AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Mehmet C. Oz, MD, MBA
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code CMS–1844–P. Medicare Program; 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

Dear Administrator Oz:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to offer our comments to the Centers for Medicare & Medicaid Services (CMS) on the calendar year (CY) 2027 Notice of Proposed Rule Making (Proposed Rule) for the Home Health Prospective Payment System, published in the Federal Register on July 6, 2026. Our comments are directed to section V.C. of the Proposed Rule, which sets forth Medicare provider and supplier enrollment provisions that are applicable to all provider and supplier types, including physicians and physician practices. As CMS states, these provisions apply to all Medicare provider and supplier types except as specifically indicated otherwise.

The AMA shares CMS' commitment to protecting the Medicare Trust Funds and Medicare beneficiaries from fraud, waste, and abuse. We recognize the seriousness of the conduct described in the Proposed Rule, and we appreciate that CMS has been responsive to concerns the AMA and others raised in prior rulemaking.[1]

At the same time, several provisions of the Proposed Rule take a different approach than the AMA previously recommended, and would do so without the clarifications that the AMA requested. Two

[1] Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program, 88 Fed. Reg. 52262 (Aug. 7, 2023). The AMA submitted comments on that proposed rule on September 11, 2023.

patterns run through those provisions. First, several would expand CMS' denial and revocation authorities while removing or declining to adopt the criteria that currently help guide how those authorities are used. Second, several would increase the consequences of an adverse action without providing a corresponding opportunity to correct the issue or to be heard. The AMA is also concerned that Medicare provider and supplier enrollment provisions that are applicable to all physicians are being proposed in a home health payment rule, which many affected physicians likely would not monitor. Our recommendations below identify those provisions specifically.

Background and Applicability

Recommendations:

- The AMA urges CMS to limit the new and expanded revocation and denial authorities in section V.C. to the provider and supplier types supported by the evidentiary record, or, in the alternative, to explain in the final rule the basis on which those authorities are extended to physicians and physician practices.

- The AMA urges CMS to propose future Medicare enrollment provisions applicable to physicians in the Medicare Physician Payment Schedule rulemaking cycle, which is the rulemaking vehicle the physician community relies on to identify such changes.

- The AMA urges CMS to publish a regulatory impact analysis addressing the effect of the proposed enrollment provisions on physician practices, including an initial regulatory flexibility analysis of their effect on small physician practices, and to seek public comment on that analysis before finalizing any of the enrollment provisions, as the impact analyses accompanying the Proposed Rule address only home health and related entities.

Section V.C.1.c of the Proposed Rule provides that the enrollment provisions apply to all Medicare provider and supplier types except as specifically indicated otherwise, and identifies four exceptions:

1. 42 CFR 424.530(a)(20), applicable to hospices;
2. 42 CFR 424.530(a)(22) and 424.535(a)(25), applicable to home health agencies (HHAs), hospices, and DMEPOS suppliers;
3. 42 CFR 424.540(b)(3)(i), applicable to hospices; and
4. DMEPOS accreditation revisions at 42 CFR 424.58.

Every remaining provision would apply to physicians and physician practices, who make up the largest component of the more than two million enrolled providers and suppliers CMS describes elsewhere in the Proposed Rule.

Several of the provisions do not merely reach physicians incidentally; they apply to physicians alone. For example, as noted in Section V.C.2.a.(4) of the Proposed Rule:

- Section 424.535(a)(14) permits revocation where a physician or practitioner has a pattern or practice of abusive prescribing;
- Section 424.535(a)(21) permits revocation where a physician or eligible professional has a pattern or practice of abusive ordering, certifying, referring, or prescribing; and
- Section 424.535(a)(22) permits revocation where a physician or other eligible professional has been subject to prior action by a State oversight board or other authority.

