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CMS Finalizes Rule on Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program Without Major Changes

On November 28, 2025, the Centers for Medicare & Medicaid Services (CMS) released Calendar Year (CY) 2026 Home Health Prospective Payment System and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program (CBP) Final Rule. CMS released a fact sheet accompanying the final rule. This summary is specifically on provisions related to DMEPOS sections of the final rule, which mostly reflect the policies laid out in the proposed rule.

CMS finalizes the following provisions:

- Create a new remote item delivery competitive bidding program,
- Reclassify continuous glucose monitors and insulin pumps to the frequent and substantial servicing payment category,
- Establish new methodology for determining single payment amounts for lead items in a competitive bid product category,
- Update certain CBP bid processes,
- Add new items to CBP, including urological and ostomy supplies,
- Update DMEPOS provider enrollment,
- Update DMEPOS supplier accreditation process, and
- Establish a process to exempt DMEPOS suppliers from prior authorization of certain DMEPOS items.

In the fact sheet, CMS announces a goal timeline for the implementation of the new CBP as no later than January 1, 2028. CMS also states that there will be a 6 month transition period for beneficiaries to switch suppliers.

This final rule is scheduled to be published in the *Federal Register* on December 2, 2025.

CMS TO CREATE REMOTE ITEM DELIVERY (RID) CBP FOR CERTAIN HIGH VOLUME ITEMS

FINALIZED AS PROPOSED- Page 527

CMS finalizes that items generally furnished from remote supplier locations should be included under a "remote item delivery" CBP or RID CBP. According to CMS, Medicare claims data shows several high-volume categories of items are furnished to beneficiaries throughout the nation from remote supplier location. CMS calculated that the average distance between the beneficiary address and the supplier locations is several hundred miles for lead items in high volume categories of items. As such, rather than implementing hundreds of local competitive bidding contracts and competitive bidding areas, **CMS finalizes creating a nationwide RID CBP or several large regional RID CBPs for several new product categories.**

In this rule, CMS does not determine which specific areas would be included under a RID CBP. However, if regional RID CBPs are established, these areas could cover smaller regions such as a State, territory, or the District of Columbia, or they could cover larger areas such as a group or combination of States, territories, and/or the District of Columbia.

In its fact sheet, CMS lists the product categories that could be included under the RID CBP. These include:

- Class II Continuous Glucose Monitors (CGMs) and Insulin Pumps
- Urological Supplies
- Ostomy Supplies
- Hydrophilic Urinary Catheters
- Off-The-Shelf (OTS) Back Braces
- OTS Knee Braces
- OTS Upper Extremity Braces

CMS also lists the specific Healthcare Common Procedure Coding System (HCPCS) codes within each product category that may be included in the RID CBP[1] but caveats that this table is for illustration purposes only. CMS states that the actual products included in each category will be designated through program instructions.

Contract suppliers will have the option to furnish these items on a non-mail order basis as well as on a mail-order basis, but would be required to furnish the items on a non-mail order basis.

Under § 414.402, the term "Remote item delivery competitive bidding program" will be defined as "a competitive bidding program wherein contract suppliers are responsible for furnishing remote item delivery items under the product category primarily to all Medicare beneficiaries regardless of where they live in the CBA. The CBA could be one nationwide CBA that includes all areas (all States, territories, and the District of Columbia) or a CBA covering a specific region of the country."

"Remote item delivery item" would be defined as "item falling under a remote item delivery competitive bidding program that may be shipped or delivered to a beneficiary's home, regardless of the method of delivery or picked up at a local pharmacy or supplier storefront if the beneficiary or caregiver for the beneficiary chooses to pick the item up in person." In order for a beneficiary to pick up

[1] See Table 33 on page 507-508 of the unpublished proposed rule.

the item in person at a local storefront, that supplier would be required to be a contract supplier for the time.

In response to the concerns that RID CBP would cause smaller DME suppliers to close, CMS states that it will aim to award at least 30 percent of the total number of contracts to small suppliers. This response seems to be at odds with the requirements and demand a supplier would have to meet in order to provide a product category to beneficiary nationwide.

With regards to concerns over state licensure requirements, CMS states that all suppliers would be required to have state/territory licensure for the regional area for which they submit bids by the close of the bid window. In addition, CMS states that it is up to the supplier to confirm licensure requirements with states.

