Federation of American Hospitals

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President and CEO

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Via electronic submission at *http://www.regulations.gov*

The Honorable Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1844-P
P.O. Box 8013
Baltimore, Maryland 21244-8013

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 Dr. Oz:

As the national representative of more than 1,000 leading tax-paying hospitals and health systems, the Federation of American Hospitals (FAH) appreciates the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) on the Calendar Year (CY) 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 Proposed Rule (Proposed Rule), published in the Federal Register on July 6, 2026 (91 Fed. Reg. 41216). The comments in this letter address the Medicare Provider Enrollment provisions of the Proposed Rule.[i]

FAH appreciates the Administration's continued focus on improving the transparency, efficiency, and accountability of the Medicare program, while supporting high-quality patient care. FAH and its member hospitals share the goal of advancing policies that strengthen patient outcomes, modernize program operations, and promote sustainable access to care for Medicare beneficiaries. FAH and its members are also aligned with the Administration's continued focus on ensuring that CMS has access to tools that protect Medicare beneficiaries and taxpayer dollars from fraud, waste, and abuse.

At the same time, hospitals across the United States continue to face significant financial, operational, and workforce pressures, alongside rapid changes in payment policy, quality measurement, technology, and coverage challenges across both traditional Medicare and Medicare Advantage. In this environment, it is critical that CMS advance policy changes in a manner that is transparent, operationally feasible, and supported by sufficient testing and stakeholder engagement.

EXECUTIVE SUMMARY

FAH acknowledges CMS's sincere commitment to Medicare program integrity and its efforts to safeguard the Medicare Trust Funds. We appreciate the opportunity to comment on the Proposed Rule and urge CMS to adopt the following key recommendations:

- **Clear Notice and Comment Rulemaking:** Advance cross-cutting provider enrollment reforms through standalone rulemaking or through a rulemaking directed at the broad universe of affected providers, rather than embedding them in a provider-type-specific payment rule (such as home health) where affected stakeholders are less likely to have meaningful notice and opportunity to comment.
- **Limit Retroactive Enrollment Revocations:** Limit the retroactivity of revocation effective dates to cases involving fraud or intentional misconduct.
- **Preserve Objective Standards for Revocation:** Retain the existing analytical framework, or adopt a revised set of factors, for "abuse of billing privileges" as a basis for provider revocations.
- **Require Intent Standard:** Require that provider revocations based on the submission of false or misleading information involve a showing of intent to mislead or a pattern of inaccurate submissions, rather than isolated, inadvertent errors.
- **Significantly Narrow Proposed "Managing Employee" Definition:** Significantly narrow the definition, for purposes of revocation, denial, and affiliation disclosure, to individuals who exercise direct supervisory control; distinguish disclosure obligations from the enrollment consequences that flow from managing employee status; and clarify whether any retroactive lookback or amendment of prior submissions would be required.
- **Establish Materiality Guardrails for CMS Review of Enrollment Denials:** Establish a materiality threshold and a good-faith standard for purposes of the expanded Medicare enrollment denial provisions related to Medicare debt, payment suspensions, and third-party relationships, and limit the scope of a qualifying "business or financial relationship" to only those relationships involving material influence over a provider's operations and/or Medicare billing.
- **Establish Meaningful Safeguards for Applying Reapplication Bars:** Refrain from expanding reapplication bars without meaningful safeguards and adopt factors ensuring that reasonableness and materiality standards govern the imposition and length of any reapplication bar.
- **Narrow Proposed "Same Suite" Standard for Enrollment Revocations:** Narrow the proposed "same suite" denial ground to require a demonstrated, substantive nexus between the enrolling provider and the revoked or denied provider, and exclude institutional providers from its scope.
- **Clearly Define Ownership Disclosures:** Ensure that expanded disclosure requirements related to private equity companies and real estate investment trusts are implemented with clear definitions and reasonable compliance timelines.
- **Protect Good-Faith Providers:** Retain a reasonable temporal limitation on affiliation disclosure requirements and adopt a safe harbor for providers that make good faith efforts to identify and disclose relevant information.
- **Target High-Risk Enforcement:** Ensure that enforcement tools are proportionate and risk-based, focusing enhanced scrutiny on the provider types and geographic areas where fraud risk is demonstrably greatest.

FAH looks forward to working with CMS to advance program integrity goals in a manner that is transparent, proportionate, and supportive of our members' abilities to serve Medicare beneficiaries. We stand ready to provide continued input on policies that support patient access, promote high-quality care, and ensure the long-term stability of the nation's hospitals and health systems. Our detailed comments are included in the following pages in Appendix A of our letter.

Should you have any questions regarding our comments or require additional information, please contact Katie Tenoever, SVP and General Counsel, at ktenoever@fah.org or (202) 624-1500.

Sincerely,

/s/
Charlene MacDonald
President and CEO
Federation of American Hospitals

APPENDIX A:
FAH Detailed Comments on Proposed Rule (CMS-1844-P)

BACKGROUND

On July 6, 2026, CMS published a Proposed Rule that, in part, proposes amendments to the regulations codifying enrollment procedures for a provider seeking inclusion in the Medicare program. The Proposed Rule includes certain new provider enrollment provisions, including the potential for retroactive revocations, and adds or expands upon the grounds for revocation or denial of provider enrollment applications.

Historically, provider enrollment requirements have existed to prevent unqualified and potentially fraudulent individuals and entities from inappropriately billing the Medicare program, to protect Medicare beneficiaries and the Medicare Trust Funds, and to give CMS authority to take action against providers who engage in fraudulent or abusive behaviors. Taken together, the proposals advanced by CMS in the Proposed Rule would provide CMS with broader authority to achieve these goals.

