

CMS Proposes Rule Including Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program and Provider Enrollment Updates

On July 1, 2026, the Centers for Medicare & Medicaid Services (CMS) released [Calendar Year \(CY\) 2027 Home Health Prospective Payment System; Medicare Provider Enrollment, Durable Medical Equipment, Prosthetics, Orthotics, and Supplies \(DMEPOS\) Policies Proposed Rule](#). CMS released a [fact sheet](#) and [press release](#) accompanying the proposed rule. This summary is specifically on provisions related to the provider enrollment and DMEPOS sections of the proposed rule.

The proposed rule updates a contract supplier requirement for the Round 2028 Competitive Bidding Program, 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 proposed rule is scheduled for publication in the Federal Register on July 6, 2026.

Comments are due on August 31, 2026, by 5:00pm ET.

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

Pages 202-203

CMS proposes to require contract suppliers under the Competitive Bidding Program (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 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 supplier who carry the products they use. The lead item refers to the specific 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. CMS states that contract suppliers are required to maintain the accuracy of their product information for the lead item and submit this form semi-annually.

Currently, there is no field on Form C to disclose the country of origin. CMS proposes to add a new “country of origin” field to the form and directs suppliers to contact product manufacturers or distributors if they have trouble locating the country of origin. See the end of this summary for Form C.

While CMS seeks to address concerns that CBP may shift business away from American manufacturers to foreign manufacturers, it does not disclose any enforcement actions or how the collected information will be used. 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 within each category.

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

Pages 120-122

For certain DMEPOS items¹ 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 proposes 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.

In case of an audit, CMS states that providers must submit documentation from the original face-to-face encounter to demonstrate that medical necessity and 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 PROPOSES MORE CHANGES TO MEDICARE PROVIDER ENROLLMENT AND DMEPOS ACCREDITATION

Pages 123-193

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

¹ <https://www.cms.gov/files/document/required-face-face-encounter-written-order-prior-delivery-list.pdf>

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

CMS proposes 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.

Additionally, CMS proposes clarifying in regulation several aspects of the ongoing temporary enrollment moratoria issued on the enrollment of new home health agencies, hospices, and DMEPOS suppliers.

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

CMS PROPOSES TO EXPAND DME BENEFIT FOR INFUSION PUMPS AND DRUGS

Pages 194-201

To implement Section 6222(a) of the Consolidation Appropriations Act, 2026 (CAA, 2026), CMS proposes 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 proposes 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.

Additionally, section 6222(a) requires that the home infusion drug be infused at least 12 times per year. CMS proposes that to meet this requirement, home infusion drugs covered under the expanded DME benefit must be infused at least once a month.

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.

Form C: SEMI-ANNUAL REPORT

You must complete this report for every competitive bidding area (CBA)/product category combination (competition) in your Contract and disclose manufacturer and model information for each item specified below by the Centers for Medicare & Medicaid Services (CMS) that you will offer during the next six months. Please refer to your Contract (Attachment A) for a complete listing of your competitions.

Semi-annual reports are due no later than ten business days after each of the following dates: July 1 and January 1. If the due date for a particular semi-annual report falls on a federal holiday, the report is due on the next business day. Failure to submit a Form C for all CBA/product category combination(s) in your contract by the due dates may result in your organization's removal from the Medicare Supplier Directory and is a breach of contract.

Prior to submitting the required semi-annual reports, review the Medicare Supplier Directory to determine whether the information is current, including the lists that indicate which manufacturers' products you intend to furnish to beneficiaries. You must submit updates so that any outdated information can be replaced with more current information in the Medicare Supplier Directory.

You must PRINT EACH FORM. ALL forms must be sent (either by mail: Palmetto GBA, Competitive Bidding Implementation Contractor (CBIC), 2743 Perimeter Pkwy, Ste 200-400, Augusta, GA 30909-6499 or fax: 803-264-6228) to the CBIC and **RECEIVED** by the CBIC by the deadline.

Business Information

Contract Supplier's Legal Business Name*		Contract Number* (Check your contract for this number)	
If Network, Primary Supplier's Legal Business Name		Year*	Quarter*

Types of Products

Product Category* Negative Pressure Wound Therapy (NPWT) Pumps – Example Only			
Competitive Bidding Area (CBA)* Columbia, SC		Related CBA(s) Aiken and Edgefield Counties, SC, Asheville, NC, Charlotte-Concord-Gastonia, NC, Raleigh, NC	
Lead Item HCPCS Code* E2402			
Make* Advanced Pumps Therapy System			
Manufacturer/Distributor* Advanced Health			
Model Number* 58EK669964688845564488		<input type="checkbox"/> No Updates	
Non-Lead Item HCPCS Code	Make	Manufacturer/Distributor	Model Number
A6550	A1 Therapy Pump	A+ Distributing	484e5e884e
A7000	UB Wound Therapy System	UB Company	59596tyyy4667

Product Category*			
Competitive Bidding Area (CBA)*		Related CBA(s)	
Lead Item HCPCS Code*			
Make*			
Manufacturer/Distributor*			
Model Number*		<input type="checkbox"/> No Updates	
Non-Lead Item HCPCS Code	Make	Manufacturer/Distributor	Model Number

PRA Disclosure Statement

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