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June 28, 2013

Marilyn B. Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: **Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment [CMS-6045-P].**

Dear Administrator Tavenner:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am pleased to provide our comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule entitled, *Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment* [CMS-6045-P]. We share CMS' commitment to eradicate fraud from the Medicare program. We continue to emphasize, however, that CMS not take an overly broad approach in doing so, and instead employ targeted, streamlined program integrity measures. Consistent with CMS' previous determination that physicians are of limited risk to the Medicare program,[1] the examples that CMS proffers in the proposed rule focus on higher risk non-physician providers. Also, CMS' proposals appear to be geared toward greater program integrity protections in regard to non-physicians. Thus, we oppose CMS' proposal to increase the incentives under the Incentive Reward Program (IRP) unless CMS provides the safeguards outlined below to ensure that this program does not unjustly affect or burden honest physicians. We also offer our detailed comments on CMS' other specific proposals.

Incentive Reward Program

We recognize CMS' effort to increase the efficacy of the IRP, which was mandated in 1996 by Congress under the Health Insurance Portability and Accountability Act (HIPAA), and intends to align the reward amounts with those offered in other similar programs, namely the Internal Revenue Service (IRS) Whistleblower Program and the awards available to relators under the False Claims Act (FCA). **However, we are very concerned that that the provision of a significantly increased**

[1] February 2, 2011. Centers for Medicare & Medicaid Services. Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers; Final Rule, available at http://www.gpo.gov/fdsys/pkg/FR-2011-02-02/pdf/2011-1686.pdf.

award amount will encourage false reports. We urge CMS to factor in the potential downstream effect of the increased award amount on physicians, the vast majority of whom are honest and do not commit fraud, and to insert protections into this process to prevent false reporting.

We are aware that CMS recently revised its Medicare Summary Notice (MSN) to increase beneficiary awareness regarding services billed, and included a new alert in the MSN text to let beneficiaries know that they may report suspected fraudulent activity and receive a reward. We have serious concerns, however, that numerous spurious reports will be filed by individuals wishing to "cash in" on the high reward amount if CMS includes the maximum potential award amount under its proposal, $9,900,000, in the text of the MSN, or in other CMS communications targeted toward beneficiaries and other individuals. While the reward amount is only available upon the actual imposition of a sanction, it is highly likely that this proviso will be lost in translation for many individuals, who may view the high reward amount as absolute. **We think that the numerous false reports likely to be produced by the lure of the high reward amount will result in wasted CMS time and resources, and therefore urge CMS to take strong measures to emphasize the process and beneficiary responsibilities in all of its communications on this program.**

CMS should also consider that under recently promulgated regulations which allow providers' payments to be suspended pursuant to a "credible allegation of fraud," many physicians may be unjustly affected by the rise in false reports generated by the increased reward amount. We raised concern with CMS during that rulemaking process that the proposed standard of a "credible allegation of fraud"—an "indicia of reliability"—was too low, and urged CMS to instead adopt a higher, more appropriate standard.[2] In spite of our concerns, CMS finalized the "indicia of reliability" standard, leaving the door open to payment suspensions based on unsubstantiated tips through 1-800-Medicare, 1-800-HHS-TIPS, or other avenues. We recommend that CMS carefully track and publicly report on whether reports generated following the increase in reward amount are unfounded, and employ payment suspensions based on such reports judiciously.

Should CMS decide to increase the award amount, CMS must implement procedural safeguards for the IRP to deter false reports. As CMS notes in the proposed rule preamble, relators who file FCA whistleblower suits generally obtain legal counsel prior to the filing of a FCA complaint, and may be significantly involved in the development of a FCA case. In general, it is our impression that FCA whistleblowers must consider the personal commitment of reporting under the FCA prior to initiating an action. We think that individuals who report through the IRP should be similarly bound to be personally responsible for the content and veracity of their report, and therefore support CMS' proposal to require a personal attestation that the information is accurate and truthful, and an acknowledgment that failing to provide truthful information could lead to criminal or civil liability. We further recommend that CMS require personal responsibility, at a minimum, similar to that required for relators in FCA whistleblower suits, to ensure that reporting under the IRP is not an action to be taken lightly or without justification.

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[2] November 16, 2010. Letter from Michael D. Maves, MD to Donald Berwick, MD regarding Medicare, Medicaid, Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions, and Compliance Plans for Providers and Suppliers; Proposed Rule [CMS-6028-P] available at http://www.ama-assn.org/resources/doc/washington/medicare-program-integrity-16nov2010.pdf.