CMS WILL RECLASSIFY ALL CONTINUOUS GLUCOSE MONITORS AND INSULIN INFUSION PUMPS INTO A NEW PAYMENT CATEGORY AND INCLUDE THEM IN CBP

FINALIZED AS PROPOSED- Page 565-566

CMS finalizes its proposal to reclassify all continuous glucose monitors (CGMs) and insulin infusion pumps under the frequent and substantial servicing payment category under § 414.222(a) and to pay for these on a monthly rental basis under the DMEPOS CBP and in non-CBAs under the fee schedule payments. The monthly rental payment includes payment for the base durable medical equipment item and associated supplies and accessories. CMS will allow contract suppliers to bill for up to 3 months of rental for these items in advance.

This is a major shift from how CGMs and insulin pumps are currently paid under the Medicare Part B DME benefit. Currently, Medicare beneficiaries receive a replacement CGM receiver or insulin pump once every 5 years, unless their equipment is lost, stolen or irreparably damaged. CMS states that CGM and insulin pump technology will rapidly change in future years and is concerned that the current benefit limits beneficiary choice and access to newer rapidly changing technology. Under the current DME benefit, CGM receivers are classified as a routinely purchased equipment where Medicare makes a one-time payment for purchase, and insulin pumps are classified as a capped rental item where Medicare makes payments for 13 months after which the beneficiaries assumed ownership of the pump.

By finalizing the reclassification of CGMs and insulin pumps to the frequent and substantial servicing category, **CMS eliminates beneficiary ownership of CGMs and insulin pumps for new patients**; but allows beneficiaries flexibility to switch to a new technology more often than once every 5 years. **CMS did not propose criteria under which a contract supplier would be required to upgrade a beneficiary to a new CGM or insulin pump- except that the beneficiary would request such an upgrade.** CMS states that the contract supplier of the rented CGM and insulin pump will be responsible for software updates for the equipment and performing any necessary maintenance and servicing of the equipment, as well as addressing recalls and replacing recalled equipment.

All CGMs and insulin pumps will be classified as items requiring frequent and substantial servicing beginning on the date class II CGMs and insulin pumps are first phased in under the DMEPOS CBP.

Payment Based on Monthly Rental Basis

CMS establishes payment for CGMs and insulin pumps by adding up the current monthly fee schedule amounts for the base DME item and the supplies. For the base items, using 5-year reasonable lifetime requirement as a reference, CMS finalizes its proposal to divide the total fee schedule amount by 60 for the number of months over a 5-year period. This leads to the following bid limits, based on the 2025 DME fee schedule:

- **CGMs: $272.69**
    - Monthly fee schedule for CGM supplies (A4239): $267.92
    - Purchase fee schedule amount for CGM receiver (E2103): $286.03 – when divided by 60 generates a monthly payment of $4.77
    - $267.92+$4.77 = $272.69
- **Insulin pumps: $226.22**
    - Monthly fee schedule for infusion set supplies (A4224): $25.19x 4 per month = $100.76
    - Monthly fee schedule for insulin cartridges (A4225): $3.38 x 9 per month= $30.42
        - CMS states that in 2024, Medicaid paid for 7-9 units of A4225 per month on average and that is why the insulin cartridge rate (per unit) is multiplied by 9. CMS is seeking specific comments on the number of units to use for one-month supply.
    - Monthly fee schedule for insulin pump (E0784): $5,702.34/60 months = $95.04
    - $95.04+$30.42+$100.76 = $226.22
    - CMS uses the nonrural payment amounts in the current fee schedule, stating that the cost of shipping an item from a remote location to a beneficiary residing in a rural area is typically no higher than the cost of shipping an item from a remote location to a beneficiary residing in a nonrural area.

Additionally, CMS states that CGMs and insulin pumps would be included in the same competitive bid product category, but does not determine whether the CGM or the insulin pump would be the lead item for the category.

Class III devices are statutorily excluded from the DMEPOS CBP per section 1847(a)(2)(A) of the Act. Insulin pumps used in conjunction with class III CGMs would also be excluded from the DMEPOS CBP. However, CMS finalizes its proposal to make equal the payment for class II and class III CGMs and insulin pumps if the payments for class III CGMs and insulin pumps used in conjunction with class III CGMs are more than 15 percent higher than the amounts established for the class II CGMs and insulin pumps under the DMEPOS CBP.

Bidding entities competing to be nationwide contract suppliers for these items and other items in the same product category would need to submit bids that are lower than the bid limit to be considered. CMS will determine single payment amounts for lead and non-lead items in a product category after evaluating all the bids it receives from bidding entities.

For beneficiaries who own their insulin pump, coinsurance would remain relatively the same for monthly supplies when the new rules go into effect. For beneficiaries who are in the middle of the 13-month capped rental period, their coinsurance would increase as they transition to the new monthly payments which would not be reduced by the amounts attributed to the monthly rental payments already made under the capped rental rules.