At the outset, FAH wishes to make clear that we, and our members, share CMS's commitment to safeguarding the Medicare program and removing bad actors from its ranks. Providers that engage in fraud, abuse, or willful noncompliance should be identified and held accountable, and FAH supports CMS's efforts to strengthen the tools available to accomplish that goal. The integrity of the Medicare program depends on it.

However, FAH is concerned that the scope and breadth of certain proposals in the Proposed Rule cast far too wide a net. In seeking to address the conduct of a relatively small number of bad actors, CMS risks imposing sweeping new compliance burdens, enrollment risks, and potential disruptions on the vast majority of providers that are operating in good faith and working every day to serve Medicare beneficiaries. The proposals, taken together and if finalized, could create significant access-to-care issues for patients if legitimate, well-intentioned providers face enrollment revocations, denials, or retroactive payment clawbacks based on technical noncompliance, inadvertent errors, or the conduct of tangentially related individuals or entities.

Moreover, the consequences of provider enrollment actions do not occur in isolation. For example, when a hospital's Medicare enrollment is revoked or denied, even temporarily, the ripple effects are significant: patients lose access to services, employees face uncertainty, and the continuity of care can be disrupted across an entire community. For a provider that is not a bad actor, these consequences are disproportionate and punitive, and they undermine the very access to care that CMS is charged with protecting.

CMS also must consider whether the proposed changes will meaningfully reduce fraud in the Medicare program. CMS analysis in the Proposed Rule does not demonstrate that the specific proposed enrollment reforms will prevent or detect a significant volume of fraud that would not otherwise be addressed by existing tools. Without such evidence, it is difficult to conclude that the compliance costs, administrative burdens, and access risks imposed by these proposals are justified by their incremental program integrity benefits.

GENERAL COMMENTS

As a general matter, FAH urges CMS to reconsider its practice of embedding sweeping, cross-cutting Medicare provider enrollment reforms within a proposed rule that is ostensibly and primarily about updating payment rates for home health agencies. The Proposed Rule's title and the vast majority of its content concern the CY 2027 Home Health Prospective Payment System rate update, the Home Health Quality Reporting Program, and the Expanded Home Health Value-Based Purchasing Model. Yet, buried within Section V.C. of this 100+ page rulemaking, are dozens of Medicare provider enrollment proposals that would affect ***all*** Medicare providers and suppliers, including FAH members, and that have absolutely nothing to do with home health payment policy.

This approach to rulemaking raises significant concerns about adequate notice and the integrity of the notice-and-comment process under the Medicare Act and the Administrative Procedure Act. Organizations such as FAH and our members routinely monitor proposed rules affecting affected payment systems, such as the Inpatient Prospective Payment System (IPPS), Inpatient Psychiatric Facility Prospective Payment System (PPS), Inpatient Rehabilitation Facility PPS, Outpatient Prospective Payment System (OPPS), and Physician Fee Schedule (PFS). However, given that our membership typically does not provide home health services, our focus on the Home Health Prospective Payment System proposed rule does not have the same level of scrutiny since the focus of HH PPS rulemaking efforts is on the home health industry. Yet, the provider enrollment provisions in this current Proposed Rule, if ultimately

finalized, will have direct and material consequences for hospitals and health systems. By situating these proposals in an unrelated payment rule, CMS risks depriving affected stakeholders of meaningful notice and the opportunity to provide informed comment.

In future rulemaking cycles, CMS should publish provider enrollment reforms that apply across all provider and supplier types in a standalone proposed rule or, at a minimum, within a rulemaking that is more naturally directed at the broad universe of affected providers, such as the IPPS or OPPS proposed rules. Doing so will promote transparency, ensure that the full range of affected stakeholders is on notice, and yield a more robust and representative public comment record.

FAH also wishes to emphasize its strong support for CMS's ongoing mission to detect, prevent, and deter Medicare fraud, waste, and abuse. Protecting the Medicare Trust Funds and ensuring that only qualified, compliant providers participate in the program are goals that FAH and our members share with the agency. However, FAH respectfully submits that many of the proposals in Section V.C. of the Proposed Rule represent a blunt and administratively burdensome approach to fraud prevention that is not well calibrated to the actual sources of fraud risk in the Medicare program. The proposals impose new compliance burdens and risks on ***all*** Medicare providers, which are already subject to extensive existing regulatory oversight through Medicare Conditions of Participation, accreditation requirements, state licensure, and regular survey and certification processes. These existing mechanisms already provide CMS with substantial tools to assess and ensure the ongoing compliance and integrity of providers.

FAH believes that CMS has more targeted and efficient tools at its disposal that would more effectively address fraud while minimizing the burden on compliant providers, including:

- **Enhanced data analytics and claims monitoring.** CMS's own program integrity contractors and the Office of Inspector General (OIG) have increasingly incorporated sophisticated data analytics capabilities to identify aberrant billing patterns, outlier claims, and networks of potentially fraudulent providers. Investing in these tools is more efficient than imposing across-the-board enrollment restrictions.

- **Targeted enforcement actions.** The existing framework of Medicare Fraud Strike Force operations, civil monetary penalty authorities, False Claims Act enforcement, and Office of Inspector General (OIG) exclusion authorities already provides CMS with tools to address identified bad actors without burdening the entire provider community.

- **Risk-based screening.** CMS also has at its disposal an established tiered screening framework (limited, moderate, and high risk) that is designed to concentrate enhanced scrutiny on provider types and geographic areas where fraud risk is greatest. CMS could refine this existing risk-based approach rather than layering additional requirements on lower-risk providers.

