AAHOMECARE
DIABETES COUNCIL

CGMs and Insulin Pumps Should Not Be Added to the DME Competitive Bidding Program

OVERVIEW

In the recently published CMS proposed rule, CMS is proposing to include continuous glucose monitors (CGMs) and insulin pumps to the Durable Medical Equipment (Competitive Bidding Program (CBP). If finalized as written, CGMs and insulin pumps would be bundled into one product category and consolidate hundreds of current suppliers into fewer than 10 contract awardees nationwide. It is estimated that one in every three Medicare beneficiaries have been diagnosed with diabetes and 3.1M are on some form of insulin therapy.* Applying CBP to CGMs and insulin pumps creates serious risks to patient safety and access. With so few contract awardees, beneficiaries could face reduced options and disruption in their care. This would be especially harmful for beneficiaries on insulin, for whom reliable supplier services are life-sustaining.

INDUSTRY POSITIONS

1. **Competitive Bidding Would Jeopardize Patient Access**
   - CMS' proposal to reduce suppliers from hundreds to fewer than 10 contractors is unworkable. Contractors would need to scale 35–40x capacity overnight, leading to delays and access breakdowns.
   - Patients with both CGMs and insulin pumps could be forced to obtain products from different suppliers, creating compatibility risks and therapy delays.

2. **History Shows CBP for Insulin Pumps Doesn't Work**
   - CMS tried including insulin pumps in a 10-market pilot during Round 1 Recompete but due to several challenges, the program collapsed. CMS subsequently removed pumps from CBP.
   - Repeating this mistake of reintroducing insulin pumps risks mass disruption to diabetes care. Nothing in the latest proposal overcomes the flaws of the previous failed CBP.

3. **FDA Regulations Make CGMs Incompatible with CBP and FSS**
   - Under FDA requirements, manufacturers are responsible for device updates, software downloads, recalls, and warranty replacements, not suppliers.
   - Reclassifying CGMs to the frequent and substantial servicing (FSS) payment category inappropriately shifts responsibilities to suppliers which are inconsistent with FDA regulations and would challenge manufacturer oversight of device safety.

4. **Beneficiaries overwhelmingly oppose rental-only models****
   - 87% of surveyed Medicare beneficiaries reported wanting to own their CGM or pump.
   - 85% shared ownership is critical because devices store their personal health information.
   - 84% reported that software updates improved device performance.

5. **CGMs and pumps are highly personalized, non-transferable devices**
    - Integrated into automated insulin delivery systems with proprietary algorithms.
    - Not interchangeable across brands; switching requires significant retraining and disrupts therapy.
    - Manufacturer restrictions and FDA requirements prevent safe reuse across patients.

6. **Clinicians warn of safety and access risks**[**]
    - 94% of endocrinologists say continuity of device brand and supplier is critical for safe diabetes care.
    - 88% report Medicare FFS patients require major retraining when starting a new pump.
    - Frequent switching increases paperwork, confusion, and the risk of therapy gaps.

Our Ask

Prevent the inclusion of CGMs and insulin pumps in the DME Competitive Bidding Program. These devices are highly personalized, life-sustaining, and placing them in CBP would jeopardize patient access and disrupt care.

** Tseng, C. W., Masuda, C., Chen, R., & Hartung, D. M. (2020). Impact of Higher Insulin Prices on Out-of-Pocket Costs in Medicare Part D. Diabetes care, 43(4), e50–e51. https://doi.org/10.2337/dc19-1294*

***Survey results provided by an Association member company.*

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