DMEPOS Related Proposals from CMS-1844-F

OVERVIEW

On November 9, 2026, the Centers for Medicare & Medicaid Services (CMS) published the Calendar Year 2027 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the Expanded HH Value-Based Purchasing Model; Medicare Provider Enrollment, Durable Medical Equipment (DME), and DME, Prosthetics, Orthotics, and Supplies (DMEPOS) Policies (CMS-1844-F) . CMS finalized its proposal to expanding their revocation and denial authority, imposing additional provider enrollment reporting requirements, broadening the definition of DMEPOS, and requiring competitive bidding contractors to report the country of origin for their lead items.

Below is a summary of the relevant changes to the DMEPOS industry. The changes go into effect on January 1, 2027.

PROPOSALS

DMEPOS Encounter Requirements for Identical Replacement Items

- **Proposal:** A new face-to-face encounter is not required for the replacement of a DMEPOS item if the replacement item falls under the same HCPCS code as the original. A new order is still required, but a new encounter is only necessary if the beneficiary needs a different item (a different HCPCS code) due to a change in medical condition.
    - This proposal is only applicable to items on the Required Face-to-Face Encounter and Written Orders Prior to Delivery (F2F/WOPD) List.
- **Final Decision:** Proposal finalized as is. Finalizing the proposal that an additional face-to-face encounter within the 6 months preceding an order/prescription for replacement of a DMEPOS item will not be required per 42 CFR 410.38 and clarify that for purposes of 42 CFR 410.38(d)(2), a "replacement" refers to the provision of an item that replaces an item falling under the same Healthcare Common Procedure Coding System (HCPCS) code; it does not include those situations involving the provision of a different item, for example, because of a change in medical condition.

Expansion of Medicare Revocation and Denial Authorities

- **Proposal:** Make nearly all revocation reasons retroactive to the date the non-compliance began.
    - Revocation can be the date a provider/supplier knowingly sells to or allows another entity to use their billing number.
    - Revocations for failure to report required enrollment changes would be effective retroactively to the day after the reporting deadline. This includes failures to report changes such as new managing employees, a change of ownership (CHOW), banking information updates, and billing agency changes.
    - This is intended to allow the government to recoup payments from the start of any violation.
    - CMS anticipates $82 million in savings from the proposed enrollment provisions, due to the prospective effective date.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** CMS could exercise its revocation authority if it determines that a provider or supplier failed to retain all required claims documentation for the required 7-year period. CMS could exercise their revocation authority when a provider/supplier fails to provide access to required claims documentation. The revocation will go into effect the day after the date the provider/supplier was required to give access.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** Make revocations based on a False Claims Act (FCA) civil judgment effective retroactively to the date of the judgment, rather than prospectively.
    - The proposal applies when a provider/supplier or certain affiliated individuals (such as an owner, managing employee, officer, director, or organization) has received an FCA civil judgment within the previous 10 years.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** For providers/suppliers who have a debt with CMS and have been referred to the Department of Treasury, they would be subject to a retroactive revocation back to the date the debt was referred.
    - Section 424.535(a)(17) already permits revocation based on the provider/supplier's failure to repay a debt to CMS that has been referred to the Department of Treasury. This proposal changes only the revocation effective date, from prospective to retroactive.
    - CMS stated that a prospective effective date would give the provider/supplier more time to incur additional debts, and that the possibility of a retroactive revocation could encourage repayment before referral.
    - Revocation under § 424.535(a)(17) remains unavailable if the debt was discharged in bankruptcy, or if the administrative appeal of the debt has not been exhausted or the time to appeal has not expired.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** Allow CMS to impose a reapplication bar of up to 10 years regardless of the specific reason for enrollment denial.
    - Currently, a reapplication bar may only be imposed for denials based on false, misleading, or omitted information (§ 424.530(a)(4)), and CMS must weigh the factors in § 424.530(f)(2) in deciding whether to impose a bar and its length. This proposal would remove both limits.
    - Unlike re-enrollment bars, reapplication bars are discretionary, and 10 years is a maximum, not a default.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** For revoked providers/suppliers, for any services provided prior to the revocation effective date must be submitted within 15 calendar days.
    - This is a change from the current 60-day requirement.
    - CMS recognizes this is a substantial time reduction.
- **Final Decision:** Proposal was finalized as is.

