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## **CMS finalizes competitive bidding rule for diabetes devices in the DME channel, bundling CGMs, insulin pumps, and supplies into a monthly rental payment – December 2, 2025**

*Rule takes effect on January 1, 2026; contract awards expected in 2027 amid concerns about patient access and supplier readiness*

The Centers for Medicare and Medicaid Services (CMS) released today its [finalized](#) competitive bidding rules for diabetes devices last Friday morning. We believe CMS published the rules at a time (the day after a major US holiday) when they wanted to be “under the radar” and they did indeed succeed on this front. Few had been expecting this and we have always been unsure why, since the competitive bidding for CGM two decades ago, which had been on the cusp of the start of the CGM market launching, was also unexpected. We agree with many leaders that more people with diabetes may move to pump therapy as a result of this movement (see below).

Under Medicare, these rules bundle certain class II CGMs, insulin pumps, and diabetes supplies into a monthly rental payment for those using “durable device” continuous insulin delivery (traditional insulin pumps). Under this framework, suppliers submit bids to provide medical equipment and supplies, and Medicare awards contracts to selected bidders. The rule changes take effect very quickly - next month, to be specific, on January 1, with registration and bidding opening in late spring or summer 2026. Look for contract awards in 2027, if this goes according to plan.

By adding diabetes technologies to this competitive bidding structure, CMS aims to reduce costs and limit fraud. However, some concerns remain regarding the decision to classify CGMs and pumps as “substantially serviced” equipment, which may create logistical and operational challenges for suppliers, including unclear return processes and potential delays for patients during transition periods.

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### **Policy backdrop for competitive bidding policy finalization; rental model aims to better reflect rapid technology innovations and the rebalancing of overpayment**

CMS’ final [rule](#) arrives amid political pressure from the Congressional Diabetes Caucuses and a recent Office of Inspector General (OIG) report that [found](#) Medicare is overpaying for CGMs and supplies in retail markets. Medicare Part B payments for CGMs and diabetes supplies alone [rose](#) from \$109 million in 2018 to \$1.3 billion in 2023, amid many patients switching to this technology from “standalone” MDI and BGM. Medicare Part B issued more than \$1.1 billion in payments for CGMs and sensors [in 2022](#), representing about one-quarter (27%) of annual CGM revenue in the US, or \$4.1 billion. The program’s financial exposure has also increased in the last couple of years – for example, CMS [expanded](#) its CGM coverage to include [basal users](#) in 2022 and non-insulin users beginning in April 2023. Against

this landscape of expanding eligibility and rising spending, CMS indicated that it believes a rental model may be a more economically sustainable path forward.

In its [press release](#), CMS also said that CGM and pump technologies are evolving too quickly for beneficiaries to wait five years to replace and that a rental structure may better reflect the pace and complexity of modern diabetes technology, supporting more rapid transitions to newer technologies. We will say, it's hard to argue with this.

### **Timeline for the next round of competitive bidding**

As we understand it, the next competitive bidding round for CGMs and insulin pumps will follow a multi-year sequence:

- **December 2025:** CMS begins its pre-bidding supplier awareness program.
- **Late Spring/Early Summer 2026:** CMS will announce:
  - The specific registration and bidding dates;
  - The lead items and number of contracts to award for each product category; and
  - Details on its bidder education program.
- **Late Summer/Early Fall 2026:** The bidder registration period opens for suppliers to obtain user IDs and passwords, followed by the bid window opening.
- **Late Summer/Early Fall 2027:** Contracts are awarded and Single Payment Amounts (SPAs) are published, followed by CMS' beneficiary education period.
- **No later than January 1, 2028:** Contracts and SPAs take effect, with a six-month transition period for beneficiaries to switch to contract suppliers.

This timeline more explicitly reflects the logistical steps and education periods CMS will implement before the new CGM and insulin pump rental structure becomes effective.

### **Contract suppliers to retain device ownership; current beneficiaries will continue to own devices until replacements are needed**

As Medicare payments for CGMs, insulin pumps, and other accessories shift to a continuous monthly rental, contract suppliers will now retain ownership of devices and may bill beneficiaries up to three months in advance. Beneficiaries who already own their devices may continue to use them until they need a replacement or elect to switch to a new device. Regardless, contract suppliers must still furnish replacement supplies.

### **Anticipated monthly pricing limits: ~\$273 per month for CGMs**

CMS outlined new rules detailing how monthly rental payment limits and Single Payment Amounts (SPAs) will be established, specifying that CGM suppliers cannot submit rental bids that exceed the current fee-schedule-based benchmark. Using 2025 fee schedule data, CMS estimates that the maximum allowable bid for a CGM rental would be \$272.69 per month, a figure that will be updated by the 2026 adjustment factor.

CMS also introduced a revised SPA methodology. Instead of setting SPAs at the maximum winning bid, SPAs will now be calculated using the 75<sup>th</sup> percentile of winning bids, with automatic updates in Years 2 and 3 based on what is called the Consumer Price Index for all Urban Consumers ([CPI-U](#)) inflation.