By their terms, these grounds cannot be applied to a home health agency or a hospice. The consequence for a physician revoked under any of them is severe: a reenrollment bar of up to 10 years under 42 CFR 424.535(c), during which the physician may not participate in Medicare at all. The Proposed Rule would nonetheless revise the effective date provisions governing each of these grounds, assigning retroactive effective dates tied to the last prescription, order, certification, or referral in the pattern at issue. Revocation policy that applies only to physicians, and that can bar a physician from Medicare for a decade, is being made in a home health payment rule. The evidentiary record CMS assembles in support of the new authorities is, however, specific to home health and hospice providers. CMS documents concentrations of hospices and HHAs in particular buildings and neighborhoods, an increase of more than 45 percent in the number of HHAs in Los Angeles County between 2019 and 2023, findings by the Office of Inspector General regarding hospice quality and enrollment fraud, data from the Medicare Payment Advisory Commission, and correspondence from members of Congress and from home health and aging services organizations.

The AMA does not question the seriousness of that record. However, it contains no example involving a physician practice. CMS also demonstrates in the same section of the Proposed Rule that it knows how to limit an authority to the provider types its evidence concerns, having done so four times.

The analyses accompanying the Proposed Rule confirm that it was scoped as a home health rule. The regulatory flexibility analysis examines a single North American Industry Classification System code, 621610, Home Health Care Services, and reports that approximately 96 percent of HHAs are small entities. It contains no analysis of physician practices, the substantial majority of which are also small entities, and no analysis of any other supplier type to which the enrollment provisions would apply. A rule whose own impact analyses look only at home health entities should not carry enrollment provisions that reach every physician in Medicare.

CMS has previously chosen a different vehicle for the same policy. The misdemeanor conviction proposal now advanced at proposed 42 CFR 424.535(a)(16) and 424.530(a)(16) was first proposed in the CY 2024 Medicare Physician Payment Schedule proposed rule, where the AMA and others expressed concern that it was too broad and could encompass many types of misdemeanors involving comparatively modest conduct. The AMA appreciates that CMS ultimately declined to finalize that proposal.[2] CMS has likewise proposed enrollment requirements of this kind in rulemaking vehicles whose subject matter put the affected community on notice. For example, the affiliation disclosure requirements at 42 CFR 424.519 that the Proposed Rule would expand were themselves proposed in a rulemaking directed to the provider enrollment process, so that providers had reason to know their enrollment obligations were at issue.[3] The Proposed Rule takes neither approach with respect to physicians.

The AMA also notes that this is the second consecutive home health rulemaking to revise revocation policy applicable to physicians. The retroactive revocation framework that the Proposed Rule would complete was established in the CY 2026 HH PPS final rule, which projected savings of nearly $2.2 billion from 1,442 annual revocations. The Proposed Rule would extend that framework to the remaining grounds, including the physician-specific grounds identified above. As a result, a body of revocation policy applicable to physicians has been built across two rulemakings that the physician community had little reason to follow, and this comment period may be the first opportunity many affected physicians will have had to respond to any of it.

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[2] Id.

[3] Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process, 84 Fed. Reg. 47794 (Sept. 10, 2019).

The AMA urges CMS to limit the new and expanded revocation and denial authorities in section V.C. to the provider and supplier types addressed by the evidentiary record supporting them. The AMA further urges CMS to publish a regulatory impact analysis addressing the effect of these provisions on physician practices, including an initial regulatory flexibility analysis of their effect on small physician practices, and to seek public comment on that analysis before finalizing any of the enrollment provisions, as the analyses accompanying the Proposed Rule address only home health and related entities. At a minimum, the AMA urges CMS to propose future enrollment provisions applicable to physicians through the Medicare Physician Payment Schedule rulemaking cycle, which is the vehicle the physician community reasonably relies on and monitors for such policy changes.

Revocations and Denials of Enrollment

Certain Misdemeanor Convictions

Recommendations:

- The AMA appreciates CMS' decision not to finalize the open-ended misdemeanor proposal advanced in prior rulemaking. The AMA supports and recommends revocation and denial authority for misdemeanor convictions relating to patient abuse, including sexual offenses against patients.

