July 10, 2014

Sylvia Mathews Burwell  
Secretary, Department of Health & Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Re: Department of Health and Human Services, Office of the Inspector General, Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General’s Civil Monetary Penalty Rules; Proposed Rule; May 12, 2014; OIG-403-P

Dear Secretary Burwell:

On behalf of the nearly 13,000 U.S.-based members of the American Academy of Dermatology Association (AADA), I am responding to the Department of Health and Human Services (HHS), Office of the Inspector General’s (OIG’s) proposed rule published in the Federal Register on May 12, 2014, revising the OIG’s civil monetary penalty rules. The AADA is committed to excellence in medical and surgical treatment of skin disease; advocating high standards in clinical practice, education, and research in dermatology and dermatopathology; and supporting and enhancing patient care to reduce the burden of disease. The AADA appreciates the opportunity to provide comments to HHS on how revisions to the civil monetary penalty rules should be addressed and hopes HHS will take the AADA’s concerns and recommendations into consideration when formulating future policy.

Introductory Remarks

The AADA commends HHS on its interest in updating OIG’s authority to protect Federal health care programs from fraud and abuse through the use of civil monetary penalties. Moreover, we commend the OIG’s attempt to clarify ambiguities in the regulations. We question, however, the proposed rule’s expansion of civil monetary penalty regulations that—while intended to punish wrongdoers—may, in fact, ensnare and unfairly burden innocent providers.

The proposed rules related to civil monetary penalty authority clearly set the stage for an increase in the frequency with which the OIG imposes civil monetary penalties for various actions and the amounts of penalties imposed. The stakes are high for providers because Medicare is required to notify appropriate licensing authorities, state Medicaid programs, professional organizations, and peer review organizations when penalties or
exclusions are imposed—whether fairly or unfairly and consequently, HHS OIG action may effectively shut out providers from providing health care services before there has been a finding of culpability on the principal charges against the provider. Moreover, the AADA is concerned that these extraordinary repercussions may be imposed on providers under a low evidentiary bar of “gross negligence” or “knew or should have known.” The AADA urges HHS to reconsider the unintended consequences that these rules may have.

Expansion of Civil Monetary Penalty Provisions

Overpayment

The proposed rules attempt to clarify the penalty associated with Section 1128A of the Social Security Act, as amended by the Affordable Care Act (ACA), for failure to report and return overpayments. The statute defines an overpayment as any funds received by a health care entity that are in excess of amounts to be paid under Medicare statutes and regulations. Under the act, overpayments must be reported and returned by the latter of 60 days after the date the overpayment was identified or the date any corresponding cost report is due. The statute did not set forth a specific new penalty amount for this requirement, so the default penalty amount in the civil monetary penalties law of $10,000 for each applicable item or service has been applied. The HHS OIG, however, is now proposing that the civil monetary penalties law be interpreted to allow penalties of up to $10,000 for each day a person fails to report and return an overpayment after the 60-day deadline has passed.

Currently, penalties are tied to each item or service found to be in violation of applicable requirements, and they are not imposed on a per-day basis. The AADA urges the HHS OIG to re-think its proposal to assess penalties on a per-day basis. The AADA believes the HHS OIG proposal is unjustly harsh because of the potential magnitude of the proposed penalties and the frequency with which providers and suppliers may face potential overpayments. Accordingly, the AADA recommends that HHS OIG interpret the default penalty of $10,000 as applying to each affected claim for which the provider or supplier identified an overpayment, and not on a per-day basis.

In addition, the AADA is concerned that the proposed rule does not clarify when an overpayment is “identified.” Yet, the proposed rule would impose a significant monetary penalty on anyone retaining an overpayment after the 60-day period or cost report due date. Uncertainty still exists regarding when an overpayment has been identified and when the 60-day “clock” begins. According to the proposed rule, an overpayment is considered “identified”
when a person has actual knowledge of the overpayment or acts in “reckless
disregard or deliberate ignorance” of the existence of the
overpayment. Medicare providers navigating complex billing requirements
are often faced with a difficult challenge in determining whether a particular
claim caused an overpayment. We believe that complying with the 60-day
refund rule will add untold complexity to provider processes and procedures,
and expose provider organizations to unacceptable levels of risk. The AADA
believes that clarification of this issue is critically important to providers
because of the potential False Claims Act liability for failure to timely report
and return overpayments.