- **Collaboration with law enforcement.** CMS's partnerships with the Department of Justice (DOJ), the OIG, and state Medicaid Fraud Control Units have yielded significant results in identifying and prosecuting Medicare fraud. Continued investment in these collaborative enforcement efforts is a more proportionate response than expanding the grounds for enrollment revocation.

FAH urges CMS to consider whether the incremental program integrity benefits of the proposed enrollment provisions justify the compliance costs and risks they would impose on the vast majority of Medicare providers that are operating in good faith. FAH believes that a more targeted, risk-based approach to fraud prevention will better serve the agency's program integrity objectives, the interests of providers, and Medicare beneficiaries who depend on uninterrupted access to care.

SPECIFIC COMMENTS

I. Revocations and Denials of Enrollment (Part V.C.2)

Presently, 42 C.F.R. § 424.535(a) outlines a list of bases for CMS to revoke the existing enrollment of a provider in the Medicare program. In the Proposed Rule, CMS states that the agency's "continuing obligation to establish strong payment safeguards" provides a strong rationale for amending these revocation and denial policies.[ii] However, FAH has concerns about some of the proposed changes, noting both the arbitrary nature of establishing such guardrails as well as the lack of meaningful criteria against which to measure whether providers are meeting, or failing to satisfy, such criteria.

a. Modifications to Existing Revocation Provisions

i. Abuse of Billing Privileges (42 C.F.R. § 424.535(a)(8)(ii)).

CMS proposes to remove all four factors currently set forth in § 424.535(a)(8)(ii)(A) through (D) that the agency must consider before revoking a provider's enrollment for a "pattern or practice" of submitting claims that fail to meet Medicare requirements. CMS states that these factors, which include consideration of a provider's adverse action history, the percentage of non-compliant claims relative to total claims submitted, the reason(s) for the noncompliance, and whether the provider has a history of noncompliance, have frustrated the agency's ability to invoke § 424.535(a)(8)(ii) and that requiring consideration of the factors in every case has been burdensome. Under the Proposed Rule, CMS would retain only the "pattern or practice" standard without any defined analytical framework.

FAH strongly objects to this proposal. The existing four-factor test provides essential guardrails that ensure revocations under this provision are proportionate and grounded in objective analysis rather than unreviewable agency discretion. Our members, hospitals and health systems operating across the United States, submit enormous volumes of claims to the Medicare program, with total numbers of submissions often reaching into the tens or hundreds of thousands per year. Inevitably, with such significant claims volume, some claims will contain errors or be denied for technical reasons. Without the moderating influence of the existing factors, and particularly the percentage-of-claims factor and the reason-for-noncompliance factor, CMS could theoretically invoke § 424.535(a)(8)(ii) against a hospital or health system based on a handful of noncompliant claims out of thousands, regardless of whether the noncompliance was inadvertent and promptly corrected. Additionally, without these criteria, providers have no objective standards upon which to appeal a CMS determination that a provider abused billing privileges.

Rather than eliminating the four-factor framework entirely, FAH urges CMS to retain the existing factors or adopt a revised set of factors that ensure:

- The "pattern or practice" determination is measured against a provider's total claims volume, not merely the absolute number of noncompliant claims;
- The nature and severity of the noncompliance are considered, distinguishing between technical coding errors and deliberate fraud or abuse; and
- The provider's history of compliance and any good-faith corrective efforts are weighed.

At a minimum, CMS should clarify through rulemaking or sub-regulatory guidance what constitutes a "pattern or practice" sufficient for revocation, so providers have meaningful notice of the standard to which they will be held.

ii. False or Misleading Information (42 C.F.R. § 424.535(a)(4)).

CMS proposes to expand the scope of 42 C.F.R. § 424.535(a)(4) so that revocations may be based on the submission of false or misleading information on ***any*** CMS or Medicare enrollment-related form and not just on the provider enrollment application itself. CMS states in the Proposed Rule that the "ultimate aim of the submission" is immaterial, and that what matters is the truthfulness of the information shared by a provider.[iii]

While FAH supports the principle that all submissions to CMS must be truthful, this proposed expansion as a potential basis for revoking a provider's Medicare enrollment is concerning in its breadth. Providers, particularly hospitals and health systems, submit voluminous amounts of data and documentation to CMS and its contractors on a routine basis, including change-of-information reports, electronic funds transfer data, revalidation materials, and numerous other forms. If the proposed expansion is finalized, unintentional errors or discrepancies in any of these submissions could serve as grounds for revocation, even where there is no intent to deceive and no harm to the Medicare program.

FAH urges CMS to clarify that revocation under this expanded provision requires a showing of intent to mislead or a pattern of inaccurate submissions, and will not be used to identify isolated, inadvertent errors as a basis for revoking otherwise legitimate provider enrollments.

iii. Extension of Revocation (42 C.F.R. § 424.535(i)).

CMS is proposing to expand 42 C.F.R. § 424.535(i) so that if ***any*** enrollment application submitted by a given provider is denied, CMS could use this as a basis to revoke all of that provider's other existing enrollments. In the Proposed

Rule, CMS justifies this by noting that certain denials have been based on conduct as serious as that underlying a revocation.

FAH has strong concerns about this proposal and urges CMS not to finalize it. A hospital or health system may operate under multiple Medicare enrollments across different provider types and geographic locations. An enrollment denial for a new practice site, which potentially may be based on incomplete documentation or a dispute over operational readiness, could, under this proposal, cascade into the revocation of well-established, fully compliant enrollments the hospital or health system provider already holds. The potential for disproportionate and far-reaching consequences is significant.

