NATIONAL ASSOCIATION OF SPECIALTY PHARMACY

August 31, 2026

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1844-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CY 2027 Home Health Prospective Payment System Rate Update; Medicare Provider Enrollment, DME, and DMEPOS Policies, 91 Fed. Reg. 41216—File Code CMS-1844-P; DME Benefit Expansion for Infusion Pumps and Drugs and Provider Enrollment Provisions[1]

Dear Administrator Oz:

The National Association of Specialty Pharmacy (NASP) appreciates the opportunity to comment on the CY 2027 HH PPS proposed rule. NASP is the only national association representing all stakeholders in the specialty pharmacy industry, with more than 200 corporate members and 3500 total members members, including specialty pharmacies, integrated health systems and hospitals, pharmacy benefit managers, manufacturers, distributors, group purchasing organizations, data and technology vendors, logistics providers, patient advocacy organizations, and practicing pharmacists, nurses, and pharmacy technicians.

These comments address two specific sets of provisions of particular importance to specialty pharmacies that are enrolled as Medicare Part B suppliers, including those enrolled as DMEPOS suppliers furnishing external infusion pumps, supplies, and associated home infusion drugs. First, the proposed implementation of the DME benefit expansion for external infusion pumps and associated home infusion drugs under section 6222(a) of the Consolidated Appropriations Act of 2026. Second, the provider enrollment proposals, which would significantly increase the consequences of Medicare enrollment noncompliance for every entity considered a supplier, including pharmacies.

[1]Medicare and Medicaid Programs; 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, 91 Fed. Reg. 41216 (July 6, 2026) (File Code CMS-1844-P). https://www.federalregister.gov/d/2026-13602

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I. Summary of NASP's Recommendations

- Finalize the proposed definition of "health care professional," including the registered nurse standard, the exclusion of LPNs and LVNs, and the requirement that the professional be on site at the home.
- Finalize CMS' proposed reading of the 12-infusions-per-year criterion as at least monthly, and the decision not to impose a minimum or maximum number of infusions.
- Before April 1, 2027, publish subregulatory guidance explaining how drugs newly covered under the expanded DME benefit map to the Part B home infusion therapy services payment categories, with HCPCS coding and coordinated DME MAC and A/B MAC instructions.
- Confirm that a specialty pharmacy may satisfy the qualified home infusion therapy supplier condition through partnership or subcontracting arrangements consistent with section 1861(iii)(3)(D)(i) of the Act.
- Reserve retroactive revocation for material violations involving fraud, abuse, or intentional misrepresentation, and not for reporting errors, and provide written findings and appeal rights before recoupment.
- Do not finalize the affiliation proposals as drafted. Retain a defined lookback period, limit disclosable affiliations to relationships involving control or a material connection, exclude ordinary arm's-length commercial and patient-care relationships, and apply a reasonable-knowledge standard.
- Clarify how the change in majority ownership provisions apply to DMEPOS-enrolled pharmacies within larger corporate structures and confirm the accreditation and enrollment sequence for a compliant transaction.
- Do not finalize proposed section 424.535(a)(24), setting geography-based revocation authority without objective criteria or a finding of fraud, waste, or abuse. This requirement is not administrable and would put legitimate specialty pharmacies and patient access to their specialty pharmacy at risk.

II. DME Benefit Expansion for External Infusion Pumps and Associated Home Infusion Drugs

NASP supports the expansion of the DME benefit under section 6222(a) of the CAA, 2026. Specialty pharmacies dispense many of the drugs likely to become eligible for coverage, and the expansion has the potential to move complex infusions out of the hospital outpatient department and into the home to offer this option to patients and support their needs.

A. NASP supports the proposed definition of "health care professional" and the on-site requirement

CMS proposes that the health care professional who administers or supervises administration of home infusions be a physician, nurse practitioner, physician assistant, clinical nurse specialist, or registered nurse licensed in the State of administration, and that the professional be physically on site at the home.[2] NASP supports these proposals. The drugs most likely to move into the expanded benefit carry meaningful risk of infusion-related and hypersensitivity reactions, and the presence of a clinician who can independently recognize and treat an adverse event is a patient safety requirement, not an administrative formality. NASP supports CMS' decision not to extend the definition to LPNs and LVNs, whose scope of practice varies by State with respect to emergency medications, and not to permit remote supervision.[3]

B. Pump-necessity determinations should reflect clinical need and FDA labeling, not infusion rate alone. CMS states that no home infusion drugs presently appear to require an external infusion pump based on infusion rate and therefore proposes not to add drugs under section 1861(n)(3)(B) of the Act at this time.[4] NASP asks CMS to confirm that this conclusion is not a permanent limitation. Whether a pump is medically necessary depends on the drug's characteristics — titration and ramp-up requirements, viscosity and volume, dosing precision, stability and hang-time constraints — and on the individual patient's clinical situation, as reflected in the FDA-approved prescribing information. CMS should direct the DME MACs to apply objective, published criteria in a coverage policy, establish a transparent process for adding drugs as labeling and clinical practice evolve, and avoid an administrative rule under which a drug that clinically requires programmable pump delivery is excluded.