Suppliers with existing rental agreements in place at the time CBP is implemented will be grandfathered as non-contract suppliers until the beneficiary requires or requests a new device. The noncontract suppliers will be paid based on the monthly rental amounts established under DMEPOS CBP.

During the public comment process, the diabetes industry, including patient and advocacy organizations, strongly opposed the inclusion of CGMs and insulin pumps in the CBP and the reclassification of these products into the frequent and substantial servicing payment category. However, CMS disagreed with the majority of the concerns raised by stakeholders and finalized the new policies largely as proposed.

CMS FINALIZES ADDING ITEMS CONSIDERED MEDICAL SUPPLIES TO CBP

FINALIZED AS PROPOSED- Page 503

Despite backlash from stakeholders that CMS has exceeded its authority, CMS finalizes its proposal to include urological and ostomy supplies in the RID CBP. CMS is proposing to include ostomy, tracheostomy, and urological supplies to the definition of "medical equipment items". Specifically, this includes home health medical supplies such as intermittent catheters, catheter supplies, ostomy bags, supplies related to ostomy care, and certain covered osteoporosis drugs. These items are currently covered under the prosthetic benefit under Medicare Part B and have previously been excluded from CBP as a result. By reinterpreting the statute, CMS believes these items are included in the definition of "medical equipment" and therefore can be included in CBP. Given the strong comments regarding this proposal, it is possible there will be a legal challenge from stakeholders.

BACKGROUND ON THE COMPETITIVE BIDDING PROGRAM

The primary goal of the DMEPOS CBP is to save the Medicare program money by reducing excessive payments for items and services by awarding contracts to a certain suppliers with the lowest bid amounts and who have the capacity to furnish items needed in each competitive bidding area (CBA).Per statute, in order for CBP to be implemented, the total amounts to be paid to CBP contract suppliers in an area must be less than the total amounts that would have otherwise been paid under the DMEPOS fee schedule. In other words, CBP must save the program money or CMS cannot implement CBP in the specific area where there are no savings. CMS also believes that CBP prevents supplier fraud because it decreases the incentive to commit fraud by lowering the allowed amounts paid for items.

CMS FINALIZES CHANGES TO ESTABLISHING SINGLE PAYMENT AMOUNTS AND UPDATES TO CBP PROCESSES

FINALIZED AS PROPOSED- Page 476

CMS establishes a fixed payment amount known as the single payment amount (SPA) for a particular item in a CBA after the bidding process is complete. In the most recent round of CBP, CMS set the SPA for the lead item in a product category at the highest winning bid amount for that item within the CBAs. SPAs for non-lead items in the same product category were then calculated based on the lead item's SPA.

CMS finalizes the following modifications to the CBP:

- Lower number of suppliers: process for selecting the number of contract suppliers sufficient to furnish items and services in a competition[2]
- Methodology for establishing SPAs for lead and non-lead items: **Single payment amount for a lead item furnished under the competitive bidding program will be equal to the 75th percentile of bids instead of the maximum bid.**
- **Supplier Capacity:** Supplier capacity will be estimated using data on actual contract supplier capacity from previous rounds of DMEPOS CBP.
- **Documentation Required for Bidding Entities:** Reduce the number of documents that bidding entities are required to submit during the bid window by no longer requiring the submission of a tax return extract, income statement, balance sheet, and statement of cash flows. Instead, CMS will only require bidding entities to submit a business credit report.
- **Codify Surety Bond Requirements:** Codify certain requirements for bid surety bonds.

For new categories added to the CBP, the number of contract suppliers needed to furnish items and services would be at least 2 and no more than 125% of the number of suppliers that furnished at least 3% of the total utilization for the lead item in the product category and CBA during the most recent calendar year.

To help bidders provide more certainty in their bids, CMS will apply an annual inflation update when appropriate to help account for unforeseen changes (i.e. public health emergency, inflation). The inflation would be equal to the percentage change in the Consumer Price Index for all Urban Consumers (CPI-U) of the prior year. CMS also states that if there is a public health emergency (PHE), items and services in a PHE-impacted area are immediately terminated or modified so that DMEPOS can be sent to the PHE-impacted area.

[2] Defined as "a CBA and product category combination"

CMS finalizes that it will not award a contract under the DMEPOS CBP if the total amount paid under the program is greater than all payments that would otherwise be made.

CMS FINALIZES CHANGES TO MEDICARE AND MEDICAID PROVIDER ENROLLMENT POLICIES

FINALIZED AS PROPOSED – pages 268, 273, 275, 277, 279, 281, 284, 286

CMS finalizes several changes to existing Medicare provider enrollment regulations and a change to Medicaid provider enrollment provisions.

