduct both pre-payment and post-payment reviews of claims, and these contractors could focus a portion of their reviews on this issue. If payment rates change for Class 3 devices, CMS may be able to reduce the scope of these reviews in the future.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with both of our recommendations.

In response to our first recommendation—that CMS pursue reductions to Medicare's payment rates for CGMs and supplies—CMS referred to its recent proposed regulatory changes to how it pays for CGMs and supplies. CMS proposed to pay for CGMs and supplies on a monthly rental basis. CMS also proposed to set payment rates for Class 2 CGMs and supplies using the CBP and to set payment limits for Class 3 CGMs and supplies using its inherent reasonableness authority, if certain conditions are met. The proposed rule is undergoing the public notice and comment process. CMS noted that any policies established as a result of rulemaking or the inherent reasonableness process would ultimately determine any potential savings for the Medicare program and enrollees.

In response to our second recommendation—that CMS take action to prevent overpayments caused by suppliers' improper use of billing codes for CGMs and supplies to achieve potentially millions of dollars of cost savings for Medicare and enrollees—CMS stated that it will take our findings and recommendation into consideration as it determines appropriate next steps.

Fur the full text of CMS's comments, see the Agency Comments appendix at the end of the report.

DETAILED METHODOLOGY

Medicare Payments and Payment Rates

We used the Integrated Data Repository to identify the Medicare Part B claims for CGMs and supplies. Our population of claims data is for services provided from July 1, 2022, through June 30, 2023, with allowed amounts greater than \$0.

We used allowed amounts in our population data to calculate total Medicare payments and Medicare payments per item. Unless it is otherwise specified, we use the term "Medicare payments" to include both Medicare's portion and enrollees' contributions, such as enrollees' coinsurance. To describe the enrollee responsibility, we calculated these values as 20 percent of Medicare payments. We use the term "payment per item" to reflect the allowed amount per item or claim. Exhibit 5 shows average Medicare payments per item and total Medicare payments for CGMs and supplies in our population data.

Exhibit 5: Medicare payments for CGMs and supplies exceeded \$1.3 billion from July 2022 through June 2023.

Item	Average Medicare Payment per Item	Number of Claims	Percentage of Total CGM and Supply Claims	Total Medicare Payments (Millions)	Percentage of Total CGM and Supply Payments
Class 2 CGMs	\$259.60	251,125	5%	\$65.2	5%
Class 3 CGMs	\$278.65	84,178	2%	\$23.5	2%
Class 2 Supplies	\$244.62	3,472,078	66%	\$849.3	63%
Class 3 Supplies	\$274.46	1,460,788	28%	\$400.9	30%
Total	N/A	5,268,169	100%	\$1,339	100%

Source: OIG analysis of CMS claims data from the Integrated Data Repository. Note: Due to rounding, the values in a column may not sum to the total value.

Supplier Acquisition Costs

From this population, we selected a stratified random sample of 1,000 claims with four total strata: Class 2 CGMs, Class 2 supplies, Class 3 CGMs, and Class 3 supplies. Medicare requires suppliers to include a KF modifier for Class 3 CGMs and supplies, and we used this modifier to stratify the sample. Each stratum had 250 claims. We requested that suppliers report (1) the acquisition cost for the item they provided and (2) whether the item was provided by mail order. We also asked suppliers to provide supporting documentation that verified the reported acquisition cost, the model provided, and the delivery method.

We defined sampled suppliers as unresponsive if they either did not complete the documentation request or were involved in ongoing work by OIG's Office of Investigation. We did not distribute a survey to those suppliers that were involved in ongoing work by OIG. Of the sampled claims, 34 percent came from suppliers that did not complete the documentation request, and 17 percent were from suppliers involved in ongoing OIG work. Further, of the total claims among unresponsive suppliers, 27 percent were for suppliers that CMS has subsequently revoked or deactivated since we pulled our sample.³⁶

Our response rate varied by stratum. Class 2 CGMs had a response rate of 53 percent (133 out of 250 claims); Class 3 CGMs had an 11-percent response rate (27 out of 250 claims); Class 2 supplies had an 80-percent response rate (200 out of 250 claims); and Class 3 supplies had a 50-percent response rate (126 out of 250 claims).