CMS should narrow this authority so cross-enrollment revocations based on a denial are limited to situations involving fraud, material misrepresentation, or conduct that directly threatens beneficiary safety. CMS should not be permitted to jeopardize a provider's entire portfolio of Medicare enrollments based on a denial that may stem from administrative or documentation deficiencies at a single site.

iv. Expansion and Reorganization of Retroactive Revocation Grounds (42 C.F.R. § 424.535(g)).

CMS is proposing to make all Medicare enrollment revocation effective dates retroactive to the date the provider's noncompliance began, regardless of the ground for revocation. Currently, certain revocations are effective prospectively, typically thirty (30) days after the date CMS or its contractor mails notice to the affected provider. Under the Proposed Rule, CMS would eliminate this prospective framework in favor of universal retroactivity.

FAH opposes this proposal in its current form. While we understand the policy rationale for retroactive effective dates in cases involving fraud or intentional misconduct, applying blanket retroactivity across all revocation grounds, including instances involving technical non-compliance and administrative errors, is disproportionate and punitive. A hospital or health system that inadvertently fails to timely report a change in enrollment information, for example, could face claw back of Medicare payments stretching back months or years, even though the underlying noncompliance was neither willful nor harmful to Medicare beneficiaries or the Medicare Trust Funds.

FAH urges CMS to limit retroactive effective dates to revocation grounds involving fraud, intentional misrepresentation, or conduct that poses a direct threat to patient safety or Medicare program integrity. Similarly, FAH requests that CMS consider retaining prospective effective dates for revocations imposed on the basis of technical or administrative noncompliance, such as the failure to timely report changes in enrollment information (424.535(a)(1)) or the failure to respond to documentation requests (424.535(a)(10)). FAH also urges CMS to at a minimum, establish a safe harbor or good faith exception for providers that promptly cure noncompliance upon discovery or notification.

v. Claim Submissions After Revocation (42 C.F.R. § 424.535(h)).

CMS proposes to reduce the time period during which revoked providers may submit Medicare claims from sixty (60) days to fifteen (15) days. This proposal has the potential to result in all types of providers forfeiting payments for services that were properly furnished to Medicare beneficiaries before the effective date of a revocation, because fifteen (15) days is an inadequate window to ensure that all legitimate claims for services already rendered are submitted. This is especially challenging for hospitals and health systems, which often have complex billing cycles, large volumes of outstanding claims, and third-party billing arrangements.

FAH urges CMS to retain the existing sixty (60) day claims submission window or, at a minimum, extend it to no fewer than thirty (30) days.

b. Additions of New Revocation Provisions

i. High-Risk Enrollments (42 C.F.R. § 424.535(a)(24)).

In the Proposed Rule, CMS proposes a new revocation ground that would allow the agency to revoke a provider's enrollment if CMS determines that the enrollment presents a "high risk of fraud, waste, or abuse" because the provider is located within a "limited geographic area" that has an "excessive number of providers and suppliers."

This proposal is too vague and overbroad. The terms "limited geographic area" and "excessive number" are undefined in the Proposed Rule, which would result in CMS having virtually unchecked discretion to revoke the enrollment of any

provider in any area that CMS subjectively deems "excessive". Hospitals are often concentrated in metropolitan areas alongside numerous other providers and suppliers. That is the natural result of population density and patient demand, and is not dispositive evidence of fraud. The proposal, if adopted in its current form, could penalize providers simply for being located in the communities they serve. It also would create, in essence, a federal certificate of need law and it would be inappropriate for CMS to use its enrollment authority in this manner.

If CMS proceeds with this provision, FAH urges the agency to define the terms "limited geographic area" and "excessive number" with specificity, using objective, quantifiable criteria. FAH also urges CMS to exclude institutional providers, including hospitals and health systems, from the scope of this potential revocation ground. Finally, FAH asks CMS to require that an independent, articulable basis be demonstrated for concluding that a specific provider's enrollment, as opposed to the general density of providers in a given geographic area, is what presents a high risk of fraud, waste, or abuse.

c. Modifications to Existing Denial Reasons.

i. Medicare Debt, Payment Suspension, and Other Program Terminations / Suspensions (42 C.F.R. §§ 530(a)(6)-(7), (14)).

CMS proposes to significantly expand the scope of the existing denial provisions under 42 C.F.R. §§ 424.530(a)(6), (a)(7), and (a)(14). Currently, these provisions permit denials of enrollment applications based on a provider's own Medicare debt (§ 424.530(a)(6)), payment suspensions involving the provider or its owners / managing employees (§ 424.530(a)(7)), and/or terminations or suspensions from other programs involving the provider itself (§ 424.530(a)(14)). CMS proposes to broaden all three of these denial provisions to encompass not only the provider's owners and managing employees but also any individuals or entities with "any form of business or financial relationship" with the provider. FAH objects to these proposed expansions, which have significant potential to be overbroad in their application.

The proposed revisions to these standards could capture a wide range of routine commercial relationships that have no bearing on a provider's fitness to participate in the Medicare program. Hospitals and health systems maintain business and financial relationships with hundreds, if not thousands, of vendors, contractors, consultants, staffing agencies, and other entities. As proposed, a Medicare debt or payment suspension involving ***any*** of these parties could serve as a basis for denying a hospital's or health system's Medicare enrollment application, change-of-information submission, or revalidation. The stated rationale in the Proposed Rule that parties other than owners and managing employees can have significant influence over a provider is very understandable in principle. In practice, however, the proposed standard of "any form of business or financial relationship" is so broad as to sweep in entities with no meaningful connection to the provider's Medicare operations.