C. NASP supports the at-least-monthly reading and the absence of a minimum or maximum infusion count. NASP supports CMS' proposal to treat the statutory 12-infusions-per-year criterion as satisfied where the prescribing information directs that a drug be infused at least once per month, and supports CMS' decision not to impose a minimum or maximum number of infusions, recognizing that duration and frequency of therapy may depend on individual patient response and that labeling commonly directs treatment to continue until progression, toxicity, or intolerance.

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[2]91 Fed. Reg. at 41305-06 (42 C.F.R. sections 410.74, 410.75, and 410.76; section 1861(r) of the Act; on-site requirement).

[3]Id. at 41305 (declining to include licensed practical nurses and licensed vocational nurses and declining to permit remote supervision).

[4]Id. at 41305-06 (sections 1861(n)(3)(A) and (B) of the Act, as amended by section 6222(a) of the CAA, 2026).

NASP urges CMS, however, to clarify how the criterion applies when FDA-approved labeling provides for more than one dosing interval. Some labels establish different maintenance intervals across indications or expressly permit the dosing interval to be adjusted based on a patient's clinical response. CMS' proposal does not specify whether the induction regimen, maintenance regimen, or most frequent FDA-approved dosing interval should govern the qualification determination.

NASP recommends that CMS confirm that a drug satisfies the criterion where any FDA-approved regimen in its labeling directs infusion at least once per month, and that qualification, once established, is not lost when a patient transitions to a longer FDA-approved maintenance dosing interval based on clinical response. Otherwise, eligibility could conflict with the clinical principle of using the lowest effective dose, whether by reducing the dose administered or extending the dosing interval, and could disadvantage patients whose dosing regimen has been appropriately adjusted based on their clinical response to treatment.

CMS should also provide additional guidance regarding loading doses, temporary treatment interruptions, and therapies intended to continue monthly but discontinued early because of toxicity or intolerance.

D. The rule does not explain how newly covered drugs relate to the home infusion therapy benefit. The proposed rule would condition coverage on administration or supervision by a qualified home infusion therapy supplier in the patient's home, effective April 1, 2027.[5] It does not, however, explain how drugs newly covered under the expanded DME benefit will map to the existing Part B home infusion therapy services payment categories, what HCPCS coding will apply, or how the DME MACs and A/B MACs will coordinate to address coverage. Without that guidance, a specialty pharmacy cannot determine in advance whether a given therapy will be payable or how to build the operational and financial model that a new service line requires. NASP urges CMS to publish, well in advance of April 1, 2027: (1) subregulatory guidance addressing the interaction between the expanded DME benefit and the home infusion therapy benefit; (2) HCPCS-level coding and payment category assignments for affected drugs; and (3) coordinated DME MAC and A/B MAC instructions.

NASP requests that CMS distinguish the enrollment, accreditation, and billing roles when one organization is both a DMEPOS supplier and a qualified HIT supplier versus when a specialty pharmacy partners with a separate qualified HIT supplier. It would be helpful to have a step-by-step enrollment and claims example identifying the responsible NPI/PTAN, accrediting scope,

[5] Id. at 41306 (proposed revision to 42 C.F.R. section 414.202, effective April 1, 2027).

prescriber/order documentation, drug/pump/supply claim, professional-service claim, and information on how to address denials and appeals. NASP also recommends that CMS conduct pre-implementation claims testing and ensure there is MAC education provided before April 1, 2027.