Due to Class 3 CGMs having such a low (11-percent) response rate, we do not include Class 3 CGMs in our analysis of acquisition costs. This low response rate is attributed to multiple factors. Of the 250 CGM claims in this stratum, we did not obtain a response for 26 percent because the suppliers were involved in ongoing work by OIG's Office of Investigations. An additional 61 percent of non-response claims were from suppliers that had their Medicare enrollments revoked or deactivated.

On the basis of supplier data, we estimated the total supplier acquisition costs for the items (CGMs and supplies) provided in our sample, including discounts received from manufacturers or intermediaries. We calculated the cost differences between our sampled supplier acquisition costs and Medicare payments per item. We then projected this difference to the population. We projected our estimates only to the portion of the population of CGM and supply claims that correspond to the sample claims for which we received responses from suppliers.

Suppliers' Other Costs

To calculate suppliers' estimated total costs (i.e., acquisition costs + other costs), we used the acquisition costs from our sample of Medicare suppliers and added AAH's estimate of other costs when providing these items to Medicare enrollees. For every \$1 in acquisition costs, the AAH estimate added approximately \$0.56 in other costs to obtain the estimated total costs.

To obtain this estimate, AAH surveyed its members that have a significant amount of business providing CGMs and supplies to Medicare enrollees. AAH asked members to provide information on their costs of goods sold (acquisition costs), as well as direct and indirect costs (other costs). The survey revealed that, on average, acquisition costs are 64 percent of total costs, and other costs sum to 36 percent of total costs (21 percent for direct costs and 15 percent for indirect costs). AAH also listed the direct (e.g., labor, marketing) and indirect (e.g., benefits, rent, utilities, claims processing, documentation collection and retention) costs. However, AAH did not

distinguish which of these costs apply to brick-and-mortar businesses versus mailorder businesses or how estimated costs would differ between the two types of businesses. AAH did indicate, though, that providing DMEPOS items to Medicare enrollees requires suppliers to incur additional other costs that are not otherwise incurred in providing these items to the retail market.

To perform our illustrative analysis of other costs, we applied the AAH estimate of other costs equally to each of the three billing items. We multiplied our estimates of acquisition costs by 0.5625 (i.e., 36/64). We described the ratio as \$1.00 in acquisition costs and \$0.56 in other costs, which approximates the percentage values provided by AAH. We used the monetary example for clarity and readability.

Retail Market Prices

To assess the potential cost differences between Medicare payments and prices available to consumers, we used the median price from a list of prices available on Internet pharmacies. We gathered all available pricing data from two prominent websites in June 2023. We searched each website for each model of CGM supplies in our review. Our sample included four models of supplies from two brands (each brand had two models). The results list pharmacy chains providing each model and the price per model for each pharmacy chain. The number of pharmacy chains offering each model ranged from 8 to 13. We compiled all of the prices for each model, inclusive of discounts and manufacturer coupons, across the two websites and calculated a median price for each model.

After determining the pricing available through retail pharmacy chains, we calculated the potential cost differences for these items by comparing the median prices available to consumers through these retail pharmacy chains to Medicare payments per item. We projected the cost differences to the population on the basis of the proportion of models in our sample and the response rates.

In some cases, we had to adjust the retail market prices to ensure an equitable basis for comparison. For one model, we included the price of the transmitter as part of the cost for supplies. Therefore, we prorated the price of the 90-day transmitter (by dividing the cost by 3) and added the prorated amount to the total monthly supplies. For another model, the sensors last 14 days. Therefore, for most months, the enrollee would only need two sensors, but for other months, an enrollee may require three sensors. Therefore, we calculated a pro-rated 30-day price for a 14-day sensor.