Additionally, the proposed revisions present practical challenges as far as how to discover, track, and manage the relevant information. For example, a provider may not know about an old unpaid Medicare debt, especially if such a debt originated from a historical acquisition by the provider organization; yet, the existence of such debt could be used to deny the provider's Medicare enrollment application. While FAH agrees that providers carry an ongoing responsibility to conduct reasonable due diligence, particularly when it involves financial debt, an obligation of this nature typically carries alongside it a good faith, reasonableness standard.

FAH urges CMS not to adopt this provision, but if the agency were to move forward with it, we urge CMS to:

- Establish a reasonable, good-faith standard to allow providers the opportunity to conduct appropriate due diligence but not to be held responsible for relevant disclosures that may not be discovered despite the exercise of reasonable diligence;
- Establish a materiality threshold so that incidental relationships and/or disclosures ultimately deemed to be immaterial in nature do not trigger these denial provisions;
- Define and limit the scope of a qualifying "business or financial relationship" to relationships involving entities that exercise material influence over the provider's operations, management, or Medicare billing; and
- Allow affected providers the opportunity to demonstrate, before a denial is imposed, that any relationships at issue do not affect Medicare program integrity.

d. Additions of New Denial Reasons.

i. Revocation or Denial in Same Suite (42 C.F.R. § 424.530(a)(19)).

CMS proposes a new denial ground under 42 C.F.R. § 424.530(a)(19) that would allow CMS to deny a provider's enrollment if its practice location is in the same suite or office as another provider whose Medicare enrollment has been revoked or denied. CMS acknowledges that shared office space is common—for example, among physicians within a group practice—and asserts that the agency will "only invoke § 424.530(a)(19) when proper."[iv]

Nonetheless, FAH objects to this proposal as drafted. The provision is particularly difficult to apply fairly or consistently in institutional settings such as hospitals and health systems. Hospitals routinely house multiple provider types within the same facility, including physician practices, outpatient clinics, ambulatory surgery centers, and laboratory services, each of which may maintain separate Medicare enrollments. While these providers often have operational relationships with the hospital, such as through credentialing, privileging, or contractual arrangements, those relationships are fundamentally different from the common ownership, management, or control arrangements that typically are indicative of fraud risk. Under the Proposed Rule. a revocation or denial affecting any of these co-located providers could create a basis for CMS to deny enrollment to other providers operating within the same hospital campus, building, or suite, even where the providers at issue have no common ownership or management and the sole connection between them is their shared physical presence within the facility.

CMS's assurance that it will exercise this discretion judiciously provides insufficient comfort. The regulatory text as proposed confers broad authority on the agency without objective limiting criteria.

As such, FAH urges CMS to:

- Exclude institutional providers and hospital- or health system-based practices from the scope of this provision, or, at a minimum, limit it to situations involving shared suites among small, independently owned provider entities;
- Demonstrate a substantive nexus, such as common ownership, management, or operational control, between the enrolling provider and the revoked or denied provider, rather than relying solely on physical proximity; and
- Establish a presumption against denials in instances where the enrolling provider can demonstrate that it has no ownership, management, financial, or operational relationship with the revoked or denied provider.

e. Reapplication Bar

CMS should not finalize the proposed amendments to the reapplication bar for enrollment denials (42 C.F.R. § 424.530(f)) without incorporating meaningful constraints on the agency's discretion. Expanding the bar beyond denials involving false or misleading information may serve legitimate program integrity objectives, but eliminating the factors CMS must weigh in setting a bar's length, while authorizing bars of up to ten (10) years for **any** denial reason, is arbitrary, disproportionate, and inconsistent with fundamental principles of administrative law. The prospect of a lengthy reapplication bar for any denial reason will discourage provider participation in the Medicare program and chill new applications, particularly among smaller and independent practices unable to absorb a prolonged exclusion. Any resulting contraction in the provider population will harm Medicare beneficiaries by exacerbating access challenges that already affect vulnerable populations.

Under the current regulatory framework, CMS may impose a reapplication bar for up to ten (10) years when a provider's enrollment application is denied for containing false or misleading information. To do so, CMS is required under the existing regulation to consider specific factors in calibrating the length of the bar—for example, the severity of the underlying conduct, the degree of culpability, and any mitigating circumstances. These factors serve the critical function of ensuring that any bar imposed bears a rational relationship to the nature and seriousness of the conduct at issue and that providers receive individualized consideration rather than blanket punishments.

The Proposed Rule would dismantle this framework by extending the agency's ability to issue a bar for any denial reason, regardless of whether the denial involves culpable conduct, and would eliminate the specific factors the agency must consider, replacing structured analysis with unfettered discretion. CMS has not articulated a reasoned basis in the Proposed Rule for removing these safeguards or explained why the existing framework is insufficient.

Without guiding factors, a provider denied enrollment for a minor technical deficiency (e.g., an incomplete application, a documentation error, a failure to meet a newly imposed condition) could face the same length bar on enrollment as a

provider that is denied for submitting fraudulent credentials. Nothing in the Proposed Rule prevents CMS from imposing the maximum length bar in every case. Paired with the substantially expanded denial triggers proposed elsewhere in the Proposed Rule, CMS would have the ability to deny provider enrollments on a wider array of grounds and to then ban providers from reapplying for up to a decade, with no obligation to justify the length of any bar imposed. Allowing CMS to have unchecked authority in this manner would be inconsistent with the Administrative Procedure Act's prohibition on arbitrary and capricious actions, and would raise serious due process concerns for providers whose livelihoods depend on Medicare participation.