- The AMA is concerned that the proposed category of financial misconduct is undefined and extends beyond the misdemeanor categories Congress specified at 42 U.S.C. 1320a-7(b)(1)(A) and (b)(3), and recommends that CMS limit the category to misdemeanors involving fraud in connection with the delivery of a healthcare item or service.

- The AMA recommends that CMS shorten the 10-year lookback period for considering misdemeanor convictions for denial or revocation.

The AMA has previously agreed that the two cases CMS cited to support its open-ended misdemeanor proposal, involving a physician convicted of attempting to obtain controlled substances by fraud and a physician convicted of assault with a dangerous weapon, were appropriate grounds for action, and supported implementing the fraud and patient abuse categories. The AMA objected to the overly broad additional category permitting action based on any misdemeanor CMS deems detrimental to the best interests of the Medicare program and its beneficiaries, explaining that this effectively removed all limits on the offenses that could disqualify a physician.

CMS declined to finalize the proposal and acknowledges in this Proposed Rule that commenters found it too broad. The AMA appreciates that CMS has narrowed the categories to sexual assault and financial misconduct. Two concerns remain.

First, the Proposed Rule states that terms such as "financial misconduct" would be given their plain meaning. Financial misconduct, understood in its ordinary sense, could encompass a wide range of offenses bearing no relationship to the delivery of healthcare items or services or to the Medicare program. In contrast, the exclusion statute is specific in its application to misdemeanor convictions relating to fraud in connection with the delivery of a healthcare item or service, and separately to offenses relating to controlled substances. A general financial misconduct category is not congruent with either. The AMA respectfully asks CMS to align the regulatory text with the statutory categories that Congress established.

Second, the practical concern the AMA has previously raised applies with particular force to financial offenses. Many physicians are small business owners who cannot bear the cost or the reputational exposure of contesting a charge, and who may accept a misdemeanor disposition for reasons unrelated to the merits. Financial misconduct charges are among the categories in which such dispositions are most common.

Coupling a 10-year lookback with an undefined category will put substantial pressure on physicians to defend such charges vigorously simply to protect their Medicare participation. That pressure is not evenly distributed. A physician employed by a hospital or health system typically has access to institutional counsel and risk management; a physician in a small or independent practice bears the cost of a defense personally, and is the physician most likely to accept a disposition for reasons unrelated to the merits. The undefined financial misconduct category compounds this, because the business functions from which such charges arise, including billing, payroll, tax, and lease obligations, are performed by the physician owner in a small practice and by the employer in a larger organization. The result is a category that reaches independent practice owners more readily than employed physicians, without regard to any difference in conduct. The AMA further notes that the proposed addition of these misdemeanors to the definition of "final adverse action" at 42 CFR 424.502 would extend their consequences beyond the proposed denial and revocation grounds themselves, including by triggering reporting obligations. The AMA respectfully asks CMS to address that interaction expressly in the final rule. If the agency intends these misdemeanor categories to carry broader consequences across the Medicare enrollment framework, it should say so directly and provide a reasoned explanation for that choice, rather than allowing those consequences to arise indirectly through a definitional change.

Abuse of Billing Privileges

Recommendations:

- The AMA urges CMS not to finalize the proposed deletion of the factors at 42 CFR 424.535(a)(8)(ii)(A) through (D) that currently guide pattern-or-practice determinations.
- In the alternative, the AMA urges CMS to adopt a revised set of factors that addresses the operational concerns CMS identifies while preserving a defined standard for what constitutes a pattern or practice.

CMS proposes to remove all four factors that currently inform a determination that a provider has a pattern or practice of submitting claims that fail to meet Medicare requirements: the percentage of claims denied, the provider's history of final adverse actions, the type of billing non-compliance and the surrounding facts, and any other relevant information. CMS explains that the adverse action factor tends to weigh against a finding for providers with no adverse history, and that the denial percentage factor is difficult to satisfy for high-volume billers.