Supplier Use of KF Modifier

Finally, we determined whether sampled suppliers improperly coded claims by using the KF modifier. First, we reviewed the sampled claim lines to determine whether the KF modifier was included on the claim. Then, we reviewed supplier-provided documentation to determine the type of CGM or supply provided for the claim in our sample. We then determined whether the model indicated in supplier documentation

was classified by FDA as Class 2 or Class 3. We did this by obtaining the publicly available FDA approval documents (i.e., the 510(k) substantial equivalence determination for Class 2 items and the premarket approval for Class 3 items). We then assessed whether the KF modifier was only included on claim lines for items classified by FDA as Class 3.

APPENDICES

Appendix A: Data on Supplier Acquisition Costs

Exhibit A-1: Medicare's payments exceeded supplier acquisition costs by \$377 million.



Source: OIG analysis of Medicare claims and documentation from suppliers in our sample of claims.

Exhibit A-2: Overall, Medicare's payments were 69 percent more than the suppliers' acquisition costs for Class 2 CGMs and Class 2 and 3 supplies.

Item	Medicare	Acquisition Cost (in Millions)	Cost Difference (in Millions)	95-Percent	95-Percent	Percentage by Which Medicare Payments Exceeded the Acquisition Cost**
Class 2 CGMs	\$35.0	\$16.4	\$18.6	\$16.0	\$21.3	114%
Class 2 Supplies	\$682.4	\$427.3	\$255.1	\$232.0	\$278.1	60%
Class 3 Supplies	\$205.4	\$101.9	\$103.5	\$90.2	\$116.9	102%
Total	\$922.8	\$545.5	\$377.2	\$350.5	\$404.0	69%

Source: OIG analysis of Medicare claims and documentation from suppliers in our sample of claims.

Note: We did not include Class 3 CGM claims in our analysis due to a low response rate among suppliers in our sample. Due to rounding, the values in a column or row may not sum to the total value.

Medicare Payments for Continuous Glucose Monitors and Supplies Exceeded Supplier Costs and Retail Market Prices,
Indicating Medicare Can Save At Least Tens of Millions of Dollars in One Year
OEI-04-23-00430
Appendix A | 20

^{*}The total Medicare payment amount for these items was \$1.3 billion. We prorated the Medicare payment amount on the basis of the sample weights of the total payments represented by each respondent. That is, our respondents represent approximately 70% of the total payment amounts for these items (i.e., \$923 million of the \$1.3 billion). This allows for a conservative estimate of the cost difference that we are calculating.

^{**}This is calculated by dividing the cost difference by the acquisition cost and multiplying by 100.

Exhibit A-3: Medicare payments per claim exceeded suppliers' acquisition costs for CGMs and supplies.

Item	Medicare Payment per Claim	Average Supplier Acquisition Cost per Claim	Cost Difference (Per Claim)	Percentage by Which Medicare Payments per Claim Exceeded the Acquisition Cost*
Class 2 CGMs	\$263.77	\$123.33	\$140.45	114%
Class 2 Supplies	\$245.67	\$153.84	\$91.83	60%
Class 3 Supplies	\$278.98	\$138.36	\$140.62	102%

Source: OIG analysis of Medicare claims and OIG estimates of acquisition costs using documentation from suppliers in our sample of claims provided from July 2022 through June 2023.

Note: We did not include Class 3 CGM claims in our analysis due to a low response rate among suppliers in our sample.

Exhibit A-4: Confidence intervals for the cost difference between Medicare payment per item and suppliers' acquisition costs for CGMs and supplies.

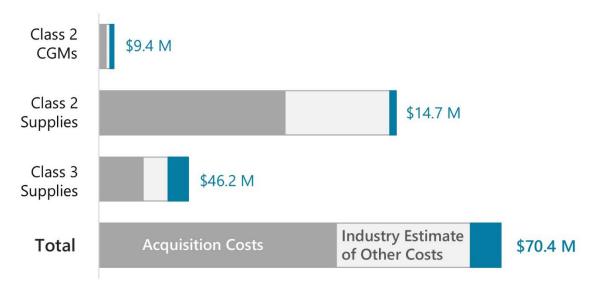
Item	Mean Cost Difference (Per Claim)	Lower 95-Percent Confidence Interval	Upper 95-Percent Confidence Interval
Class 2 CGMs	\$140.45	\$129.07	\$151.82
Class 2 Supplies	\$91.83	\$85.82	\$97.84
Class 3 Supplies	\$140.62	\$135.38	\$145.87

Source: OIG analysis of Medicare claims and documentation from suppliers in our sample of claims.