CMS should, at a minimum, retain the existing requirement that the agency weigh enumerated factors in setting the length of any reapplication bar. To the extent CMS expands the bar beyond denials involving false or misleading information, it should also expand the list of factors to ensure proportionality across the broader range of denial scenarios. Specifically, CMS should be required to consider:

- ***The nature and severity of the basis for denial.*** A denial rooted in fraudulent or intentionally misleading conduct warrants a longer bar than a denial based on a technical or administrative deficiency.
- ***Whether the deficiency is curable.*** Where the basis for denial is a correctable error, such as an incomplete application or an expired license that has since been renewed, a lengthy bar serves no legitimate program integrity purpose and merely punishes the provider for a remediable shortcoming.
- ***The provider's history of compliance.*** A provider with an otherwise clean compliance record should not face the same bar as a provider with a pattern of prior violations, sanctions, or adverse actions.
- ***The impact on beneficiary access to care.*** CMS should be required to consider whether imposing a lengthy bar will diminish beneficiary access to necessary services, particularly in underserved areas or specialties experiencing workforce shortages.
- ***Any mitigating circumstances.*** Providers should have a meaningful opportunity to present mitigating factors, and CMS should be obligated to address them in its determination.

Beyond retaining guiding factors, CMS should adopt explicit reasonableness and materiality standards governing the imposition and length of any reapplication bar, so that:

- ***The bar must be reasonable in relation to the basis for denial.*** The length of any bar should be rationally related to the seriousness of the conduct or deficiency underlying the denial. A ten (10) year bar should be reserved for the most egregious circumstances—fraud, abuse, or conduct that poses a direct threat to program integrity or patient safety—and should not be available as a default or routine sanction.
- ***The basis for denial must be material.*** CMS should not impose a reapplication bar for immaterial deficiencies that do not implicate program integrity, patient safety, or the provider's fitness to participate in Medicare. Extending the bar to every conceivable denial reason without a materiality threshold invites disproportionate enforcement and undermines the legitimacy of the enrollment process.
- ***CMS must articulate its reasoning.*** Any determination to impose a reapplication bar should be accompanied by a written explanation of how CMS weighed the relevant factors and why CMS believes the chosen bar length is reasonable in light of the circumstances. This requirement promotes transparency, facilitates meaningful appellate review, and constrains the risk of inconsistent or arbitrary application across CMS contractors and regional offices.

Unquestionably, CMS has a legitimate interest in maintaining enrollment integrity. FAH agrees that a judiciously applied reapplication bar can serve that interest. However, program integrity is not advanced by vesting the agency with unconstrained authority to impose severe sanctions that are untethered from the underlying conduct. CMS should retain and expand its guiding factors and adopt explicit reasonableness and materiality standards to ensure that any bar imposed is proportionate, transparent, and subject to meaningful review.

II. Private Equity Companies and Real Estate Investment Trusts (Part V.C.7)

In the Proposed Rule, CMS announces its intention to expand the existing requirement to disclose whether any organizations reported on certain types of Medicare provider enrollment forms are Private Equity Companies (PECs) and Real Estate Investment Trusts (REITs) to additional types of enrollment forms. While transparency in ownership is a legitimate regulatory objective, FAH urges CMS to ensure this requirement is implemented with clear definitions and reasonable compliance timelines. Many hospital and health system ownership structures are multi-layered and may involve entities that do not fit neatly into the PEC or REIT categories. CMS should issue guidance defining these terms with precision and provide a reasonable transition period for compliance. We note that in discussing this proposal, CMS outlines concerns with ownership in the health care sector by PECs and REITs, and we urge the agency also to consider

that certain PECs bring a long-term commitment to patient care and communities with crucial capital resources needed to drive meaningful improvements, such as facility modernization, technology adoption, and operational improvements, that improve patient care delivery, access, and outcomes.

III. Managing Employees (Part V.C. 11)

Longstanding CMS policy requires Medicare providers to disclose certain information about "managing employees" on enrollment applications, the rationale being that managing employees can have as much influence as an owner over a provider's day-to-day operations. In the Proposed Rule, CMS seeks to expand the definition of "managing employee" in 42 C.F.R. § 424.502 to explicitly identify additional categories of individuals who fall within the definition, including medical directors, clinical directors, departmental heads (such as a hospital's Chief of Cardiology), supervising physicians, nursing directors, alternate administrators, and "all other clinical personnel" who meet the managing employee definition. CMS states that these individuals have "always qualified" as managing employees and that the proposed change is merely a clarification.

FAH questions the statement in the Proposed Rule that "managing employees sometimes have as much or more influence over a provider's daily operations as an owner."[v] Arguably, the roles, responsibilities, and influence of someone who is serving, for example, in a hospital medical or nursing director role are very different from the roles, responsibilities, and influence of someone who owns a hospital. While CMS acknowledges in the Proposed Rule that the addition of the new categories does not include establishing any particular thresholds for when an individual's level of responsibility or influence creates an obligation to disclose, it is precisely this lack of measurable criteria (for meeting such thresholds) that makes ***any*** employee potentially eligible for disclosure, and does not allow providers to set clear reporting standards.

FAH also disagrees that this proposal is a "clarification" and is concerned about its practical implications for hospitals. If finalized, this expansion would dramatically increase the number of individuals whom hospitals must report as "managing employees" on enrollment applications. Critically, this expansion would subject hospitals and health systems to the full range of enrollment consequences that flow from "managing employee" status.