The AMA understands the operational difficulty CMS describes. We are concerned, however, that deletion leaves 42 CFR 424.535(a)(8)(ii) without any articulated standard. CMS states that a pattern or practice might be established by a finding that several of a provider's claims do not meet Medicare requirements, while cautioning that this establishes no minimum threshold. For a physician practice submitting thousands of claims annually under a body of coding, coverage, and documentation requirements of considerable complexity, a standard resting on the word "several" provides no notice of what conduct places Medicare participation at risk.

If CMS concludes that the existing factors are unworkable, the AMA would welcome the opportunity to work with the agency on a revised set that distinguishes billing error from abuse. Factors directed at intent, at the proportion of claims involved relative to volume, at whether the physician self-identified and refunded, and at whether the physician was previously educated on the requirement at issue would address CMS' concerns without leaving the ground unbounded.

High-Risk Enrollments

Recommendations:

- The AMA urges CMS not to finalize proposed 42 CFR 424.535(a)(24) as drafted, which would permit revocation based on provider location in an area CMS deems high-risk for fraud, waste, or abuse.

- If CMS proceeds, the AMA urges CMS to state in regulatory text that the provision does not apply on the basis of proximity alone, to require consideration of enumerated factors, and to require some finding of risk specific to the provider whose enrollment is at issue.

Proposed 42 CFR 424.535(a)(24) would permit revocation where CMS deems an enrollment to present a high risk of fraud, waste, or abuse because of the provider's location within a limited geographic area having an excessive number of providers and suppliers. CMS states that "limited geographic area" and "excessive number" would carry their plain meanings, that the ground does not require the surrounding providers to be of the same type, that no finding of actual fraud, waste, or abuse is required, and that CMS is not proposing any factors.

CMS acknowledges that many physicians practice in medical office buildings, multi-building complexes, and dense urban neighborhoods alongside numerous other physicians and suppliers, and states that providers should not assume they would be revoked merely because they operate near other providers. The AMA appreciates that acknowledgment. Our concern is that nothing in the proposed regulatory text reflects it. As drafted, the elements of the ground are satisfied by geography and by a CMS determination of risk, neither of which requires any evidence of misconduct by the physician whose enrollment is being revoked.

The AMA also notes the practical consequence for physicians. A revocation carries a reenrollment bar, appears in the National Practitioner Data Bank reporting and credentialing environment, triggers the extension provision at 42 CFR 424.535(i) reaching the physician's other enrollments, and, under this Proposed Rule, would take effect retroactively as of the date CMS made its determination. Applied to a physician who has done nothing other than practice in a busy medical district, that is a severe result. If CMS retains the provision, the AMA asks that the regulatory text require consideration of factors specific to the individual provider.

Revocation or Denial in Same Suite

Recommendations:

- The AMA urges CMS not to finalize proposed 42 CFR 424.530(a)(19) as drafted, which would permit location-based denials, and urges CMS to include in regulatory text an express exception for physicians joining an established group practice or otherwise enrolling at a location where the revoked or denied provider is no longer present.

Proposed 42 CFR 424.530(a)(19) would permit denial of an enrollment application where the applicant's practice location is in the same suite or office as a provider whose enrollment has been revoked or denied. CMS offers the example of a 10-physician group in which one physician is revoked, and states that an eleventh physician seeking to enroll would not automatically be denied.

That example illustrates the difficulty. Physicians routinely join established practices, and a physician has no practical means of determining whether any current or former occupant of a suite has ever been denied or revoked. A physician recruited to a group carries no responsibility for a predecessor's conduct. The AMA asks that the exception CMS describes in preamble appear in the regulation itself, and that the ground be limited to circumstances in which the applicant has a demonstrated relationship with the revoked or denied provider beyond a shared address.

False or Misleading Information

Recommendations:

- The AMA requests that CMS confirm in the final rule that revocation under the expanded 42 CFR 424.535(a)(4) requires more than an inadvertent error, and that CMS state the standard it will apply.