^{*}This is calculated by dividing the cost difference by the acquisition cost and multiplying by 100.

Appendix B: Data on Suppliers' Total Estimated Costs

Exhibit B-1: We found that Medicare payments exceeded the estimate of total costs by \$70 million in one year.



Source: OIG analysis of CMS claims data, suppliers' reported acquisition costs from suppliers in our sample, and other costs provided by AAH in October 2024.

Note: Due to rounding, the values may not sum to the total value.

Exhibit B-2: The estimate of suppliers' total costs shows an opportunity for savings among our sampled suppliers that provided Class 2 CGMs, as well as Class 2 and Class 3 supplies.

Item	Medicare Payment per Claim	Acquisition Cost per Claim	Industry Estimate of Other Costs	Estimate of Total Costs	Percentage by Which Medicare Payment Exceeded the Estimate of Total Costs*
Class 2 CGMs	\$263.77	\$123.33	\$69.37	\$192.70	37%
Class 2 Supplies	\$245.67	\$153.84	\$86.54	\$240.38	2%
Class 3 Supplies	\$278.98	\$138.36	\$77.83	\$216.18	29%

Source: OIG analysis of CMS claims data, suppliers' reported acquisition costs from suppliers in our sample, and other costs provided by AAH in October 2024. The calculation used a ratio of \$0.5625 in other costs per \$1 in acquisition costs.

^{*}This is calculated by subtracting the total costs from the Medicare payment per claim, dividing that number by the total costs, and multiplying by 100. Due to rounding, the values in a row may not sum to the total value.

Appendix C: Sampled CGMs and Supplies Provided via Mail Order

Exhibit C-1: The proportion of claims provided by mail order.

Item	Projected Proportion Mail Order in Population	Lower 95-Percent Confidence Interval	Upper 95-Percent Confidence Interval
Class 2 CGMs	100%	97.3%	100%
Class 2 Supplies	99.0%	96.4%	99.9%
Class 3 Supplies	95.2%	89.9%	98.2%
Weighted Mean for the Population*	98.3%	96.4%	99.2%

Source: OIG analysis of Medicare claims and documentation from suppliers in our sample of claims.

^{*}We estimated the population weighted mean for these three strata by weighting the average by the proportion of claims in the population.

Appendix D: Retail Market Pricing Data

Exhibit D-1: Medicare payments for CGM supplies from July 2022 through June 2023 exceeded the retail market prices for the same models.

Model	Average Medicare Payment per Item	Median Retail Market Price per Item	Cost Difference Between Medicare Payment and Retail Prices per Item	Percentage by Which Medicare Payments Exceeded Retail Prices per Item
Model 1-A (Class 3 Supplies)	\$278.98	\$151.98	\$127.00	84%
Model 1-B (Class 2 Supplies)	\$246.39	\$151.98	\$94.41	62%
Model 2-C (Class 2 Supplies)	\$255.01	\$177.73	\$77.28	43%
Model 2-D (Class 2 Supplies)	\$244.70	\$197.00	\$47.70	24%

Source: OIG analysis of Medicare payment rates and the median prices available from pharmacy chains.

Exhibit D-2: Medicare payments for CGM supplies from July 2022 through June 2023 exceeded the retail market prices by \$290 million.

Model*	Projected Difference	Lower 95-Percent Confidence Interval	Upper 95-Percent Confidence Interval
Model 1-A (Class 3 Supplies)	\$93.5 million	\$81.7 million	\$105.3 million
Model 1-B (Class 2 Supplies)	\$125.9 million	\$105.8 million	\$145.9 million
Model 2-D (Class 2 Supplies)	\$66.9 million	\$56.4 million	\$77.4 million
Total	\$289.5 million	\$269.9 million	\$309.1 million

Source: OIG analysis of Medicare payment rates and the median prices available from pharmacy chains.

