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CMS Releases Proposed Rule on Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program

On June 30, 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) Proposed Rule. CMS released a fact sheet accompanying the proposed rule. This summary is specifically on provisions related to DMEPOS sections of the proposed rule.

In this rule, CMS proposes to:

- Create a new remote item delivery competitive bidding program,
- Include continuous glucose monitors and insulin pumps in future competitive bidding program and sets bid limits for each product 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.

CMS states, in its fact sheet, that the proposed rule is not an announcement of product categories that will be bid in the next round of CBP and that a future announcement will provide product details and timeframe for the next competition. However, the provisions included in the proposed rule signal to the changes the agency is thinking of making in the next CBP.

This proposed rule is scheduled to be published in the *Federal Register* on July 2, 2025. Comments are due September 2, 2025.

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

CMS is proposing that items that are 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 proposes to create a nationwide RID CBP or several large regional RID CBPs, which would consist of all areas where a beneficiary resides or received covered items under the product categories.

CMS provides a table of potential product categories that could be included under a future RID CBP[1] but caveats that this table is for illustration purposes only. The potential product categories are as follows: Class II continuous glucose monitors and supplies, insulin pumps and supplies, urological supplies, ostomy supplies, off-the-shelf knee braces, off-the shelf upper extremity braces and off-the-shelf back braces. Contract suppliers would 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. CMS stated the actual product categories to be phased in under RID CBP would be designated through program instructions at a later time.

Under § 414.402, the term "Remote item delivery competitive bidding program" would 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 the item in person at a local storefront, that supplier would be required to be a contract supplier for the time.

CMS PROPOSES TO INCLUDE CONTINUOUS GLUCOSE MONITORS AND INSULIN INFUSION PUMPS IN FUTURE CBP

CMS proposes 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 would include payment for the base durable medical equipment item and

[1] See Table 46 on page 373 of the unpublished proposed rule.

associated supplies and accessories. CMS would 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.

If the agency's proposal to reclassify CGMs and insulin pumps to the frequent and substantial servicing category is finalized, **CMS would eliminate beneficiary ownership of CGMs and insulin pumps for new patients**; but allow for 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**. CMS states that the contract supplier of the rented CGM and insulin pump would 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.

Class III devices are statutorily excluded from the DMEPOS CBP per section 1847(a)(2)(A) of the Act. CMS proposes that insulin pumps used in conjunction with class III CGMs would also be excluded from the DMEPOS CBP. However, CMS proposes 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 single payment amounts (SPAs) established for the class II CGMs and insulin pumps under the DMEPOS CBP.

Payment Based on Monthly Rental Basis

CMS proposes to phase in payment on a monthly rental basis for CGMs and insulin pumps all related supplies under DMEPOS CBP and establish bid limits for the first time these items are phased in as the lead items in a product category under a nationwide or regional CBA(s).CMS proposes to establish 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 proposes 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 proposes to use 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.

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. Note that 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**. Additionally, CMS states that CGMs and insulin pumps would potentially be included in the same competitive bid product category, with CGM being the lead item.**

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. The proposed rule does not address beneficiary coinsurance for those who already own a CGM and do not want a new receiver when the new rules go into effect.

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

CMS establishes a fixed payment amount known as the single payment amount (SPA) for a particular item in a competitive bidding area (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 is proposing to make modifications to the process for selecting the number of contract suppliers sufficient to furnish items and services in a competition[2] and the 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.** CMS is

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

also proposing to estimate supplier capacity using data on actual contract supplier capacity from previous rounds of the DMEPOS CBP.

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 proposes to 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.

CMS is proposing that it would 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.

Additionally, CMS proposes to reduce the number of covered 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 proposes to only require bidding entities to submit a business credit report. CMS will also require the bidding entity to verify that all the bidding entities included on the bid have a gross revenue that is under the small supplier threshold. CMS also proposes to codify certain requirements for bid surety bonds.

CMS PROPOSES TO ADD ITEMS CONSIDERED MEDICAL SUPPLIES TO CBP

As Section 1847(a)(1) of the Act requires that all included items and services fall under competitive bidding, 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 catheters, catheter supplies, ostomy bags, supplies related to ostomy care, and certain covered osteoporosis drugs.

CMS PROPOSES CHANGES TO MEDICARE AND MEDICAID PROVIDER ENROLLMENT POLICIES

CMS is proposing several changes to existing Medicare provider enrollment regulations to 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 proposes 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 proposing 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 proposing 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 proposing 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 proposes 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 proposes 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 proposing to change the aforementioned "and" reference to "or" consistent with statutory language.

CMS PROPOSES CHANGES TO DMEPOS SUPPLIER ACCREDITATION PROCESS

CMS proposes 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 proposes stricter requirements for becoming and remaining a DMEPOS accrediting organization (AO) 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.
- Proposing 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 PROPOSES EXEMPTION PATHWAY FOR COMPLIANT SUPPLIERS FROM DMEPOS PRIOR AUTHORIZATION

To reduce administrative burden and improve efficiency, CMS proposes a new exemption process for certain DMEPOS suppliers who demonstrate high compliance with Medicare rules. Under the proposal, 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 would 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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