CMS proposes to expand 42 CFR 424.535(a)(4) to reach false or misleading information submitted on or in connection with any CMS or Medicare enrollment-related form, together with supporting documentation, without regard to whether the submission was made to gain or maintain enrollment and without regard to whether the information was certified as true. The AMA does not dispute that physicians must submit accurate information. We are concerned that removing the certification element and extending the ground to supporting documentation and to submissions made for any purpose creates exposure for clerical error.

The current provision is tied to a certification, which supplies a measure of deliberateness. The proposed provision is not. Because CMS also proposes to make revocations under this ground retroactive to the date the information was submitted, which may be years earlier, the consequence of an error would be substantial. The AMA therefore asks CMS to state expressly that the provision applies to knowing or reckless submissions, not inadvertent mistakes.

Extension of Revocation

Recommendations:

- The AMA urges CMS not to finalize the proposed expansion of 42 CFR 424.535(i) to permit revocation of a provider's other enrollments on the basis of a denial.

- If CMS proceeds, the AMA urges CMS to require in regulatory text an individualized finding that the conduct underlying the denial presents a material program integrity risk with respect to each enrollment CMS proposes to revoke, together with notice and an opportunity to respond before that revocation takes effect.

Section 424.535(i) currently permits CMS to revoke a provider's other enrollments when one enrollment is revoked. CMS proposes to extend that authority so that a denial of one enrollment application may also support revocation of the provider's remaining enrollments. CMS illustrates the proposal with a supplier that submitted an application for a false storefront accompanied by misleading information, and emphasizes that the authority would remain discretionary.

The AMA does not question CMS' interest in the conduct that example describes. Our concern is that the proposed authority is far broader than the example used to justify it. A denial may rest on grounds far removed from deliberate misconduct, including the new and expanded grounds discussed above. For example: a denial under proposed 42 CFR 424.530(a)(19) turns on the applicant's address, and denials under the expanded 42 CFR 424.530(a)(6) and (a)(7) may turn on the circumstances of a third party. Yet under the proposal, a denial on any of these grounds could support revocation of every other enrollment the physician holds.

For physicians, that consequence is extraordinary and is compounded by other proposals in this rule. Physicians commonly maintain multiple enrollments, across group practices, across states, and as both individual practitioners and reassigned members of a group. Revocations extended under 42 CFR 424.535(i) would carry reenrollment bars of up to 10 years under 42 CFR 424.535(c) and would now take effect retroactively under the proposed revisions to 42 CFR 424.535(g), and the underlying denial could itself support a reapplication bar of up to 10 years under the proposed revisions to 42 CFR 424.530(f). A single denial could therefore end a physician's Medicare participation nationwide, retroactively, without any finding that the physician engaged in misconduct. The AMA therefore asks that CMS require an individualized determination as to each affected enrollment before extending a denial in this manner.

Changes to Existing Denial Reasons

Recommendations:

- The AMA urges CMS not to finalize the extension of 42 CFR 424.530(a)(6) and (a)(7) to individuals and entities having any other form of business or financial relationship with the provider, and instead to define the covered relationships with specificity.

CMS proposes to extend the debt and payment suspension denial grounds beyond owners and managing employees to individuals and entities with any other form of business or financial relationship with the provider. CMS explains that parties other than owners and managers, including those furnishing services or financing, have been substantially involved with problematic providers.

The AMA appreciates CMS' concern. Our concern is that the proposed language has no apparent limiting principle. A physician practice has business or financial relationships with its landlord, its bank, its equipment vendors, its billing company, its electronic health record vendor, its malpractice carrier, and the hospitals and practices with which it contracts. Under the proposal, a Medicare debt or payment suspension involving any of those parties could support denial of the practice's enrollment application, without regard to whether the practice had any knowledge of or control over the other party's circumstances giving rise to the debt or suspension. For physician practices, that is a sweeping result. It would make Medicare enrollment turn not only on the practice's own conduct, but also on the status of outside parties with whom the practice routinely does business. The AMA therefore asks CMS to define the relationships covered, or at minimum to require that the relationship bear some meaningful connection to the conduct giving rise to the debt or suspension.