Modifications to Existing Revocation and Denial Reasons

- **Proposal:** Remove the specific factors CMS currently must consider when determining if a provider has a "pattern or practice" of improper billing.
    - Regulation at § 424.535(a)(8)(ii) includes a list of situations where CMS determines that the provider has a pattern or practice of submitting claims that fail to meet Medicare requirements.
    - This change is intended to give CMS more flexibility.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** Expand revocation authority when false or misleading information is submitted on any CMS or Medicare enrollment-related form or documentation, not just the initial enrollment application. Revocation could also occur even if the information was not certified as "true" or was not intended to gain or maintain enrollment.
    - Applies to all enrollment-related forms, not just the 855.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** Allow CMS to revoke all of a provider's enrollments if a single enrollment application is denied under § 424.530(a).
    - Currently, this authority is limited to situations where an existing enrollment has been revoked.
    - CMS emphasizes that this would be a discretionary authority. A denial will not automatically lead to a revocation of the provider/supplier's other enrollments.
    - Example from the Proposed Rule: *Suppose Supplier X has three separate enrollments. It submits a fourth application for a new supplier site. The application is denied because CMS discovers that-- (1) the new site is actually a false storefront; and (2) X furnished misleading information on its application. Although this conduct reflects on Supplier X as a whole, we could not take action against X's other enrollments under existing § 424.535(i), since the fourth enrollment was denied rather than revoked. This is disconcerting because X could repeat this behavior via its three remaining enrollments, hence placing the Trust Funds and Medicare beneficiaries at risk.*
- **Final Decision:** CMS did not finalize the proposal.

- **Proposal:** Broaden CMS's authority to deny an enrollment application if the provider/supplier is under a Medicare or Medicaid payment suspension to include any individuals or entities with any form of business or financial relationship with the enrolling provider/supplier.
- **Final Decision:** CMS did not finalize the proposal. Commenters raised concerns that it could result in denials based on debts of parties with only minimal involvement with the provider/supplier.

New Revocation and Denial Reasons

- **Proposal:** Allow CMS to revoke enrollment if a provider/supplier is located in a geographic area with an excessive number of providers, presenting a high risk of fraud, waste, or abuse.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** Allow CMS to deny a provider/supplier if their practice location is in the same suite or office as another provider/supplier whose Medicare enrollment has been revoked or denied.
    - CMS recognizes every situation is different and will only invoke the proposal when it is proper.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** HHAs, hospices, or DMEPOS suppliers that fail to comply with the 36-month rule and related requirements regarding changes in majority ownership will have their numbers revoked or denied.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** CMS proposes a new ground to deny or revoke enrollment if a provider, owner, or managing employee was convicted of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years.
    - This proposal is narrower in scope compared to the CY 2024 proposal.
    - CMS emphasizes that not every such conviction would result in revocation.
- **Final Decision:** Proposal was finalized as is.

Clarification on Moratoriums

- **Proposal:** Clarify that the moratorium's effective date is the date the notice is filed with the Office of Federal Register (OFR).
    - Currently, the effective date of the moratorium is published in the Federal Register.
    - Intended to prevent "rush" applications between the publication date and the effective date of the moratorium.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** Clarify that the moratorium applies to initial enrollment, change of ownership applications, re-entry applications, reactivations, and re-enrollment applications.
- **Final Decision:** Proposal was finalized as is.

Expansion of Medicare Provider Enrollment Reporting Requirements

- **Proposal:** DMEPOS suppliers would be required to identify whether any organizations disclosed on their enrollment application (Form CMS-855S) are Private Equity Companies or Real Estate Investment Trusts (REITs).
    - This is already a requirement for Form CMS-855-A.
- **Final Decision:** Proposal was finalized as is. CMS welcomes additional stakeholder feedback during the PRA notice-and-comment process.