FAH also has concerns with the proposed breadth of the expanded definition of who will be considered a "managing employee" in terms of the quantity of employees in a given hospital setting who potentially would qualify. In a typical hospital setting, for example, multiple individuals can potentially fill any of the stated roles. There is, in other words, not merely one individual who serves as a medical director for a given hospital, but potentially many individuals who serve in this role for the hospital, and thus, many individuals would need to be disclosed as medical or nursing directors for that hospital. For a hospital system, the expanded definition could encompass potentially hundreds of clinical leaders across departments and service lines, and there often is considerable turnover in many of these positions with each personnel change triggering another filing. Each of these individuals would become a potential vector for enrollment risk to the entire institution. The burden of continuously monitoring and reporting on this expanded universe of managing employees would be substantial.

Moreover, the Medicare enrollment system (PECOS) does permit editing applications that are under Medicare Administrative Contractor (MAC) review. Yet, providers likely would be required to update the Medicare enrollment form as MACs are reviewing previous updates to "managing employees," which would create an infeasible standard for providers to meet. In addition, providers currently are burdened by frequent mismatches to sanctions databases the MACs use to verify individuals disclosed in the Medicare enrollment form. These require providers' time and resources to resolve, and expanding the reporting universe will inevitably compound these issues.

Finally, FAH questions whether the proposed revisions to the "managing employee" definition, and in turn the standard for disclosing the individuals who serve in these roles, would require providers to do a retroactive lookback at individuals who previously filled these roles in order to amend existing provider enrollment applications and/or complete revalidations.

If CMS were to move forward with these proposals, FAH urges CMS to:

- Significantly narrow the revised "managing employee" definition for purposes of the enrollment-related consequences discussed in the Proposed Rule, including revocation, denial, and affiliation disclosures, to individuals who exercise direct supervisory control;

- Distinguish, at a minimum, between ***disclosure*** obligations for "managing employees" and ***consequences*** that flow from "managing employee" status, which FAH believes should be more limited to individuals who have genuine influence over program integrity; and
- Give providers a reasonable transition period to identify and report any newly identified managing employees, and issue sub-regulatory guidance clarifying how providers should apply the revised definition to their specific organizational structures.
- Clarify how providers should be prepared to handle any necessary retroactive reporting of employees whose roles and responsibilities may not have previously met the definition of a "managing employee" but may need to be reported due to the revised definition.

IV. Affiliations (Part V.C.15)

CMS also requires providers to disclose certain "affiliations" on Medicare enrollment applications. The current standard for requiring such reporting is that the provider or any of its owning or managing employees has, or within the previous five (5) years, had an "affiliation" with a currently or formerly enrolled Medicare, Medicaid, or Children's Health Insurance Program (CHIP) provider that has a disclosable event. FAH has previously commented on the nature of this definition, believing it is too broad and imposes undue burdens on providers with concomitant risk mitigation for government payers.[vi]

Per 42 C.F.R. § 424.502, the definition for an "affiliation" currently includes any of the following:

(i) a five (5) percent or greater direct or indirect ownership interest that an individual or entity has in another organization;
(ii) a general or limited partnership interest, regardless of the percentage, that an individual or entity has in another organization;
(iii) an interest in which an individual or entity exercises operational or managerial control over, or directly or indirectly conducts, the day-to-day operations of another organization (including sole proprietorships);
(iv) an interest in which an individual is acting as an officer or director of a corporation; and/or
(v) any reassignment relationship under § 424.80 (prohibiting claims reassignments by suppliers).[vii]

The Proposed Rule discusses that certain aspects of the current reporting requirements for such "affiliations" hinder their effectiveness. CMS is therefore proposing to remove the 5-year period from 42 C.F.R. § 424.519(b), which would require an "affiliation" to be reported regardless of how long ago such an affiliation occurred or ended. Under the Proposed Rule, providers would be required to disclose affiliations regardless of how long ago they occurred or ended. In the Proposed Rule, CMS also seeks to broaden subpart (iii) of the definition of "affiliation" to include the owning or managing employees or organizations of an entity that exercises operational or managerial control over another organization. In addition, CMS is proposing to expand the definition of "affiliation" to add a new subpart (vi) to the definition that would result in the inclusion of any marketing, business, fulfillment, financial, managerial, or beneficiary relationships in the definition.

FAH is concerned about these proposals for several reasons. First, the elimination of any temporal limitation on "affiliation" disclosure creates an open-ended and potentially unmanageable compliance obligation, particularly for providers such as hospitals and health systems that have long operating histories and complex, multi-tiered ownership and management structures. A hospital or health system that has been in operation for decades may have had thousands of individuals cycle through roles that qualify as "managing employees" under CMS's proposed expanded definition. Each of these individuals' affiliations, extending back indefinitely, would need to be tracked and disclosed.

Second, the proposed reporting requirements around so many different types of "affiliations" may potentially capture an infinite number of roles within a typical hospital system setting. For example, this raises a question of whether every clinician is technically involved in a "beneficiary relationship" by providing care to the hospital's patients. Without clarity as to the types of roles that will be captured, particularly by the inclusion of the new category in proposed subpart (vi), providers face an ongoing challenge to decide when, and for whom, disclosure obligations exist.

Third, this proposal also raises serious practical concerns about data availability. Providers, and particularly large providers such as hospitals and health systems, may have no feasible way to identify "affiliations" involving former managing employees from ten, twenty, or thirty years ago, particularly when those individuals have long since departed the organization. Requiring disclosure of information that a provider cannot reasonably be expected to know or obtain is arbitrary and imposes compliance risk without a corresponding Medicare program integrity benefit.