Retroactive Revocation Grounds and Claim Submissions After Revocation

Expansion and Reorganization of Retroactive Revocation Grounds

Recommendations:

- The AMA urges CMS to pair any expansion of retroactive revocation effective dates with a mechanism protecting payment for services actually furnished to beneficiaries before the physician received notice of the revocation, consistent with the position the AMA has previously taken on the stay of enrollment.

- The AMA urges CMS to extend CAP availability beyond 42 CFR 424.535(a)(1) to the grounds that are curable, including 42 CFR 424.535(a)(9) and (a)(10).

The Proposed Rule would make every revocation ground at 42 CFR 424.535(a) retroactive and would restructure 42 CFR 424.535(g) to remove the prospective default. CMS projects $82 million in annual savings and estimates that 337 providers each year would be affected.

The AMA understands that CMS should not pay a provider that is out of compliance. The difficulty is that the effective date, under many of the proposed grounds, precedes the physician's knowledge that a problem exists. A physician who fails to timely report a change in a managing employee would be revoked effective the day after the reporting deadline under proposed 42 CFR 424.535(g)(1)(ix), which may be months before CMS identifies the omission. The services furnished in the interval were furnished to beneficiaries who received care.

The AMA has previously supported the 60-day stay of enrollment but stated that we did not support CMS declining to pay for services furnished during the stay, and asked at minimum for a process to dispute non-payment where the physician submitted correct paperwork within the window. The Proposed Rule contains no comparable protection. The AMA asks CMS to consider one, and to expand CAP availability so that a physician whose deficiency is curable has a means of curing it. At present a CAP is available only for revocations under 42 CFR 424.535(a)(1), leaving physicians revoked under the reporting and documentation grounds with no cure mechanism at all.

False Claims Act

Recommendations:

- The AMA urges CMS not to finalize a retroactive effective date for revocations under 42 CFR 424.535(a)(15), and renews the concerns it has previously raised regarding that authority.

The AMA has previously urged CMS not to finalize revocation authority based on a civil judgment under the False Claims Act, explaining that the authority would reach good-faith physicians who inadvertently submitted claims that did not meet requirements, and that situations genuinely warranting revocation were already addressed by existing criteria requiring intent and a pattern of abuse. CMS finalized the authority. The Proposed Rule would now make revocations under it retroactive to the date of judgment.

The AMA is concerned that this compounds the original difficulty. A civil judgment under the False Claims Act may follow years of litigation, and a retroactive effective date extending back to the date of judgment would expose a physician to recoupment for an extended period of care furnished while the physician remained an enrolled Medicare participant in good standing.

Debts Referred to Treasury

Recommendations:

- The AMA requests that CMS clarify the circumstances under which a provider is treated as having failed to repay a debt referred to the Department of the Treasury, the period a provider has before that determination is made, and the number of contacts CMS will attempt beforehand.

- The AMA urges CMS not to finalize a retroactive effective date for revocations under 42 CFR 424.535(a)(17) until that clarification is provided.

The AMA has previously raised concerns that the expansion of 42 CFR 424.535(a)(17) was overly broad and would result in physicians being revoked unfairly. We appreciated CMS' assurance that it would consider the factual circumstances behind unpaid debts and requested clarification of the circumstances that would lead to revocation, the duration before a physician falls into the category of failure to repay, and how many points of contact CMS would attempt. That clarification has not been provided.

The Proposed Rule would make revocation under this ground retroactive to the date CMS referred the debt to the Department of the Treasury. Because a physician may be unaware that a referral has occurred, and because appeals of the underlying overpayment determination may still be pending in fact if not formally exhausted, the AMA asks CMS to resolve the scope questions described above before increasing the consequence.