We support CMS' proposal to exclude rewards for the same or substantially similar information that was the basis for a payment or a share of the amounts collected, under the FCA or any other state false claims act, or for the same or substantially similar information that is the subject of a pending FCA case. We also support CMS' proposal to clarify that an individual is not eligible for a reward if she or he is eligible for a reward for furnishing the same or substantially similar information to the federal government under any other federal reward program or payment under federal law. This exclusion is likely to deter forum shopping and decrease investigative and enforcement duplication, and could be strengthened by providing that an individual is excluded if eligible for a reward under any law, including state law.

We understand that the IRP statute permits awards for reports of fraud and abuse. Because "abuse" is a subjective term whose meaning is likely unknown to beneficiaries or other individuals who may report through the IRP, we strongly urge CMS to carefully review complaints related to abuse and to act on such complaints with caution.

Further, we note that the IRP statute permits rewards for reports regarding violations of the anti-kickback and civil monetary penalty (CMP) statutes. **We strongly oppose IRP rewards stemming from such reports, as beneficiaries and other individuals are not equipped to determine these types of violations, and should not be eligible to benefit financially from federal efforts to establish such violations.** Increasing the reward for such tips will only incentivize beneficiaries and other individuals to seek out activities for which they have no legal expertise to identify, and will result in false reports. We urge CMS to eliminate the anti-kickback and CMP statutes from the scope of the IRP program or, alternatively, eliminate reports regarding the anti-kickback and CMP statutes from the increased reward amount.

Provider Enrollment

Definition of Enrollment

Physicians have communicated a number of questions and concerns regarding provisions in the Affordable Care Act (ACA) that require providers who order or refer patients for certain Medicare and Medicaid services to be enrolled in those programs.

In regard to CMS' proposed rule, we understand that CMS intends to alleviate provider confusion by proposing to clarify in the Code of Federal Regulations (CFR) that enrollment in Medicare for purposes of ordering and referring does not afford billing privileges. However, we are concerned that without a proactive education effort by CMS, this confusion will persist. Physicians who have completed the 855-O enrollment form to enroll for purposes of ordering and referring are unlikely to appreciate the difference between enrolling for the purpose of ordering and referring Medicare services, and enrolling for the purpose of participating in and billing Medicare. In fact, from a physician's perspective, once enrolled, a physician should be able to enjoy all of the benefits of enrollment, namely, the ability to bill. **Should CMS decide to adopt the proposed clarification, CMS should make clear on the 855-O enrollment form, the online enrollment system, and all related educational materials that providers who enroll only to order and refer will not be accorded billing privileges, and that those physicians who intend to bill should instead enroll as Medicare participating providers.**

Opt-Out Status

CMS has clarified that physicians who have validly opted-out of the Medicare program are not required to enroll in Medicare for purposes of ordering and referring. We support this clarification. In addition, the AMA House of Delegates (HOD) recently considered the issue of Medicare requirements to opt-out, and adopted a resolution expressing concern about the requirement that a physician re-file an affidavit every two years to maintain opt-out status. This requirement creates the unnecessary burden of submitting documentation every two years, and failure to submit such documentation may expose physicians to significant penalties. **We urge CMS to amend its opt-out policy to allow physicians to opt-out of the Medicare program without a requirement to reaffirm that opt-out. After the two-year minimum required by law, the opt-out period should be effective indefinitely unless and until the physician chooses to terminate his or her opt-out status and private contracts with patients in order to rejoin Medicare as a participating or nonparticipating physician.**

Debts to Medicare

We support CMS' proposal to extend its enrollment denial authority, which currently permits CMS to deny an enrollment application if the current owner, physician, or non-physician provider has an existing overpayment at the time of filing of an enrollment application, to other providers and supplier entities. Because physicians have been determined by CMS to be of limited program integrity risk, and because CMS has identified other providers that present a heightened risk, it makes sense that CMS revise its enrollment denial authority to more effectively focus on those higher risk providers.

We do not support CMS' proposal to extend its enrollment denial authority to include the enrolling provider's or supplier's managing employees, corporate officers, corporate directors, and/or board members. We urge CMS to seriously consider that, pursuant to the ACA, many physician practices are adopting new delivery models through which they provide comprehensive, coordinated care in concert with other providers. We are concerned that CMS' proposal would require physician practices to undergo significant review of the managing employees, corporate officers, corporate directors, and/or board members of the entities with which they have integrated. To ensure that the implementation of new care delivery models is not impeded, we ask that CMS rescind this proposal. Alternatively, we urge CMS to exempt physicians, who are of limited program integrity risk, from the reach of this denial authority.