Medicare Provider Enrollment Provisions

Currently, if the provider or supplier certified misleading or false information on their enrollment application as "true," revocation or denial is permitted. CMS finalizes an addition that reiterates and emphasizes the policy that suppliers and providers are legally responsible for the accuracy and completeness of all information provided with their applications regardless of who completed the application.

CMS is permitted to revoke or deny a provider's enrollment if their ability to prescribe drugs has been suspended or revoked by the licensing or administrative body for any state where they practice. CMS is finalizing the proposal to amend "prescribe drugs" to read "prescribe one or more drugs" to clarify that in this context, a prohibition involving even one drug is adequate grounds for revocation or denial if CMS deems it necessary to protect beneficiaries and the Trust Funds.

Under § 424.535(a)(14), CMS may revoke a provider's enrollment if the individual has a pattern of abusive prescribing of Part B or D drugs. Drugs associated with services covered under Part A do not currently fall within the purview of § 424.535(a)(14) and accordingly CMS is finalizing the proposal to amend this provision to state "Medicare-covered drugs" to encompass Medicare Parts A, B, and D.

Currently, revocation is permitted in the case of a provider abusing their billing privileges and § 424.535(a)(8) includes potential situations in which this can apply. CMS is finalizing the proposal to add the scenario in which the beneficiary attests that the items or services identified on the claim in question were not rendered or furnished as a potential situation.

CMS additionally finalizes proposals to:

- Expand the bases for which the agency can apply a retroactive revocation effective date,
- Impose new deactivation authority in terms of billing for certain services,
- Revise stay of enrollment authority,
- Have the authority to require the submission of certain other documentation needed for verification of information included on the enrollment application,
- Reassign effective dates,
- Amend DMEPOS Liability Insurance requirements, and
- Clarify deactivation reasoning.

Medicaid Provider Enrollment Provisions

CMS finalizes a language clarification to Medicaid and CHIP termination requirements. § 455.416(c) states that the provider's termination must be from Medicare and Medicaid or CHIP program of any state. Thus, CMS is finalizing to change the aforementioned "and" reference to "or" consistent with statutory language.

CMS FINALIZES CHANGES TO DMEPOS SUPPLIER ACCREDITATION PROCESS

FINALIZED WITH MODIFICATION – page 414

CMS finalizes various regulatory changes to the current DMEPOS accreditation process to address fraud, waste, and abuse problems, **including requiring DMEPOS suppliers to be resurveyed and reaccredited annually instead of every three years**. CMS also finalizes stricter requirements for becoming and remaining a DMEPOS accrediting organization (AO), with a few modifications to timeframes and to provide clarification, and to not finalize a few redesignations of language, including:

- Restructuring language that explains the process by which an entity may apply or reapply to become an AO for ease of comprehension.
- Requirements that mandate the AO to explain, in detail, its policies and procedures for avoiding conflicts of interest involving individuals who conduct surveys or participate in accreditation determinations.
- Requiring the AO describe its process for identifying and correcting deficiencies within its accreditation program.
- Requiring the AO to describe its data management, analysis, and reporting system for its surveys and accreditation determinations.
- Requiring the AO to explain their procedures for responding to and investigating complaints against its suppliers.
- Requiring the AO to furnish information about its ability to conduct timely reviews of supplier accreditation applications.
- Requiring the AO to describe its decision-making process.
- Modifications to exercise greater oversight and gain a clearer understanding of AOs' corrective action plan (CAP).
- Requiring greater explanation of how an AO defines the term "deficiency" and whether the AO has different levels of supplier deficiencies.
- Outlining of AO application for reapproval of DMEPOS accreditation program.

CMS FINALIZES EXEMPTION PATHWAY FOR COMPLIANT SUPPLIERS FROM DMEPOS PRIOR AUTHORIZATION

FINALIZED AS PROPOSED – page 420

To reduce administrative burden and improve efficiency, CMS finalizes a new exemption process for certain DMEPOS suppliers who demonstrate high compliance with Medicare rules. Suppliers with a

prior authorization affirmation rate of at least 90% would be exempt from prior authorization requirements, effective until CMS withdraws the exemption. Exemptions will be rescinded if the supplier's non-compliant claim rate exceeds 10%. CMS would provide a 60-day notice before granting or withdrawing an exemption and seeks public comment on the proposed changes.

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This Applied Policy® Summary was prepared by Simay Okyay McNutt with support from the Applied Policy team of health policy experts. If you have any questions or need more information, please contact her at sokyay@appliedpolicy.com , or at (202) 558-5272.