E. Specialty pharmacies will often need partnership or subcontracting arrangements, and CMS should confirm that path. Section 1861(iii)(3)(D)(i) of the Act and 42 C.F.R. section 486.505 expressly permit a qualified home infusion therapy supplier to subcontract with a pharmacy, physician, provider of services, or supplier to meet the applicable requirements.[6] NASP asks CMS to confirm in the final rule that partnership and subcontracting arrangements satisfy the proposed condition, and to describe the documentation the MACs will expect to allow subcontracting with a pharmacy. This matters because the existing supplier base is thin: CMS' own monitoring data show that a small number of home infusion therapy supplier organizations account for a majority of billed visits,[7] and only a very small number of suppliers nationwide currently bill for infused drugs under the DME benefit.[8]

III. Medicare Provider Enrollment Provisions

NASP understands that CMS proposes no pharmacy-specific Medicare enrollment requirements. However, the Medicare enrollment proposals outlined apply to all Medicare provider and supplier types,[9] and they would significantly increase the consequences of ordinary enrollment noncompliance for every entity that is considered a supplier — including specialty pharmacies enrolled to furnish external infusion pumps, supplies, and other Part B items that support administration of a specialty drug. NASP supports CMS' program integrity objectives and appropriate action to address noncompliance and abusive practices. But as proposed, the provisions under this section of the rule would shift consequences from the deliberate to the inadvertent, and the compliance burden falls hardest on legitimate pharmacies and others operating within corporate structures.

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[6]Id. at 41304 (a qualified home infusion therapy supplier "may subcontract with a pharmacy, physician, provider of services, or supplier to meet these requirements").

[7]CMS, Home Infusion Therapy Services Monitoring Report (Feb. 2026). https://www.cms.gov/files/document/hit-monitoring-report-feb-2026.pdf

[8]CMS, Medicare Durable Medical Equipment, Devices & Supplies public use data (2023). https://data.cms.gov/provider-summary-by-type-of-service/medicare-durable-medical-equipment-devices-supplies

[9]91 Fed. Reg. at 41283 (provisions "apply to all Medicare provider and supplier types except as specifically indicated otherwise").

A. Retroactive revocation should be reserved for material violations. CMS proposes to make the remainder of its currently prospective revocation grounds retroactive, so that revocation would reach back to the date noncompliance commenced regardless of the underlying reason.[10] For a Part B-enrolled pharmacy, the exposure is not theoretical: a retroactive revocation date converts months of properly furnished pumps, supplies, and drugs into overpayments subject to recoupment, even where the underlying defect is a late-reported change of information rather than any fraud or harm to a beneficiary. NASP urges CMS to limit retroactive effective dates to only material violations involving fraud, abuse, intentional misrepresentation, or the absence of a required license or accreditation; adopt objective standards distinguishing material violations from reporting and administrative errors; issue written findings identifying the retroactive date and its basis; stay any recoupment pending appeal; and identify the specific noncompliance date and affected claims in any revocation notice.

B. The expansion of section 424.535(i) to denial-triggered revocations compounds pharmacy exposure. CMS proposes to permit revocation of a provider's other enrollments where a triggering application is denied, not only where an enrollment is revoked.[11] A specialty pharmacy may hold many enrollments across locations, contractor jurisdictions, and supplier types. Combined with retroactive effective dates, a single denial at one new location could place an entire multi-site specialty pharmacy and the patients it serves at risk. NASP asks CMS to confirm that this authority will be exercised only where the conduct underlying the denial reflects organization-wide risk, and to commit to individualized determinations rather than automatic cross-enrollment action.

C. The affiliation proposals are too broad to administer. CMS proposes to remove the 5-year lookback from the disclosure requirement, to add a new affiliation category covering any marketing, business, fulfillment, financial, managerial, or beneficiary relationship, and to extend the denial and revocation authorities to affiliations held by a provider's owning or managing employees or organizations.[12] Read literally, an unlimited lookback combined with "business," "fulfillment," and "beneficiary" relationships would require a specialty pharmacy to identify and report every wholesaler, hub services vendor, third-party administrator, payer, manufacturer program, referring practice, and patient relationship and every such relationship of every owner and managing employee without regard to control, materiality, or the passage of time. That is particularly unworkable where a pharmacy is one subsidiary within a large diversified

[10]Id. at 41285-86 (restructuring 42 C.F.R. section 424.535(g)).

[11]Id. at 41284 (42 C.F.R. section 424.535(i); CMS states the authority remains discretionary).

[12]Id. at 41302 (42 C.F.R. sections 424.519(b), 424.502, 424.530(a)(13), and 424.535(a)(19)).

organization, because the reportable universe extends to affiliates with which the pharmacy has no operational connection. NASP strongly recommends that CMS retain a defined lookback period, limit affiliation to relationships involving control or a material financial or operational connection, expressly exclude ordinary arm's-length commercial and patient-care relationships, apply a reasonable-knowledge standard, rely on data already available in CMS systems rather than shifting the search to applicants, and make individualized risk determinations. NASP also strongly disagrees with CMS that these changes, as proposed, impose no additional information collection burden.

