



*The Nation's Advocacy Voice for
Community-Based Infusion*

3307 Northland Dr, Ste 160 ▪ Austin, TX 78731
www.infusioncenter.org ▪ info@infusioncenter.org

August 28, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Submitted electronically via www.regulations.gov

Re: 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-P]

Dear Administrator Oz,

The National Infusion Center Association (NICA) is a nonprofit organization formed to support community-based infusion centers caring for patients in need of provider-administered medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in safe, more efficient, and cost-effective alternatives to hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in safety across care settings, and foster patient access to the highest-quality, lowest-cost setting.

On behalf of the infusion providers we represent throughout the country, we write to provide feedback on relevant proposals in the aforementioned rule.

Provider Enrollment

Revocations and Denials of Enrollment

Modifications of Current Revocation Provisions. NICA recognizes CMS' responsibility to protect Medicare beneficiaries and the program from providers and suppliers that pose legitimate program integrity risks. However, several of the proposed new and expanded grounds for revocation rely on standards that may be difficult for providers to interpret or apply consistently, including "abuse of billing privileges," "false or misleading information," and "high-risk based location." Without clear definitions and objective criteria, these provisions could expose compliant providers to significant consequences for conduct that does not reflect fraud, abuse, or a threat to beneficiaries.

NICA is particularly concerned about the proposed expansion of retroactive revocation. Retroactive revocation can result in recoupment of Medicare payments for services that were medically necessary, appropriately furnished, and otherwise payable simply because an enrollment deficiency is later identified. For community-based infusion providers, potentially significant repayment liability could result from an administrative or technical enrollment issue unrelated to the quality or legitimacy of the care provided. ***We urge CMS to limit retroactive revocation to circumstances in***

which the underlying conduct warrants such a significant consequence and to provide providers an opportunity to correct technical or administrative enrollment deficiencies. We also ask that CMS establish clear definitions and objective standards and provide sufficient education and implementation time before enforcing newly expanded requirements.

Revised and New Denial Reasons. NICA has similar concerns with proposed denial provisions that could make a provider's Medicare enrollment dependent on information about third parties that may not reasonably be available to the provider. Infusion practices routinely interact with laboratories, pharmacies, other physician practices, and numerous other health care providers and suppliers in coordinating and delivering patient care. An infusion provider may have no practical means of determining whether every entity with which it has a relationship has outstanding Medicare debt, is subject to a payment suspension, or has experienced another adverse enrollment action. ***We urge CMS to not deny enrollment based on the conduct or enrollment status of a third party unless the applicant knew or reasonably should have known of the relevant circumstances and there is a meaningful connection between those circumstances and the applicant's own program integrity risk.***

NICA is also concerned about denying enrollment based on the presence of another provider or supplier at the same practice location whose Medicare enrollment has been denied or revoked. Shared medical office arrangements are common, and providers occupying the same building, suite, or clinical space may be legally and operationally independent of one another. An infusion provider may have neither knowledge of nor access to another provider's enrollment history. ***We urge CMS to not deny enrollment based solely on a shared practice location without evidence of a meaningful relationship between the applicant and the provider or supplier whose enrollment was denied or revoked.***

Reapplication Bar. NICA is concerned about CMS' proposal to permit a reapplication bar of up to ten years for any enrollment denial while eliminating the existing regulatory factors used to determine whether a bar is warranted and its appropriate duration. A consequence of this magnitude should reflect the nature and seriousness of the underlying conduct and should not result from a technical or administrative enrollment issue. ***We urge CMS to retain objective factors governing the imposition and duration of reapplication bars and to reserve lengthy bars for circumstances involving demonstrated program integrity risk.***

Preclusion List

NICA is concerned with CMS' proposal to expand the Medicare Preclusion List to account for felony convictions of a provider or supplier's owners, managing employees, managing organizations, directors, or officers, regardless of whether those individuals or entities are or were enrolled in Medicare. Given the significant consequences of preclusion, ***NICA urges CMS to ensure that a felony conviction involving an affiliated individual or entity does not automatically result in preclusion of an otherwise compliant provider or supplier.*** CMS should consider the nature of the conviction, the individual's role within the organization, and whether the conduct presents a meaningful risk to Medicare beneficiaries or the Medicare program.

Private Equity Companies (PECs) and Real Estate Investment Trusts (REITs)

NICA understands CMS' interest in greater transparency regarding private equity and real estate investment trust ownership and control of Medicare providers and suppliers. As CMS implements these new reporting requirements, however, it should recognize that health care organizations may have complex investment and ownership structures and that an enrolled provider may not have

visibility into every upstream investor or subsequent change in ownership. ***We urge CMS to clearly define the PEC and REIT interests that must be reported and limit provider responsibility to ownership and control information that can reasonably be identified and verified.*** CMS should also provide sufficient implementation time and education to allow providers to understand and comply with these new reporting obligations.

