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CMS Finalizes Rule Including Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Provider Enrollment Updates

On November 4, 2026, the Centers for Medicare & Medicaid Services (CMS) issued its Calendar Year (CY) 2027 Home Health Prospective Payment System; Medicare Provider Enrollment, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policies Final Rule. CMS released a fact sheet and press release accompanying the final rule. This summary is specifically on provisions related to the provider enrollment and DMEPOS sections of the final rule.

The final rule updates a contract supplier requirement for the Round 2028 Competitive Bidding Program (CBP), clarifies a face-to-face encounter requirement for certain DMEPOS items, changes provider enrollment and DMEPOS accreditation provisions, and expands the DME benefit to include certain infusion pumps.

This final rule is scheduled to be published in the *Federal Register* on November 9, 2026.

CMS FINALIZES PROPOSAL TO REVISE CBP TO ADD A REQUIREMENT TO DISCLOSE THE COUNTRY OF ORIGIN

FINALIZED AS PROPOSED

Pages 355-360, 371-374[1]

CMS finalizes its proposal to require contract suppliers under the CBP to disclose the country of origin for the lead items furnished during the CBP contract period. CBP contract suppliers are those who will be awarded contracts in the next round of the CBP, which is scheduled to begin January 1, 2028.

CBP contract suppliers are required to use Form C to report the product information (manufacturer name, model name, and model number) for the lead item they furnish. This information is then published by CMS online in the Supplier Directory so that beneficiaries can search for the suppliers who carry the products they use. The lead item refers to the specific

[1] All page numbers listed are from the unpublished final rule.

product identified by its HCPCS code within a product category that results in the highest total allowed charges nationwide. Suppliers submit bids for an entire product category based on the pricing of this item. Contract suppliers are required to maintain the accuracy of their product information for the lead item and submit this form semi-annually.

In response to comments, CMS clarifies that the primary purpose of this change is to increase transparency about product information for beneficiaries but notes that the agency may use aggregate country of origin data to inform future policy, such as whether reliance on a limited amount of countries for specific DMEPOS items creates supply chain issues. CMS also notes that this reporting alone won't entirely address larger ownership structure or supply chain security goals so the agency may explore additional policy approaches. CMS also notes that since the publication of the proposed rule, the number of contracts to be awarded to suppliers for each product category included in Round 2028 has been published and totals to 43 contracts. However, since CMS may award additional contracts to meet the small supplier participation target and to ensure beneficiary demand is met, the agency estimates that approximately 50 contracts will be awarded for Round 2028.

CMS acknowledges concerns from stakeholders about the burden of manual Form C entry and notes the agency anticipates providing a drop-down menu from which DMEPOS contract suppliers select the country of origin for the lead item in the product category. CMS also notes they will explore additional options to streamline reporting, including a bulk data entry method. Lastly, the agency states its intention to educate beneficiaries on country of origin of lead items.

CMS finalizes its proposal to proceed with an information collection revision, at a future date, to update Form C to include country of origin of the lead item but notes that they can expand the policy to non-lead items in the future if necessary. CMS directs suppliers to contact product manufacturers or distributors if they have trouble locating the country of origin. As this form is currently only required to be submitted by contract suppliers every six months, CMS will provide guidance on the expected timeframe for updates to this form after a product change and is considering establishing a correction process to promptly amend inaccurate entries.

CMS reveals further information as to how country of origin information may be used to inform future policy and clarifies that at this time, this requirement is to increase beneficiary transparency and not to establish a new enforcement mechanism. Furthermore, contract suppliers will provide multiple products under various codes but will only be required to submit the country-of-origin information for the lead item

CMS LOOSENS BURDENSOME FACE-TO-FACE ENCOUNTER REQUIREMENT FOR IDENTICAL REPLACEMENT ITEMS

FINALIZED AS PROPOSED

Pages 159-165

For certain DMEPOS items[2] CMS mandates a face-to-face encounter with the beneficiary and the prescribing provider within six months before the written order. Suppliers must obtain and keep this documentation before fulfilling orders and billing Medicare. If a beneficiary needs a replacement, a new face-to-face encounter may be required for coverage. CMS finalizes its proposal to clarify that there is no "face-to-face" examination of the beneficiary required when a beneficiary needs a replacement item that is the same type of item (same HCPCS code) as the original item.

CMS states that providers must retain documentation from the original face-to-face encounter to demonstrate that coverage requirements have been met.

CMS defines identical item by the same HCPCS code. Accordingly, if the replacement item is a different brand but classified under the same HCPCS code, then a new face-to-face encounter also would not be required.

CMS FINALIZES ADDITIONAL CHANGES TO MEDICARE PROVIDER ENROLLMENT AND DMEPOS ACCREDITATION

FINALIZED AS PROPOSED

Pages 159-337

To further address fraud, waste, and abuse CMS finalizes provider enrollment provisions that would impact all providers and suppliers participating in the Medicare program. Finalized provider enrollment provisions include, but are not limited to:

- Additional grounds for denying or revoking a provider's or supplier's Medicare enrollment including if a supplier violates the requirement to reenroll in Medicare as a new provider and undergo an accreditation if they experience certain changes in majority ownership.
- Expansion of the grounds under which CMS can impose a retroactive effective date for provider and supplier revocations to make all revocation grounds retroactive.
- Expansion of the reapplication bar able to be imposed regardless of the denial reason. Currently, CMS can impose up to a 10-year reapplication bar if the provider or supplier

[2] https://www.cms.gov/files/document/required-face-face-encounter-written-order-prior-delivery-list.pdf

is denied enrollment on the grounds of submitting false or misleading information in or alongside their enrollment application.

CMS also finalizes changes to DMEPOS accreditation in § 424.58, including a new requirement that an accrediting organization report suspected fraud, waste, or abuse to the agency within three calendar days.

These finalized changes seek to address fraud, waste, and abuse observed by the agency and may, in turn, increase compliance costs for legitimate providers and suppliers.

CMS FINALIZES EXPANSION OF DME BENEFIT FOR INFUSION PUMPS AND DRUGS

FINALIZED WITH MODIFICATION

Pages 345-354

To implement Section 6222(a) of the Consolidation Appropriations Act, 2026 (CAA, 2026), CMS finalizes its proposal to revise the DME definition by providing that certain external infusion pumps, associated home infusion drugs, or other associated supplies are treated as meeting the "appropriate for use in the home" requirement when specified statutory criteria are met.

Section 6222(a) of the CAA, 2026 amends the definition of DME as found in section 1861(n) of the Social Security Act by expanding the scope of the DME benefit to include certain external infusion pumps and associated home infusion drugs or other associated supplies that wouldn't otherwise meet the definition of DME because the use of that device would not meet the "appropriate for use in the home" requirement applicable to the DME definition at 42 CFR 414.202.

CMS did not finalize its proposal to limit "health care professional," in the context of home infusions of the newly covered drugs, to registered nurses, clinical nurse specialists, nurse practitioners, physician assistants, or physicians. By not finalizing the proposal, this allows more health care professionals to provide services if it is within their scope of practice.

Additionally, section 6222(a) requires that the home infusion drug be infused at least 12 times per year. CMS is not finalizing its proposal to interpret that 12 times per year means at least once per month.

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