^{*}The total includes Model 2-C. However, we did not produce an estimate for Model 2-C individually due to a small sample size.

Exhibit D-3: Medicare payments for CGM supplies from July 2022 through June 2023 would exceed the retail market prices by hundreds of dollars per year.

Model*	Average Annual Medicare Payment per Item	Median Annual Retail Price per Item	Annual Cost Difference Between Medicare Payment and Retail Price per Item
Model 1-A (Class 3 Supplies)	\$3,348	\$1,824	\$1,524
Model 1-B (Class 2 Supplies)	\$2,957	\$1,824	\$1,133
Model 2-D (Class 2 Supplies)	\$2,936	\$2,364	\$572

Source: OIG analysis of Medicare payment rates and the median prices available from pharmacy chains.

^{*}We did not produce an estimate for Model 2-C due to a small sample size.

Appendix E: Agency Comments Following this page are the official comments from CMS.

Administrator
Washington, DC 20201

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DATE: November 12, 2025

TO: Ann Maxwell

Deputy Inspector General for Evaluation and Inspections

Office of Inspector General

FROM: Dr. Mehmet Oz

Administrator

Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Payments for

Continuous Glucose Monitors and Supplies Exceeded Supplier Costs and Retail Market Prices Indicating Medicare Can Save At Least Tens of Millions of Dollars

in One Year (OEI-04-23-00430)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

The Durable Medical Equipment, Prosthetic Devices, Prosthetics, Orthotics, & Supplies (DMEPOS) Competitive Bidding Program has been an essential tool to help Medicare set market-based payment rates for DMEPOS items, save money for beneficiaries and taxpayers, and limit fraud and abuse in the Medicare Program. The DMEPOS Competitive Bidding Program has saved billions of dollars since its implementation while safeguarding access to quality items and services. Under the DMEPOS Competitive Bidding Program, DMEPOS suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items in competitive bidding areas. The statute requires that single payment amounts replace the current Medicare DMEPOS fee schedule payment amounts for competitively bid DMEPOS items and services furnished in competitive bidding areas of the country. The single payment amounts are determined by using bids submitted by DMEPOS suppliers.

Continuous glucose monitors (CGMs) and supplies have not previously been included in the DMEPOS Competitive Bidding Program. However, as discussed in the Calendar Year (CY) 2026 Home Health Prospective Payment System (HH PPS) proposed rule (90 FR 29108), CMS intends to phase class II CGMs into future rounds of the DMEPOS Competitive Bidding Program. Class III CGMs are statutorily excluded from the DMEPOS Competitive Bidding Program per section 1847(a)(2)(A) of the Act. Therefore, in the CY 2026 HH PPS proposed rule, CMS also proposed that once class II CGMs are phased into the DMEPOS Competitive Bidding Program, payment limits would be implemented in accordance with 42 C.F.R. § 405.502 if the payment amounts for class III CGMs and insulin infusion pumps used in conjunction with class

_

OEI-04-23-00430

¹ Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies (CMS-1828-P). Available at: https://www.federalregister.gov/documents/2025/07/02/2025-12347/medicare-and-medicaid-programs-calendar-year-2026-home-health-prospective-payment-system-hh-pps-rate

III CGMs are more than 15 percent higher than the payment amounts established under the DMEPOS Competitive Bidding Program for class II CGMs and insulin infusion pumps not used in conjunction with class III CGMs. CMS proposed to pay for class II CGMs and insulin infusion pumps not used in conjunction with class III CGMs on a monthly rental basis under the DMEPOS Competitive Bidding Program. CMS also proposed to reclassify all CGMs subject to the fee schedule payment rules under section 1843(a) of the Act under the frequent and substantial servicing payment category at section 1834(a)(3) of the Act, as implemented under 42 C.F.R.§ 414.222(a), because CGMs are subject to rapid technological change, requiring frequent and substantial servicing. If finalized, CMS would pay for all CGMs on a monthly rental basis under both the DMEPOS Competitive Bidding Program, and in non-competitive bidding areas under the fee schedule payments. The monthly rental payments would include payment for any necessary supplies and accessories.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that CMS pursue reductions to Medicare's payment rates for CGMs and supplies.