Claim Submissions After Revocation

Recommendations:

- The AMA urges CMS to retain the current 60-day period for submitting claims following revocation.

- The AMA appreciates CMS' proposal to measure the period from the date of the revocation letter rather than the revocation effective date and supports that change.

CMS proposes to reduce from 60 days to 15 days the period within which a revoked provider must submit claims for items and services furnished before revocation. The AMA has previously opposed a parallel reduction, from 30 days to 15, of the period for terminating a relationship with an offending party and documenting that termination under 42 CFR 424.535(e). We explained that providers must ordinarily proceed through administrative channels and that a 15-day period was not achievable for parties acting in good faith.

The same concern applies here. A practice that has just been revoked must identify every unbilled encounter, complete outstanding documentation, and submit the claims, frequently while also responding to the revocation itself, arranging for continuity of patient care, and notifying its other payers. The AMA appreciates that CMS has anchored the period to the date of the revocation letter, which resolves the ambiguity the AMA previously identified, and asks that CMS pair that improvement with retention of the 60-day period.

<u>Opt-Out</u>

Recommendations:

- The AMA supports the proposed revisions to 42 CFR 405.400, 405.450(a), and 498.3(b)(19).

CMS proposes two clarifications. The first would replace the reference in 42 CFR 405.450(a) and 42 CFR 498.3(b)(19) to a failure to timely renew opt-out with a reference to a failure to timely cancel automatic renewal, reflecting that opt-out periods renew automatically under section 1802(b)(3) of the Social Security Act absent affirmative notice. The second would provide that the opt-out period begins on the date the first submitted affidavit is signed, rather than on the date of a subsequent affidavit submitted at a Medicare Administrative Contractor's request.

The AMA supports both. The first corrects language that has caused confusion about whether affirmative action is required to maintain opt-out. The second protects physicians from losing opt-out time on account of contractor processing and aligns opt-out with the approach CMS applies to effective dates of billing privileges under 42 CFR 424.520(d).

Corrective Action Plans (CAPs), Rebuttals, and Appeals

Recommendations:

- The AMA supports the extension of CAP availability to denials under 42 CFR 424.530(a)(1), the addition of electronic mail as an acceptable form of notice, and the establishment of a rebuttal process for reactivation effective dates and urges CMS to confirm how receipt will be established.

The AMA supports these proposals. Extending CAP availability to denials under 42 CFR 424.530(a)(1) codifies existing practice and gives applicants a means of curing a deficiency rather than reapplying. Permitting notice by electronic mail should shorten the interval between a determination and the physician's awareness of it, which matters given the 15-day and 30-day periods that govern rebuttals, CAPs, and reconsiderations. The AMA asks that CMS confirm how receipt will be established, since the response periods run from the date of the notice.

The AMA also supports allowing physicians to rebut an assigned reactivation effective date under 42 CFR 424.546. A reactivation effective date determines whether a physician is paid for services furnished during a deactivation period, and physicians should have an avenue to be heard on it.

Savings, Costs, and Other Impacts Concerning the Provider Enrollment Provisions

Recommendations:

- The AMA urges CMS to publish for public comment revised information collection requirements accounting for the reporting and compliance burden these provisions would impose on physician practices, consistent with the Paperwork Reduction Act, before finalizing them.

- The AMA urges CMS to prepare and publish an initial regulatory flexibility analysis addressing small physician practices, which constitute a substantial share of the affected universe, or to state the basis for any certification that these provisions will not have a significant economic impact on a substantial number of small entities.

CMS projects annual savings of approximately $82 million from the expansion of retroactive revocation grounds, and approximately $1.4 million in annual survey or accreditation costs attributable to the hospice reactivation proposal. CMS states that it does not anticipate any information collection request costs stemming from the proposed provisions, and that it is unable to estimate additional savings from the new and expanded revocation reasons because it cannot predict how frequently those authorities would be used.