D. Revocation for false or misleading information should retain a materiality element. CMS proposes to reach false or misleading information on or associated with any CMS or Medicare enrollment-related form, including contractor-created forms and supporting documentation, and to eliminate both the requirement that the information be certified as true and the requirement that the submission be intended to gain or maintain enrollment.[13] Enrollment records may contain hundreds of data elements that change routinely. Without a materiality element, a transposed address, an outdated managing employee entry, or an inconsistent attachment could support revocation. NASP recommends that CMS retain a materiality requirement, distinguish inadvertent errors from misrepresentation, and provide notice and a comment period before revocation for non-material discrepancies.

E. Change in majority ownership and Medicare enrollment. CMS proposes new authority to deny or revoke enrollment where a DMEPOS supplier fails to comply with the change in majority ownership provisions.[14] For DMEPOS-enrolled specialty pharmacies, this makes acquisitions, corporate restructurings, and other transactions materially more consequential, because a non-exempt change in majority ownership within 36 months requires the supplier to enroll anew and obtain a new accreditation. CMS separately proposes to conform the moratoria regulation so that a change in majority ownership requiring initial enrollment is subject to an enrollment moratorium.[15] A national enrollment moratorium was previously applied to new DMEPOS medical supply companies for a 6-months, starting on February 27, 2026, and recently concluding on August 27, 2026. For potential future enrollment moratoria, these proposed regulatory changes could mean that an otherwise legitimate

[13]Id. at 41284 (42 C.F.R. section 424.535(a)(4); "the submission need not be intended to gain or maintain Medicare enrollment").

[14]Id. at 41294-95 (new 42 C.F.R. sections 424.530(a)(22) and 424.535(a)(25); sections 424.550(b) and 424.551).

[15]Id. at 41296 (proposed conforming change to 42 C.F.R. section 424.570(a)(1)).

transaction involving a DMEPOS-enrolled pharmacy could leave that pharmacy unable to reenroll at all, with beneficiaries mid-therapy.

F. NASP opposes geography-based revocation. CMS proposes new section 424.535(a)(24), permitting revocation where CMS deems an enrollment to present a high risk of fraud, waste, or abuse because of the supplier's location within a limited geographic area that has an excessive number of providers and suppliers.[16] CMS declines to define "limited geographic area" or "excessive number," stating that both will carry their "ordinary, plain-language meanings," and declines to adopt distance or numerical thresholds.[17] Under CMS' proposal, a revocation could be issued with no finding of fraud, waste, or abuse by the revoked supplier and no standard against which the determination could be tested on appeal. Pharmacies serving complex patient populations can often be located near academic medical centers, cancer centers, and specialty clinics for sound clinical reasons, and a single pharmacy location may legitimately hold multiple enrollments as a DME MAC-enrolled supplier for external infusion pumps and as an A/B MAC-enrolled supplier of home infusion therapy services. A density-based test that does not require the affected suppliers to be of the same type could treat that legitimate structure, or an ordinary medical office building, as evidence of risk. NASP strongly urges CMS not to finalize this provision. If CMS proceeds, it should require an independent finding of fraud, waste, or abuse specific to the revoked supplier, publish objective criteria, and provide pre-revocation notice and an opportunity to respond/appeal.

IV. Conclusion

NASP supports the DME benefit expansion and urges CMS to finalize the clinical safeguards it has proposed while providing the coding, coverage, and operational guidance that specialty pharmacies need before April 1, 2027. NASP also urges CMS to reconsider and reevaluate the enrollment proposals so that program integrity authority is directed at deliberate misconduct rather than administrative error, and not to finalize proposed section 424.535(a)(24). NASP requests that CMS conduct post-implementation monitoring and public reporting of such measures as the number of therapies added, beneficiary uptake, home-versus-outpatient utilization, claim denials and appeal outcomes, time to therapy, cost-sharing differences, rural access, infusion-related adverse events, supplier participation, and any deactivations or revocations and how that impacts active therapy. We recommend CMS work to convene stakeholders and make corrections if access or safety problems emerge. NASP welcomes the opportunity to work with CMS on implementation.

[16]Id. at 41290 (proposing new 42 C.F.R. section 424.535(a)(24)).

[17]Id. at 41290 ("ordinary, plain-language meanings"; no distance or numerical thresholds).

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Thank you for considering these comments. Please contact me at sheila.arquette@naspnet.org with any questions.

Respectfully submitted,

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