In the same vein, we oppose CMS' proposal that a denial of enrollment is warranted if the provider, supplier, or current owner thereof was the owner of another provider or supplier that had a Medicare debt that existed when the latter's enrollment was voluntarily or involuntarily terminated or revoked. We believe this proposal is overreaching and exhibits a lack of understanding of the complexities of the new coordinated care models that are evolving pursuant to payment and delivery reform advanced by the ACA. We posit the following example: Physician Practice A is applying for enrollment in Medicare. Hospital B owns Physician Practice A, and was also owner of Home Health Agency C, who voluntarily terminated its Medicare enrollment last year and has an outstanding Medicare debt resulting from a recovery auditor (RAC) audit currently under appeal. Physician Practice A's enrollment application could be denied because Hospital B owns Physician Practice A and previously owned Home Health Agency C, even if Home Health Agency C

is an entity with which Physician Practice A shared no patients, and had no practical affiliation or even knowledge of an affiliation. CMS should strongly consider that this situation will not be isolated; many of today's systems of care are diverse, geographically large, and encompass numerous entities and groups. In this environment, expanding the reach of CMS' enrollment denial authority to automatically deny enrollment based on second degree associations does not make sense. Furthermore, this proposal exceeds CMS' statutory authority at 42 U.S.C. 1395cc(j)(5), which provides that the Secretary *may* deny an application based on a disclosure of a current or previous affiliation, subject to a finding of "undue risk." At a minimum, CMS should revise the proposed CFR text to include the criteria for a finding of undue risk, as described in the proposed rule preamble, and to stipulate that a denial of enrollment "may be warranted," rather than "is warranted."

CMS also solicits comment on whether the term "overpayment" should be replaced with the term "debt" for purposes of CMS' authority to deny enrollment based on an outstanding overpayment. As a threshold matter, we urge CMS to consider that not all overpayments should be the basis for an enrollment denial. For example, CMS should not deny enrollment based on the overpayment determination of a Medicare auditor that is undergoing physician appeal. The purpose of providing appeal rights is to establish due process. Furthermore, Congress envisioned that physicians may equitably delay payment pending an appeal when it passed section 935 of the Medicare Modernization Act (MMA), the limitation on recoupment, which explicitly allows a physician to extend their repayment of an overpayment pending appeal. CMS should not employ its current authority to deny enrollment based on such outstanding overpayments. We are also concerned that similar inequities would result from an extension of the word "overpayment" to the word "debt." For example, denials due to debts resulting from coordination of benefits issues with secondary payers, and debts due to meaningful use audits, could unjustly prompt an enrollment denial. **We urge CMS to strictly narrow the scope of the term that it finalizes to ensure that physicians do not unreasonably experience enrollment denials.**

Felony Convictions

We appreciate CMS' statement in the proposed rule preamble that "certain felony convictions may raise more concerns than others, and [CMS] will continue to carefully assess the types of felony convictions that pose greater risk to Medicare beneficiaries and the Medicare trust fund." However, we note that CMS proposes to delete language in the CFR which currently provides that "CMS will consider the severity of the underlying offense" before denying an enrollment application due to a felony conviction. We believe the current language is consistent with CMS' stated rationale, and therefore urge CMS to retain this language. While some felony convictions may bear directly on the ability of a provider to care for patients, other felony convictions may be irrelevant to patient care, especially those that may be as many as ten years old. We ask that CMS judiciously employ its authority to deny or revoke the Medicare billing privileges of a provider or supplier due to a felony offense within the past ten years, and to use a reasonableness standard when considering such denials or revocations.

Abuse of Billing Privileges

We strongly oppose CMS' proposal to permit revocation of Medicare enrollment if CMS determines that a provider or supplier has a pattern or practice of billing for services that do not meet Medicare requirements, such as, but not limited to, the requirement that the service be

reasonable and necessary. We are concerned that this proposal is overreaching and could have unintended consequences for honest physicians. Should CMS adopt this proposal, we strongly urge CMS to exclude physicians, who are of limited program integrity risk.