CMS Response

CMS concurs with this recommendation. As stated above, CMS has recently proposed several changes regarding the payment for continuous glucose monitors (CGMs) and supplies. CMS has also proposed improvements to the DMEPOS Competitive Bidding Program. CMS is currently engaged in the required notice and comment process for these proposals. CMS will take OIG's findings and recommendation into consideration when determining appropriate next steps.

CMS notes that any policies established as a result of rulemaking or the inherent reasonableness process would ultimately determine any potential savings for the Medicare program and beneficiaries.

OIG Recommendation

The OIG recommends that CMS address improper use of billing codes for CGMs and supplies, which resulted in \$7 million of overpayments during the year of our review.

CMS Response

CMS concurs with this recommendation. CMS will take OIG's findings and recommendation into consideration as we determine appropriate next steps.

ENDNOTES

- ¹ Northwestern Medicine, *How Do Continuous Glucose Monitoring Systems (CGMs) Work*?, May 2024. Accessed at https://www.nm.org/healthbeat/healthy-tips/How-Do-Continuous-Glucose-Monitoring-Systems-CGMS-Work on Feb. 4, 2025.
- ² CMS Ruling CMS-1682-R, Classification of Therapeutic Continuous Glucose Monitors as "Durable Medical Equipment" under Medicare Part B (January 12, 2017). In CMS-1682-R, CMS categorized CGMs as therapeutic (non-adjunctive) or non-therapeutic (adjunctive) and classified therapeutic (non-adjunctive) CGMs as durable medical equipment. According to CMS, when the 2021 DMEPOS final rule was drafted "there were no 'adjunctive' or 'non-therapeutic' CGM receivers being manufactured and sold on the market." 86 Fed. Reg. 73860, 73898 (Dec. 28, 2021).
- ³ Sensors must be replaced at specific frequencies, typically every 7 to 15 days, depending on the type of sensor. American Association of Clinical Endocrinology, *CGM Device Comparison*. Accessed at https://pro.aace.com/cgm/toolkit/cgm-device-comparison on Sept. 17, 2025. For some CGMs, the sensor and transmitter are one combined piece. However, other CGMs have a standalone transmitter that must be replaced (e.g., Dexcom's G6's transmitter needs to be replaced every 3 months). Dexcom, *Using Your Sensor and Transmitter*. Accessed at https://www.dexcom.com/faqs/how-long-does-dexcom-g6-transmitter-last on Feb. 4, 2025.
- ⁴ 86 Fed. Reg. 73860, 73891-99 (Dec. 28, 2021), effective February 28, 2022, and CMS Ruling CMS-1738-R, *Medicare Part B and Part C Reimbursement Claims for Continuous Glucose Monitors (CGMs)* (May 13, 2022). CMS-1738-R rescinded CMS-1682-R and classified as durable medical equipment therapeutic (non-adjunctive) CGMs, non-therapeutic (adjunctive) CGMs, and insulin pumps that function as a CGM monitor or receiver.
- ⁵ This review focuses on therapeutic CGMs because adjunctive items are a very small portion of billing (i.e., approximately 1 percent of total Medicare payments in 2022).
- ⁶ Medicare does not cover supplies for CGMs that solely display results on a smartphone because smartphones do not meet the definition of durable medical equipment. CMS, *Glucose Monitor Policy Article (A52464)*. Accessed at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52464 on Jan. 31, 2025. However, if an enrollee is using a durable CGM receiver that meets the definition of DME as a backup, but primarily uses a smartphone to display glucose readings, Medicare will cover disposable CGM supplies. Medicare does not cover or provide payment for the smartphone. 86 Fed. Reg. at 73899.
- ⁷ The supply allowance encompasses all items necessary for the use of the device for 30 days and is typically a recurring expense. CMS, *Glucose Monitor Policy Article (A52464)*.
- ⁸ CMS, <u>DMEPOS Fee Schedule Files</u>. Accessed on Mar. 25, 2025.
- ⁹ CMS, DMEPOS Quality Standards. Accessed on July 17, 2025.
- ¹⁰ SSA § 1834(a)(14).
- ¹¹ FDA approves medical devices and sorts the devices into three regulatory classifications based on risk (e.g., including the extent of information available regarding safety and effectiveness) and the intended use of the device. Class 1 includes devices with the lowest risk and Class 3 includes devices with the greatest risk. FDA, *Classify Your Medical Device*. Accessed at https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device on Jan. 31, 2025.
- ¹² Policy Article A52464: *Glucose Monitor Policy Article*. See also MLN Matters Number MM11334 Revised (stating that, since July 2019, CMS has required suppliers to use the KF modifier when billing for Class 3 CGMs and their supplies).
- ¹³ CGMs are eligible for replacement by Medicare no more frequently than every 5 years under normal circumstances, or more often if the item is lost, stolen, or irreparably damaged, or there is a change in medical condition. CMS, *Standard Documentation Requirements for All Claims Submitted to DME MACs* (A55426), effective January 1, 2017.