- **Proposal:** Expand the requirement for all suppliers to maintain a permanent visible sign posting their hours of operation.
    - CMS recognizes that physical signs may not be practical for all businesses and provides some exceptions.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** Clarify and expand the definition of "operational" (§ 424.502), to include having adequate administrative and logistical ability to submit valid claims and maintain written policies for patient care and safety.
- **Final Decision:** Proposal was finalized as is. CMS is also making a technical correction in the regulatory text.

- **Proposal:** Provider/supplier must have adequate written policies and records regarding their operations, including patient care, patient safety.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** Clarify that providers and suppliers in the "high" screening category that are subject to fingerprinting must use the CMS-designated fingerprinting contractor to ensure consistency.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** Enrollees must disclose all affiliations, regardless of time. As part of the proposal, CMS will remove the 5-year lookback period for reporting affiliations under 42 CFR § 424.519(b).
    - Affiliations include: marketing, business fulfillment, financial, managerial, or beneficiary relationships.
- **Final Decision:** CMS finalized the proposed revised affiliation provisions with two modifications, both of which involve proposed paragraph (6) of the "affiliation" definition.
  "*The first, as mentioned, is the removal of beneficiary relationships there from. The second involves adding the following language at the end of said paragraph: "whether direct or indirect (including, for example, common use of the same organization to perform these services." In our view, this additional language – which we do not believe is different in intended scope from what we proposed and is primarily a clarification -- will help stakeholders more clearly understand the concepts and examples outlined in the proposed and final rules. Such transparency is critical given: (1) the concerns that commenters expressed; and (2) what we perceived to be some provider confusion as to the meaning and scope of certain aspects of our proposal. In closing, we do not believe that the non-finalization of our proposed changes to §§ 424.530(a)(6), 424.530(a)(7), and 424.535(i) is inconsistent with our finalization of revisions to some of our affiliation provisions. This is because they can address somewhat different factual situations; for example, proposed §§ 424.535(i) referenced a denied provider potentially having its other enrollment applications revoked, whereas our affiliation changes focused more on the wider question of undue risk of fraud, waste, and abuse involving certain relationships."*

Managing Employees

- **Proposal:** Expand the definition of managing employees to include the following clinical staff: medical directors, clinical directors, departmental heads, supervising physicians, nursing directors, alternate administrators, and all other clinical personnel that meet the "managing employee" definition.
- **Final Decision:** Proposal was finalized as is.

Enrollment Notification Rebuttals, and Appeals

- **Proposal:** Allow e-mail to be an acceptable form of notice for initial enrollment determinations by CMS and MACs.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** For providers/suppliers that do not agree with their reactivation effective date, they may rebut via the general deactivation rebuttal procedures.
- **Final Decision:** Proposal was finalized as is.

DMEPOS Accrediting Organization Reporting Requirements

- **Proposal:** Set the timeframe for accrediting organizations to notify CMS of any decision to terminate, revoke, withdraw, or amend accreditation status of a DMEPOS supplier from 3 business days to 5 calendar days.
    - This is intended to align requirements with current reporting requirements.
- **Final Decision:** Proposal was finalized as is.

- **Proposal:** Accrediting organizations must agree to notify CMS of suspected fraud, waste, or abuse by a DMEPOS supplier within 3 calendar days.
- **Final Decision:** Proposal was finalized as is.

Expansion of DMEPOS Definition to Include External Infusion Pumps and Drugs

- **Proposal:** Effective April 1, 2027, the definition of DME will expand to include certain external infusion pumps and associated home infusion drugs. To qualify, the drug must require administration or supervision by a health care professional (such as a physician or registered nurse) who is physically on-site at home during the infusion. Additionally, the drug must be infused at least 12 times per year (at least once a month).
- **Final Decision:** CMS modified the proposal to remove the list of health care professionals. The final rule requires only that administering or supervising the infusion be within the professional's scope of practice under federal and state law and licensure. The final rule also removes the reference to the drug being administered once a month.

Country of Origin Reporting for Competitive Bidding (CBP)

- **Proposal:** Contract suppliers in the CBP would be required to report on the country of origin for lead items on Form C (the Semi-Annual Report).
    - This information would be displayed in the Medicare Supplier Directory for beneficiaries.
- **Final Decision:** Proposal was finalized as is.

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