Moreover, while the proposed rule suggests a great deal of accuracy in
determinations regarding healthcare-related overpayments, government
publications suggest otherwise, and call into question whether the claims
review system is inherently fair. For example, a March 2011 Government
Accountability Office (GAO) report entitled, “Private Health Insurance: Data
on Application and Coverage Denials,” found that 39 percent to 59 percent of
appeals resulted in the insurer reversing its original coverage denial; a
November 2012 HHS OIG report entitled, “Improvements Are Needed At
The Administrative Law Judge (ALJ) Level of Medicare Appeals,” found that
61% of ALJ appeals are found in favor of providers; and a July 2013 GAO
report entitled, “Medicare Program Integrity: Increasing Consistency of
Contractor Requirements May Improve Administrative Efficiency,”
recommended addressing Medicare contractors’ inefficient processes that
complicated compliance and reduced effectiveness of claims reviews. These
publications, and a myriad of others raise our concerns that providers, who
receive inappropriate payment denials, will be unfairly placed at risk for
these extraordinary civil monetary penalties.

Accordingly, the AADA urges HHS OIG to re-think the proposed rule and
implement a rule that clarifies when an overpayment is identified and allows
HHS OIG to impose penalties only when an overpayment is both identified
and the provider defendant knowingly and improperly avoided repayment.

Access to Records
The HHS OIG proposes adding a penalty not to exceed $15,000 per day for
failing to grant timely access to records, upon reasonable request, for the
purpose of audits, investigations, or other inquiries. The rule gives HHS OIG
authority to impose penalties when a provider fails to produce the requested
material by the deadline specified in a written request or fails to provide
immediate access to requested materials when there is reason to believe the
material is about to be altered or destroyed.

The AADA is troubled that the proposed rule would give HHS OIG such wide
latitude to specify the date on which the responding party must provide
access to the requested materials. HHS OIG proposes to define the term “reasonable request” as a written request, signed by a designated representative of the OIG that would include the submission deadline.

While HHS OIG indicates that it would consider the circumstances of the request, including the volume of material and capabilities of the provider, the proposed rule does not specify a minimum amount of time for a responding party to provide a response. We are concerned that this could lead to inconsistent application of the regulations, and we urge HHS OIG to provide an objective standard and set a minimum time.

**False Statements**
The AADA is troubled with the proposed rule’s expansion of HHS OIG’s authority to impose a penalty of up to $50,000 for each false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program. While the ACA authorized penalties for false statements and misrepresentations of material fact, it did not include the word “omission” in describing the penalty. Including “omission” in actionable conduct would materially broaden HHS OIG’s authority for imposing penalties and may ensnare well-intentioned, unsuspecting providers—who had no intention to deceive. The AADA urges HHS OIG to follow the guidance of the ACA and adopt language that precludes imposition of penalties for an “omission.”

**Assessing Penalties for Employing Excluded Providers**
The proposed rule addresses assessment of penalties related to the provision of items or services payable by Federal health care programs by a person who has been excluded from such programs. An excluded individual may be involved in the provision of items or services that are separately billable to a Federal health care program, or that may not be separately billable. The HHS OIG proposed regulations to address how penalties and assessments for these two distinct types of scenarios should be determined.

In instances in which the items or services provided by the excluded person are separately billable, the employing or contracting entity would continue to be subject to penalties and assessments based on the number and value of those separately billable items and services. For items and services that are not separately billable, however, the proposed rule provides an alternate methodology for penalties, which would be based upon the number of days that the excluded person was employed or contracted with, and assessments would be based on the total costs of employing or contracting with the excluded person. The proposed rule looks at the entire cost of employing or contracting with the excluded person, with no proportional adjustment to the costs of the employed or contracted excluded person.
based upon the employer or contractor’s revenue derived from a Federal health care program.

The AADA objects to the HHS OIG’s proposal that would require the total amount of the excluded person’s compensation to be repaid, even if a portion of his or her time was not involved in Federal health care program items or services. We believe that equity demands that the rule allow for an adjustment that takes into account the pro rata amount of Federal health care program billings, and we strongly urge HHS OIG to modify its proposal accordingly.

**Drug-Price Reporting**

In the proposed rule, HHS OIG sets forth provisions related to drug-price reporting. Manufacturers are required to submit monthly and quarterly data on the average manufacturer price of their products, quarterly data on the average sales price, and other sales information.

The AADA believes the HHS OIGs proposal interprets the statute in a way that could provide HHS OIG with significantly greater latitude and leverage to impose larger penalties. We are particularly concerned about the provision that allows HHS OIG to calculate penalties at the “9-digit” National Drug Code (NDC) level so that a penalty could be applied for each day that any individual 9-digit NDC was late. Under this interpretation, the HHS OIG could seek penalties of up to $50,000 per day, rather than $10,000 per day, against a manufacturer for a single late report if that report contained data for five different products.