### **~ Ten national contract suppliers expected to be chosen for the CGM/insulin pump product category**

Based on 2024 claims data, CMS anticipates selecting approximately 10 national contract suppliers for the combined CGM/insulin pump product category. This number is determined by:

- Identifying all suppliers that furnished at least 3% of national allowed services for the category's lead item in 2025;
- Increasing that number by 125% to determine how many suppliers are needed nationally; and

- Ensuring that at least 30% of winning suppliers are small suppliers, with CMS adding contracts as needed to meet this target.

Under the nationwide Remote Item Delivery (RID) program, each contract supplier must serve all Medicare beneficiaries in all states, regardless of geography, and must make available the same brands offered to non-Medicare customers.

## Questions around patient access and impact arise with final rule change

Despite these rule changes' potential to lower costs and to enable faster switching among devices for patients traditionally locked into four-year warranties, some concerns remain about access barriers under a competitive bidding program remain. Unclear specifications on coordinating device returns may create operational challenges for suppliers, which could translate into delays for patients awaiting device replacements. It remains uncertain whether new limitations to device coverage might narrow patient choices given the current device compatibility landscape.

CMS attempted to address some of these concerns by specifying that “suppliers must furnish the exact brand and model of CGM or pump prescribed by the clinician,” regardless of competitive bidding outcomes. This guideline appears intended to prevent forced switching between technology platforms for patients whose physician prescribes a specific device to avoid an adverse medical outcome. Specifically, CMS' updated rules require contract suppliers to:

- Furnish that item or mode of delivery;
- Assist the beneficiary in finding another contract supplier that can provide that item or service;
- Consult with the physician to find a suitable alternative product or mode of delivery for the beneficiary; or
- If the clinician determines that an alternative product is not acceptable, the contract supplier must furnish the item as prescribed.

We are curious to see how this requirement will be enforced and how many patients whose diabetes devices will not be supported by Medicare under this competitive bidding program may be able to continue use to prevent adverse medical outcomes with another device.

## Industry leaders highlight confidence in business models during 2Q25 following initial CMS proposal

Following CMS' initial proposal with these rule changes [in June](#), most major diabetes technology companies indicated in 2Q25 earnings calls that competitive bidding changes are not expected to materially affect businesses in the near-term. The confidence stemmed from a combination of commercial channel mix and existing pharmacy-based models. We are curious to see whether these perspectives will evolve as these final rules move toward implementation.

- **Insulet CEO, Ms. Ashley McEvoy:** “We’ve been reviewing the CMS proposal. We clearly support the increased access to the latest technology for diabetes management. As you know, we are available to patients on an as-you-go basis, a pay-as-you-go, and it's [our model] sold with near 100% of our distribution through the pharmacy channel in 47,000 pharmacies. **We clearly think that insulin delivery systems that are a part of Medicare Part D are not eligible for competitive bidding under the Part B** and we are going to continue to engage with CMS to really talk about the benefits of our differentiated Omnipod 5 technology and how we improve care for people with diabetes.”
- **Tandem CEO, Mr. John Sheridan:** “**We do not believe it will have a material impact on our business.** In fact, we anticipate it could help drive more people to pump therapy. When we think about it, traditional Medicare is less than 10% of our sales, so it's not a very big impact overall. Transitioning to a pay-as-you-go model is something that we've contemplated anyway from a commercial perspective as we've pursued the pharmacy channel. So, when we think about it transitioning for Medicare, we see that as a positive as well.”
- **Dexcom President & interim CEO, Mr. Jake Leach:** “I think there are some unique things in this version of the competitive bidding program that we need to make sure is clear regarding its impacts. **The number one thing that we want to ensure is that there's no interruption to Medicare beneficiaries as we go through this process that has happened in previous versions of competitive bidding.** That's our number one focus: to make

sure customers can get the products they need.”

- **Beta Bionics CFO, Mr. Stephen Feider:** “We don't see any associated risk from this particular proposal stemming into commercial plans or within into the pharmacy model. I will just highlight that a pay-as-you-go model that's being proposed here in the CMS proposal, which is what this rental model is, is working quite well already. In the event that the CMS wanted to shift to a pay-as-you-go model in the pharmacy channel, they would use an already existing infrastructure that that's already in place today.”
- **Abbott CEO, Mr. Robert Ford:** “If CMS chooses to go down the competitive bidding route, it's really going to be the DME that are going to be the ones doing the bidding, not the CGM manufacturers. I think this is probably going to take a couple of years to fully implement the process. And I don't expect there to be an impact on Abbott, but we're going to continue to monitor.”

### Close Concerns' Questions

1. How will CMS monitor and address potential access disruptions during the transition to bundled rental payments for CGMs and pumps?
2. Does CMS expect any restriction to patient choice with diabetes devices given the new competitive bidding program for Medicare?
3. What does CMS estimate the maximum allowable bid for a monthly rental of an insulin pump and its related supplies will be?
4. Will current beneficiaries who own their diabetes device be eligible for Medicare reimbursement for their associated supplies after the device warranty expires?
5. How might pricing change for Insulet pumps, given that pods aren't “durable” but “disposable” and so not part of the competitive bidding?

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