- ¹⁴ As of January 2025, the monthly pricing for these items ranges from \$83 to \$99 for consumers to purchase. Forbes, <u>5 Key Insights On Dexcom's Stelo And Abbott's Lingo Glucose Monitors</u>, January 25, 2025. Accessed on June 26, 2025.
- ¹⁵ CMS, Proposed Rule (CMS-1828-P), <u>Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update:</u>
 Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; <u>Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation</u>
 Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies, 90 Fed. Reg. 29108 (July 2, 2025).
- ¹⁶ For information about the most recent round of competitive bidding, see CMS, <u>Round 2021 DMEPOS Competitive Bidding Program Single Payment Amounts and Contract Offers (PDF)</u>, October 27, 2020. Accessed on Jan. 13, 2025. CMS lists 323 separate HCPCS codes in the Former Competitive Bidding Area Fee Schedule file. CMS, <u>January 2025 DMEPOS Fee Schedule</u>. Accessed at https://www.cms.gov/medicare/payment/fee-schedules/dmepos/dmepos-fee-schedule/dme25 on Mar. 17, 2025.
- ¹⁷ CMS, Medicare's DMEPOS Competitive Bidding Program: Frequently Asked Questions, April 2013.
- ¹⁸ CMS, <u>Round 2021 DMEPOS Competitive Bidding Program Single Payment Amounts and Contract Offers (PDF)</u>, October 27, 2020. Accessed on Jan. 13, 2025.
- ¹⁹ See the webpage for CMS's Competitive Bidding Implementation Contractor, at https://www.dmecompetitivebid.com/.
- ²⁰ CMS can exempt rural areas from the competitive bidding program unless there is a significant national mail-order market for particular items or services. SSA 1847(a)(3)(A).
- ²¹ Diabetic testing strips are the only DMEPOS items to have a national mail-order program.
- ²² Social Security Act § 1842(b)(8)(A)(i)(I) and 42 CFR § 405.502(g)(1)(ii).
- ²³ 42 CFR § 405.502(g)(1)(vi).
- ²⁴ 42 CFR § 405.502(g)(1)(vii)(G). Also, an example of factors that CMS can consider in establishing a payment limit is the differences in charges for items for non-Medicare patients or to institutions and other large volume purchasers per 42 CFR § 405.502(g)(2)(ii).
- ²⁵ 60 Fed. Reg. 3405 (Jan. 17, 1995).
- ²⁶ 42 USC 1395w-3(a)(2)(A) (excluding from the competitive bidding program Class 3 devices under FDA).
- ²⁷ HHS OIG and other Federal and State law enforcement partners supported the investigation. See U.S. Department of Justice, <u>National Health Care Fraud Takedown Results in 324 Defendants Charged in Connection with Over \$14.6 Billion in Alleged Fraud</u>, June 30, 2025.
- ²⁸ CMS, <u>Medicare Fee-for-Service 2024 Improper Payments Report</u>. Accessed on Apr. 30, 2025.
- ²⁹ OIG, 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 31, 2022; Medicare Allowable Amounts for Certain Orthotic Devices Are Not Comparable With Payments Made by Select Non-Medicare Payers (A-05-17-00033) October 30, 2019; Medicare Supplier Acquisition Costs for L0631 Back Orthoses (OEI-03-11-00600) December 18, 2012; Power Wheelchairs in the Medicare Program: Supplier Acquisition Costs and Services (OEI-04-07-00400) August 31, 2009; Comparison of Prices for Negative Pressure Wound Therapy Pumps (OEI-02-07-00660) March 24, 2009.
- ³⁰ Additionally, OIG identified some reductions in the use of competitively bid items, which may have been due to reductions in unnecessary utilization. OIG, Round 2 Competitive Bidding for CPAP/RAD: Disrupted Access Unlikely for Devices, Inconclusive for Supplies (OEI-01-15-00040) June 6, 2017; Round 2 Competitive Bidding for Oxygen: Continued Access for Vast Majority of Beneficiaries (OEI-01-15-00041) May 21, 2018; Round 2 Competitive Bidding for Enteral Nutrition: Continued Access for Vast Majority of Beneficiaries (OEI-01-15-00042) May 21, 2018.
- ³¹ American Association for Homecare, About Us. Accessed at https://aahomecare.org/about-us on July 1, 2025.
- ³² We applied the AAH estimate of other costs equally to each of the three billing items.