FAH requests that CMS:

- Retain the existing lookback period;
- Alternatively, at a minimum, limit the unlimited lookback to the provider entity itself and its current owners and managing employees, rather than extending it to all former managing employees and their historical affiliations;
- Adopt a reasonableness standard through notice-and-comment rulemaking that will account for providers' good faith efforts to identify and disclose relevant information, appreciating that there will sometimes be limitations to what a provider knows; and
- Provide a safe harbor for good faith compliance, recognizing that providers cannot reasonably be expected to have complete records of all historical affiliations of all individuals who ever qualified as managing employees.

FAH also strongly objects to the proposed amendments to 42 CFR 424.530(a)(13) and 424.535(a)(19). With these amendments, a provider's enrollment could be denied or revoked where there is no actual current or former affiliation with a provider or supplier that has a disclosable event, but one of the provider's "owning or managing employees or organizations" has such an affiliation. These regulations currently state that a provider's enrollment may be denied or revoked if CMS determines that the provider itself has or has had an affiliation under 42 CFR 424.519 that "poses an undue risk of fraud, waste, or abuse to the Medicare program." CMS is proposing to add language to this provision, allowing such grounds for denial or revocation to be applied based on an affiliation that extends only to "any of its owning or managing employees or organizations" and does not actually connect the provider with the provider or supplier that experienced the disclosable event under 42 CFR 424.519. FAH is concerned that the combined effect of these changes would allow CMS to "leapfrog" through ownership and management chains, accelerating the spread of denials and revocations in a manner that is disproportionate and potentially devastating to legitimate providers. This effectively allows CMS to skip links in the affiliation chain and spread revocations laterally across commonly owned or managed providers, even where the targeted provider had no knowledge of, involvement in, or connection to, the underlying misconduct.

For hospitals and health systems, this "leapfrog" dynamic presents a significant risk: a health system may own or manage dozens of providers across multiple states and provider types. If one provider within the system has its Medicare enrollment revoked, potentially for conduct that is wholly unrelated to the provider's operations, CMS could use the revised 42 CFR 424.535(a)(19) to pursue revocations of enrollments of other providers within the system, based solely on the common ownership or management link, without any showing that each individual provider itself engaged in, or was aware of, the problematic conduct resulting in the original provider's revocation. The resulting cascade of revocations could deprive entire communities of access to hospital services. This would be particularly problematic because affiliate-of-affiliate relationships are not subject to disclosure under 42 CFR 424.519 such that the revocation decision would be undertaken before information is gathered that would permit an appropriate determination as to whether the relationship creates an undue risk of fraud, waste, or abuse. Even under current law, revocations can spread rapidly through providers and suppliers—for example, if Provider A is subject to revocation due to a single, unfavorable claims audit, then Provider A's former medical director Physician B may be subject to revocation based on a finding of undue risk, then Provider C for which Physician B is a current medical director may be subject to revocation based on undue risk, and so on and so forth. Even if a finding of undue risk is ultimately overturned on review, the ripple effect of the revocation will have resulted in significant unnecessary costs and disruption of care without any material improvements in program integrity.

FAH urges CMS to:

- Require that any revocation under 42 CFR 424.535(a)(19) be supported by evidence that the provider itself, and not merely its owners or managing employees, has an affiliation that poses an undue risk of fraud, waste, or abuse to the Medicare program.
- Prohibit the use of a revised 42 CFR 424.535(a)(19) to effectuate "leapfrog" revocations through common ownership or management absent a direct nexus between an affiliated provider's misconduct and a targeted provider's operations.
- Provide affected providers with meaningful notice and an opportunity to respond before CMS revokes an enrollment for any reason, including the opportunity to demonstrate that the provider has taken corrective action to address the underlying concern.
- Establish safe harbors or good-faith exceptions for providers that promptly cure noncompliance upon discovery or notification, or can demonstrate they had no knowledge of and no involvement in conduct underlying an affiliated provider's revocation.

CONCLUSION

FAH reiterates its strong support for CMS's mission to safeguard the Medicare program and to hold bad actors accountable. Program integrity is a shared priority, and FAH and its members are committed to working collaboratively with the agency to advance that goal. At the same time, the elements of the Proposed Rule highlighted here and taken together, risk imposing sweeping compliance burdens and enrollment consequences on the vast majority of providers that are operating in good faith and serving Medicare beneficiaries every day.

FAH urges CMS to approach these reforms with the transparency, proportionality, and stakeholder engagement that the significance of these proposals requires. In particular, FAH asks that CMS define key terms with specificity and objectivity, limit retroactive consequences to cases involving fraud or intentional misconduct, calibrate enforcement tools to actual fraud risk, and provide reasonable transition periods and good faith safe harbors that allow compliant providers to meet new obligations without undue disruption to patient care.

FAH appreciates the opportunity to provide these detailed comments and looks forward to continued dialogue with CMS as these proposals are refined. We remain committed to constructive engagement in service of policies that protect Medicare beneficiaries, preserve access to care, and maintain the long-term stability of the nation's hospitals and health systems.

ENDNOTES

[i] The specific portion of the Proposed Rule that is the focus of FAH's comments can be found at 91 Fed. Reg. 41216, 41282-41306 (July 6, 2026).

[ii] *Id*. at 41284.

[iii] *Id*. at 41285.

[iv] *Id*. at 41293.

[v] *Id*. at 41300.

[vi] Comment Letter submitted by Federation of American Hospitals to The Honorable Seema Verma, regarding Program Integrity Enhancements to the Provider Enrollment Process; CMS-6058-FC; 84 Fed. Reg. 47, 794 (Sept. 10, 2019), electronically submitted via http://regulations.gov (Nov. 4, 2019).

[vii] Established via regulation in a Final Rule published in the Federal Register on Sept. 10, 2019 ("Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process," 84 Fed. Reg. 47794).