The AMA respectfully disagrees with the conclusion that these proposals carry no information collection cost. Several of them would require physician practices to gather, verify, and report information they do not collect today. Eliminating the five-year lookback at 42 CFR 424.519 would require practices to identify and report affiliations extending back to the beginning of a physician's career, including relationships with entities that no longer exist, and the proposed addition of marketing, business, fulfillment, financial, managerial, and beneficiary relationships to the definition of affiliation would enlarge that inquiry further. The expanded definition of "managing employee" at 42 CFR 424.502 would require practices to identify, screen, and report categories of clinical personnel not previously reported, and to maintain processes for reporting changes in those individuals within the timeframes at 42 CFR 424.516. The expanded definition of "operational" would require practices to develop and maintain written policies addressing patient care, patient safety, recordkeeping, and administration. The signage requirement at proposed 42 CFR 424.510(f) would require practices to install and maintain compliant signage at each applicable location. Each of these is a recurring administrative obligation with an ascertainable cost.

CMS reasons that these proposals impose no material burden because providers should already be reporting the enumerated categories of managing employees and because many providers likely already satisfy the expanded operational and documentation requirements. The AMA respectfully submits that this reasoning does not support the conclusion. If practices are not in fact reporting these individuals, the burden of coming into compliance is real and should be estimated. If CMS believes practices are already in compliance, then the premise that these are long-standing obligations sits uneasily with the proposal to enumerate them now and to make revocations for failing to report them retroactive under proposed 42 CFR 424.535(g)(1)(ix). The AMA asks CMS to quantify the burden and to seek comment on its estimates before finalizing.

The AMA also notes that CMS assesses the impact of the new and expanded denial and revocation grounds by reference to the small share of enrolled providers historically revoked and the projected 337 providers annually affected by retroactive effective dates. Those figures speak to how often the authorities have been used, not to the burden the proposals place on the more than two million providers who must interpret and comply with them. Physician practices must assess their exposure under these provisions regardless of whether an adverse action ever follows, and small practices without dedicated compliance staff bear that cost disproportionately. The AMA asks that CMS account for these effects in the final rule.

The AMA is also concerned that CMS assesses beneficiary access by reference to the number of providers who would remain enrolled. CMS states that the availability of healthcare would be unaffected, that healthcare availability would remain robust, and that access should remain strong, in each case because the proportion of providers subject to adverse action is small relative to the more than two million enrolled providers and suppliers. Access to care, however, is local and often specialty specific. A patient does not benefit from the continued enrollment of two million providers nationally if the physician who has managed that patient's care, or the only practice in the area furnishing a needed service, is removed from the program. In rural and underserved communities, and in specialties with limited local supply, the loss of a single practice can end access for a defined population.

That concern is heightened by the nature of several of the proposals. Where an enrollment action follows deliberate fraud, the loss of that provider is the intended result and beneficiaries are better protected by it. Where an action follows a late report of a managing employee, an inaccurate entry on a supporting document, a third party's Medicare debt, or the density of providers near a practice location, the physician removed from the program may be one who has furnished appropriate care to beneficiaries throughout. The patients of that practice bear the consequence. The AMA asks that CMS weigh that consequence in

the final rule, and that it evaluate access in terms of the communities and patient populations affected rather than the aggregate size of the enrolled provider universe.

Conclusion

The AMA appreciates the opportunity to comment on the provider enrollment provisions of the Proposed Rule and shares CMS' objective of protecting the Medicare program and its beneficiaries from fraud, waste, and abuse. We ask that CMS carefully consider the recommendations above, several of which restate concerns the AMA has advanced previously and that remain unresolved. We look forward to working with CMS to ensure that the enrollment regulations are appropriately targeted to the conduct CMS has identified, without creating uncertainty or disproportionate consequences for the physicians who care for Medicare beneficiaries in good faith every day.

Please reach out to me directly at 312-464-5288 or John.Whyte@ama-assn.org if you have questions or need further information.

Sincerely,

John Whyte, MD, MPH