April 25, 2016

Andrew Slavitt, MBA
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6058-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Program Integrity Enhancements to the Provider Enrollment Process; Proposed Rule; 81 Fed. Reg. 405, 424, 455 (March 1, 2016)

Dear Acting Administrator Slavitt:

The undersigned physician organizations representing national medical societies are writing to provide comments on the proposed rule (CMS-6058-P) implementing program integrity enhancements to the provider enrollment process for Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

Our organizations strongly support the efforts of the Centers for Medicare & Medicaid Services (CMS) to protect its trust funds by ensuring that unqualified or potentially fraudulent individuals or entities are precluded from billing applicable programs. However, we are concerned that certain provisions in the proposed rule would significantly increase regulatory burden without efficiently targeting enforcement toward higher-risk enrollees. Accordingly, we offer suggested modifications to the proposed rule below.

First, CMS proposes a 5-year "look-back" period for previous affiliations. However, the event triggering the disclosure is not subject to any look-back limitations, meaning that the disclosable event could have occurred long in the past and before the reporting physician even established an affiliation with that entity. As the examples included in the rule suggest, the combination of a 5-year affiliation look-back period with an unlimited look-back period for the disclosable event creates an infinite look-back obligation for reporting physicians[1]. For this reason, we highly recommend establishing a finite look-

[1] 81 Fed. Reg. at 10725-10726 (March 1, 2016). **Example 1:** A provider is submitting an initial Form CMS-855A application in May 2017. The provider was the owner of a Medicaid-enrolled group practice from August 2014 to January 2015. The group practice had its Medicaid enrollment terminated in January 2010. Although the disclosable event (the termination) was imposed more than 5 years ago, it must be reported because the affiliation occurred within the previous 5 years.

Example 2: A supplier is submitting a Form CMS-855B (OMB Control No. 0938-0685) revalidation application. The supplier currently has a managerial interest in an ambulance company that was subject to a Medicare payment suspension 8 years ago. The affiliation and the payment suspension must be disclosed even though the latter was imposed outside of the 5-year affiliation look-back period.

back period for disclosable events, which should in no case precede the date that the physician established a covered affiliation with the relevant entity.

Second, CMS proposes that a disclosable event should be reported regardless of whether an appeal is pending or whether all parties have agreed to a repayment plan for uncollected debt. We urge CMS to reconsider this view as it presumes wrongdoing and ignores pending litigation, settlement agreements, repayment arrangements, and extenuating circumstances that could clarify the extent of the affiliation or other mitigating factors. Not only would this be a significant reporting burden, but it would overlook due process and require enrollees to report actions that may later be overturned or determined to be unfounded. Reporting an event that is currently undergoing appeal and later overturned could adversely impact physicians during the enrollment or revalidation process even if the event is later rendered non-disclosable by an appellate authority. More importantly, this approach sends the wrong message to the vast majority of physicians who are playing by the rules, paying back any uncollected debt, and trying to work through the legal or administrative process to resolve payment disputes.

Third, CMS discusses incorporating a "reasonableness" standard for reporting disclosable events based on a "knew or should reasonably have known" standard. Our organizations do not believe that developing an elaborate regulatory "reasonableness" test is necessary. However, we propose that the reasonableness standard should be based on the principle of good faith, and that physicians should be neither required nor expected to ferret out information about disclosable events relevant to their affiliations that they would not otherwise be aware of in the general course of business. Specifically, physicians should not be expected to know about disclosable events that occurred before the relevant affiliation commenced or after it terminated, nor is it realistic for them to pursue such information with respect to each affiliation that may fall within the 5-year look-back period as part of the routine enrollment or revalidation process. A presumption of good faith should be applied that takes account of the limited knowledge providers may possess regarding their affiliated entities, especially when the extent or duration of the affiliation is relatively minor.

Fourth, CMS is proposing to extend the maximum reenrollment bar from three years to 10 years, to include up to 20 years for a second revocation. Whereas CMS purports to find "precedent for this timeframe" in 42 CFR § 424.535(a)(3)(ii)—for providers who have been convicted of multiple felonies—we note that felony convictions involve substantially more due process than the largely administrative adjudications at issue here. We respectfully submit that 42 CFR § 424.535(a)(3)(ii) is not a precedent for the proposed reenrollment bar, but rather a cautionary note about the degree of due process that should be afforded to providers before such a draconian ban is imposed. CMS' assurance that only "egregious cases" will be subject to the longer bars is not an adequate substitute for a finding of criminal guilt beyond a reasonable doubt by a court of competent authority and jurisdiction. As such, we urge CMS to keep the three year maximum enrollment bar in place.

Fifth, CMS estimates an annual cost to providers and suppliers of $289.8 million in each of the first three years of this rule. This estimate is based on an average of 10 hours per enrollee at $34.16 per hour for administrative staff, inclusive of fringe benefits and overhead. We believe this estimate is too low

because it does not account for lost productivity to physician practices, including diversion of staff from clinical and related duties that directly impact and support patient care. Additionally, it does not factor physician time at all, assuming that physicians will be able to delegate the entire process to administrative staff, regardless of practice model or size. This is unlikely to be the case given normal staff turnover and significant changes over the past decade in how most practices are organized, along with structural reforms—such as the disruptive transition to health information technology—that have completely transformed business and administrative processes. The passage of Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) ensures that these changes will continue for at least another decade, making CMS' cost and time estimates for this rule extremely problematic. Practices do not have the "spare" staff resources—and almost certainly not with the requisite institutional knowledge—to document affiliations for individual physicians that go back 5 years or more and which may precede the transition to electronic records or any number of organizational changes. If CMS finalizes the proposal despite these concerns, we firmly believe that the regulatory impact analysis should be revised significantly upward in recognition of the challenges with completing a 5-year look-back on affiliations in today's rapidly changing healthcare market. Furthermore, the cost estimates should reflect the reality that the 10 hours estimated to complete the paperwork will be carved out of the enrolling physician's patient care time.

Finally, to the extent that CMS envisions implementation of this rule to be effectuated via contractor support, we urge CMS to be circumspect about incentivizing contractors based on the volume or percentage of providers whose enrollment or revalidation they deny. Given some of the experiences with Recovery Audit Contractors (RACs), we are wary of potential "bounty-hunting" behaviors by contracted personnel that may negatively impact physicians without appreciably achieving CMS' laudable program integrity goals.

We appreciate and support CMS' efforts to prevent its programs from assuming undue risks of fraud, waste, and abuse, while simultaneously urging CMS to adopt a more targeted approach that minimizes regulatory burden and focuses its enforcement efforts on the sources of greatest risk. Our organizations look forward to working further with CMS to ensure that program integrity vulnerabilities are adequately addressed, physicians are treated equitably, and patients are afforded access to the highest quality health care.

Sincerely,

American Medical Association
Advocacy Council of the American College of Allergy, Asthma and Immunology
American Academy of Child & Adolescent Psychiatry
American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American College of Cardiology
American College of Emergency Physicians

American College of Gastroenterology
American College of Mohs Surgery
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Osteopathic Association
American Psychiatric Association
American Society for Clinical Pathology
American Society for Dermatologic Surgery Association
American Society of Cataract and Refractive Surgery
American Society of Plastic Surgeons
American Urological Association
College of American Pathologists
Congress of Neurological Surgeons
Infectious Diseases Society of America
Medical Group Management Association
Society for Cardiovascular Angiography and Interventions
Society of Hospital Medicine