As a preliminary matter, we note that CMS does not cite any statutory authority to extend its revocation authority to providers who have a so-called pattern of billing errors. This omission leads us to the conclusion that this proposal exceeds CMS' statutory authorization, and should therefore be rescinded.

There are also significant policy reasons for CMS to withdraw this proposal. Physicians may honestly submit claims for services that CMS subsequently determines not to be reasonable and necessary for a number of reasons, including unclear payment policies, inadequate contractor guidance, and new or revised documentation and coverage criteria. A physician may also reasonably submit a high volume of such claims because, consistent with their area of specialty, they treat patients with similar ailments, and bill the discrete set of codes that correspond to such treatments. The fact that a physician has submitted a claim that is inaccurate or incorrect, or the fact that the physician has submitted numerous such claims, is not in itself dispositive of fraud or abuse. We also remind CMS that because CMS contractors employ non-physicians to conduct many of its medical necessity reviews, medical necessity determinations are often contested and a matter of dispute. CMS contractors' poor record in regard to provider appeals of overpayment determinations is a clear indication that medical necessity determinations should not be the basis for revocation.[3]

CMS requests comment regarding whether there should be an intent standard for revocations based on the proposed policy. While we strongly disagree with the adoption of this policy, should CMS nonetheless choose to adopt, we do believe that there should be a specific intent standard. CMS should have evidence to show that a physician had "actual knowledge" at the time of claim submission that the claim did not meet Medicare requirements. We are aware of some instances when physician billing may be denied because the physician does not list the correct primary payer, and we believe that an "actual knowledge" standard would preclude enrollment revocations based on such honest mistakes. Between the two intent standards that are under CMS consideration—"reckless disregard" and "knew or should have known"—we believe "reckless disregard" would be a more appropriate standard. CMS should also include in the text of the CFR the factors that it cites in the proposed rule preamble to ensure that they continue to be used as guidelines for agency review, and should limit revocations based on the proposed policy to instances where CMS has data that indicate extreme outlier billing and an established and ongoing pattern of abusive practices.

Re-enrollment Bar

We support CMS' proposal to make clear that the re-enrollment bar does not apply in the event of a revocation based on a provider or supplier's failure to respond timely to a revalidation request or another request for information. We have worked closely with CMS to ensure that the revalidation effort is implemented appropriately, and appreciate CMS' understanding that many physicians who do not timely revalidate may fail to do so because they are unaware of the

[3] Centers for Medicare & Medicaid Services report entitled *Recovery Auditing in the Medicare and Medicaid Programs for Fiscal Year 2011*, available at http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Recovery-Audit-Program/Downloads/FY2011-Report-To-Congress.pdf. The report showed that 43 percent of provider-appealed claims were decided in favor of the provider.

requirement. We look forward to continuing to work with CMS on the revalidation effort as it moves forward and on an ongoing basis.

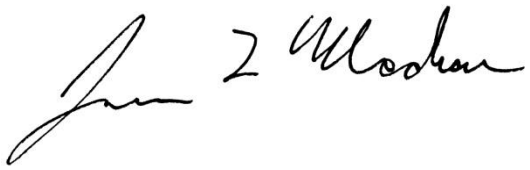
Corrective Action Plan

We do not support CMS' proposal to narrow the scope of instances in which a provider may submit a corrective action plan (CAP) to avoid revocation. We are specifically concerned with CMS' commentary in the proposed rule preamble that providers who fail to report a change in practice location should be subject to revocation without the opportunity to submit a CAP. CMS asserts that such a provider "should not be able to escape revocation merely by furnishing the truthful or updated information through a corrective action plan, as it was the provider's responsibility to provide this information earlier." CMS appears to be taking an overly punitive view in regard to the availability of CAPs, which may be appropriate in many cases, including when a provider has failed to timely update its practice location information. To ask such providers to go through the appeals process or to seek to re-enroll following revocation would be unjust. We therefore ask that CMS reconsider its proposal regarding CAPs with an eye toward excluding the option of submission only in those instances when such exclusion is truly warranted.

Conclusion

Thank you for the opportunity to provide our views on CMS' proposed rule entitled, *Medicare Program; Requirements for the Medicare Incentive Reward Program and Provider Enrollment* [CMS-6045-P]. Should you have any questions regarding our letter, please contact Carol Vargo, Assistant Director, Federal Affairs at carol.vargo@ama-assn.org or 202-789-7492.

Sincerely,



James L. Madara, MD