Managing Employees

NICA is concerned with CMS' proposal to expand the definition of "managing employee" to expressly include medical directors, clinical directors, departmental heads, supervising physicians, nursing directors, alternate administrators, and other clinical personnel who meet the definition. CMS also states that individuals in these positions may already qualify as managing employees, and therefore, should previously have been reported. We note that job titles and clinical leadership responsibilities do not necessarily reflect managerial authority over a practice. In an infusion practice, a medical director, nursing director, supervising physician, or other clinical leader may oversee clinical standards, medication administration, patient safety, or a particular clinical function without exercising operational or managerial control over the organization. This distinction is particularly important given the variety of organizational structures used by infusion providers. Indeed, a survey of NICA members regarding corporate practice of medicine (CPOM) requirements and management services organization (MSO) arrangements found that licensed professionals may retain authority over clinical standards and patient care while administrative and business responsibilities are allocated among the professional practice, an MSO, or other entities based on the organization's structure and applicable state law.

We urge CMS to determine managing-employee status based on the authority actually exercised by an individual, rather than title or responsibility for a particular clinical function. If CMS finalizes its proposal, it should provide clear examples distinguishing clinical leadership from the managerial authority that triggers reporting and provide sufficient time for providers to review and update their enrollment records.

Affiliations

NICA is concerned with CMS' proposals to eliminate the five-year lookback period for affiliation disclosures, significantly expand the types of relationships that may constitute an affiliation, and include interests over which a provider's owning or managing employees or organizations exercise operational control. We believe these changes would create an additional information collection burden for physician practices.

Eliminating the five-year lookback period could require practices to identify relationships that ended decades ago, while the expanded definition could require them to evaluate a much broader range of marketing, business, fulfillment, financial, managerial, and beneficiary relationships to determine whether they are reportable. Expanding the provision to relationships involving owning or managing employees or organizations would further increase the information practices may need to obtain and verify. These concerns are particularly important given the variety of legitimate organizational and business relationships maintained by physician practices, some of which may be influenced by state ownership, licensing, and corporate practice of medicine requirements.

NICA urges CMS to retain a reasonable lookback period, clearly define the relationships that constitute reportable affiliations, and establish reasonable expectations regarding the information providers are expected to obtain and verify. We also urge CMS to distinguish relationships involving ownership, control, or managerial authority from routine contractual, vendor, and administrative

relationships and should not impose enrollment consequences for historical or indirect relationships that a provider could not reasonably identify or evaluate.

DME Benefit Expansion for Infusion Pumps and Drugs

NICA appreciates CMS' proposals to implement the statutory expansion of the Durable Medical Equipment (DME) benefit for certain infusion pumps and associated home infusion drugs, which will provide Medicare beneficiaries with greater access to home infusion therapy. However, we are concerned about the limitations on the health care professionals who may administer or supervise administration to physicians, clinical nurse specialists, nurse practitioners, physician assistants, and registered nurses.

NICA urges CMS to permit any appropriately licensed health care professional to administer or supervise administration of an eligible home infusion drug when the professional is authorized to do so under applicable state scope-of-practice law and consistent with the FDA-approved prescribing information. States are best positioned to determine through their professional licensure and scope-of-practice requirements which clinicians are qualified to perform these services.

NICA also appreciates CMS' consideration of the potential impact of the expanded benefit on beneficiary cost sharing, and the recognition that beneficiaries receiving the same drug in the home may face different cost-sharing obligations than when receiving it in an outpatient setting. ***NICA urges CMS to ensure beneficiaries receive clear information regarding their expected out-of-pocket costs and to consider whether beneficiaries should face different financial liability for the same therapy solely based on the clinically appropriate setting in which it is furnished.*** At a minimum, CMS should closely monitor whether differences in cost sharing create financial barriers or inappropriately influence site-of-care decisions as the benefit is implemented.

Thank you for the opportunity to comment on these important issues. We would welcome the opportunity to connect with you if we can provide any other information about our concerns. Please do not hesitate to contact me, should you have any questions or wish to further discuss these issue: Brian.nyquist@infusioncenter.org

Sincerely,

A handwritten signature in black ink that reads "Brian Nyquist". The signature is written in a cursive, flowing style.

Brian Nyquist, MPH
Chief Executive
Officer
National Infusion Center Association