We are troubled that the proposed standard may result in imposition of unjustly harsh penalties for manufacturers even when the late reporting results from only one isolated event. We believe that patients, not the manufacturers, will be adversely impacted by these extraordinary penalties because any hit to the manufacturers’ bottom line will ultimately hurt patients’ access to reasonably priced medications.

**Mitigating Factors in Assessing Penalties and Exclusions**

The proposed rule lists new factors to be considered in determining penalties and exclusion periods, including the nature and circumstances of the violation, the degree of culpability of the person, the history of prior offenses, and other wrongful conduct.

The AADA is troubled that as part of the “degree of culpability” factor, HHS OIG proposes a new aggravating factor that would allow HHS OIG to consider whether a person had a level of intent to commit a violation that is greater than the minimum intent required to establish liability. Under the
proposed rule, a person who has actual knowledge of a false or fraudulent claim would not only incur liability, but would also be subject to a finding of an aggravating factor. This seems grossly unfair because it is a subjective standard that lends itself to inconsistent application. The AADA urges HHS OIG to remove this provision from the final rule.

Moreover, we are concerned that the proposed rule also provides that possessing a lower level intent to commit a violation will not be considered a defense against liability or a mitigating factor. While the proposed rule states that taking appropriate and timely corrective action would be a mitigating circumstance, the only way to qualify for this mitigating factor is to disclose the violation through OIG's Self-Disclosure Protocol and fully cooperate with OIG in resolving the violation. We believe that providers should be given broader avenues to show that they have engaged in timely corrective actions. Accordingly, the AADA believes this approach, which is overly limiting and disproportionally punitive, militates against fairness in the civil monetary penalty process. We urge HHS OIG to reconsider these provisions, to be mindful of creating an equitable system that ensures due process, and to provide an alternate proposal that affords providers a reasonable opportunity to present mitigating circumstances.

In addition, the proposed rule broadens how OIG considers the history of prior offenses or other wrongful conduct factors. The rule provides that aggravating circumstances include the prior offenses or wrongful conduct of the entity itself, any individual who had a direct or indirect ownership or control interest in the entity and who knew, or should have known of the violations, or any individual who was an officer or managing employee of the entity. In addition, the rule proposes broadening the scope of conduct considered to include prior offenses or wrongful conduct to allow HHS OIG to consider private insurance fraud in addition to other offenses related to the delivery of healthcare items or services. These provisions reflect a grape shot approach against people or entities with only a tenuous relationship to the culpable party. The AADA recommends that HHS OIG re-think these provisions. The AADA urges HHS OIG to craft provisions focused on penalizing the truly culpable—not penalizing those who are innocent, without any knowledge of or control over the inappropriate conduct.

EMTALA Violations
The AADA is troubled by the provisions in the proposed rules, which pertain to HHS OIG’s authority to impose CMPs against physicians and hospitals for Emergency Medical Treatment and Labor Act (EMTALA) violations. Under the proposed rules, both the hospital on-call physician and the hospital itself may be subject to liability of up to $50,000 for each violation of their respective EMTALA obligations, even if such violation is based in
negligence. We believe these proposals unjustly expand OIG’s civil monetary penalty authorities and could ensnare well-intentioned providers. We urge HHS OIG to adopt a provision that does not impose penalties where a violation is based only on negligence and not on willful conduct.

**Conclusion**
Overall, the AADA believes that the proposed changes are unjustly harsh in their potential to penalize well-intentioned, innocent, and ethical providers. The proposed rule implements a punitive approach through a very low bar to enforcement that allows imposition of extraordinary penalties as well as provider exclusion based on alleged, minor and possibly inaccurate charges from the distant past. The asymmetric enforcement authority of the OIG relative to the ability of a provider to appeal a civil monetary penalty or exclusion action would practically limit significant avenues for redress in case of inappropriate decisions. Ethical, competent and committed providers should not be so excessively vulnerable to civil monetary penalties and potential exclusion from a major government program through which they provide ongoing, vital care to millions of Americans.

The AADA appreciates the opportunity to provide comments on this proposed rule revising the OIG’s civil monetary penalty authorities. We look forward to additional opportunities to comment on these issues and to provide feedback that may help guide policy development. Please contact Richard Martin, JD, Assistant Director, Regulatory Policy, at (202) 842-3555 or RMartin@aad.org if you require clarification on any of the points or would like more information.

Sincerely,

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