³³ U.S. Chamber of Commerce, *The Pros and Cons of Brick-and-Mortar Locations*, September 23, 2025. Accessed at https://www.uschamber.com/co/start/startup/opening-brick-and-mortar-location-for-your-business on Nov. 18, 2025.

³⁴ For Class 3 CGMs, we calculated the potential Medicare overpayment of \$2.3 million under the assumption that all of the Class 3 CGMs in our 1-year review period should have been billed as Class 2 CGMs. We did not calculate a statistical estimate that adjusted for the low response rate.

³⁵ The amount of potential overpayments is \$7.354 million, composed of \$2.329 million in potential overpayments for CGMs and \$5.025 million for supplies. The enrollee portion of the sum would total \$1.47 million.

³⁶ Medicare may revoke supplier billing privileges due to abusive billing or non-compliance with various supplier standards. Following the COVID-19 public health emergency, CMS began enforcing its supplier enrollment standards more vigorously, which may explain many of these recent revocations. In December 2022, GAO recommended that CMS prioritize the revalidation of higher-risk providers such as new DMEPOS suppliers. GAO also reported that 83 percent of Medicare enrollment revocations were among DMEPOS suppliers between March 2020 and March 2022. https://www.gao.gov/products/gao-23-105494.

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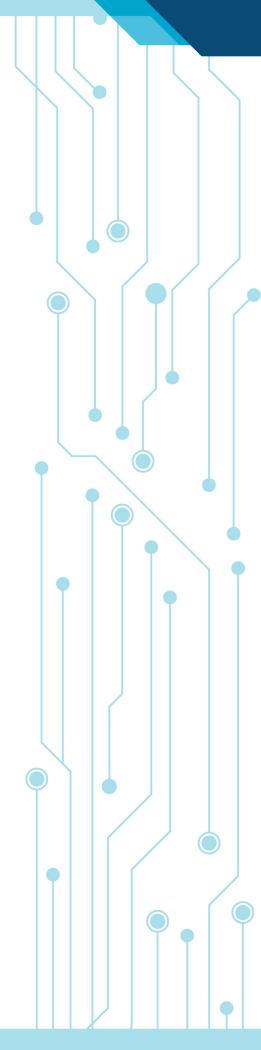
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