OIG proposes expansion and changes to civil monetary penalty regulations, including proposed penalty for failure to timely refund overpayments

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The Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) has been very busy drafting new regulations. On May 12, 2014, the OIG issued a proposed rule that would amend the civil monetary penalty (CMP) rules of the OIG to incorporate new CMP authorities, clarify existing authorities, and reorganize regulations on civil money penalties, assessments and exclusions to improve readability and clarity. Using the proposed rule, the OIG intends to update CMP regulations to codify changes made by the Affordable Care Act (ACA). We have outlined some of the key proposals below.

Expanded Scope of Conduct

Since the ACA significantly expanded the OIG's authority to protect federal health care programs from fraud and abuse, including the type of conduct that would predicate a CMP, chief among the OIG's proposals is an attempt to codify the following five new types of conduct that would subject a person to penalties, assessments and/or exclusion from participation in federal health care programs:

1. Failure to grant OIG timely access to records;
2. Ordering or prescribing while excluded;
3. Making false statements, omissions or misrepresentations in an enrollment application;
4. Failure to report and return an overpayment; and
5. Making or using a false record or statement that is material to a false or fraudulent claim.

Penalty for Failure to Report and Return Overpayments Within the 60-Day Deadline

The proposed rule establishes the penalty associated with "failure to report and return overpayments." Under the ACA, overpayments must be reported and returned by the later of 60 days after the date the overpayment was identified or the date any corresponding cost report is due, if applicable. Since no specific penalty amount was specified in the ACA and the default penalty amount of "up to $10,000 for each item or service" has generally been used, the OIG is proposing that the penalty for failing to report and return an overpayment within the 60-day timeframe be up to $10,000 for each day a person fails to report and return an overpayment by the deadline. In addition, because Congress did not specify per-day penalties for the section in the ACA pertaining to returning overpayments, the OIG is also soliciting comments on whether to instead interpret this default penalty as pertaining to each claim identified as an overpayment, rather than on a per-day basis.

CMPs Against Part D and Medicare Advantage Contracting Organizations

In the proposed rule, the OIG also addressed codification of some changes to the exposure of Part D and Medicare Advantage contracting organizations to CMPs that were made by the ACA, including that:

- The OIG can impose CMPs against Part D and Medicare Advantage contracting organizations not only for the misconduct of their employees or agents, but also of the providers and suppliers with which they contract, regardless of whether

these latter entities are agents.

- The ACA created new categories of misconduct that can serve as the basis for CMPs, including:

> 1. Enrolling individuals without prior consent;
> 2. Transferring enrollees to another plan without prior consent;
> 3. Transferring an enrollee "solely for the purpose of earning a commission;"
> 4. Failure to comply with applicable marketing restrictions; and
> 5. Employing or contracting with anyone who engages in certain wrongful conduct, including failure to provide medically necessary care and discouraging enrollment by vulnerable eligible individuals.

Changes to the Factors Relevant to Determining the Amount of a CMP

To reflect changes in the costs of health care since the regulations were last updated in 2002, the OIG proposes to increase the claims-mitigating factor by increasing the maximum dollar amount considered as mitigation from $1,000 to $5,000. The OIG noted: "We believe this updated amount is an appropriate threshold that is consistent with rationale behind the original amount. A dollar threshold as a mitigating factor for CMP purposes differentiates between conduct that could be considered less serious and more serious. Conduct resulting in more than $5,000 in federal health care program loss is an indication of more serious conduct." Similarly, the OIG also proposes to revise the claims-aggravating factor from the vague "substantial" to "$15,000 or more" in order to "increase transparency and provide" better guidance to the provider community on OIG's evaluation of this factor."

Additional proposed changes to determining the amount of a CMP include:

- Proposed aggravating factor – degree of culpability factor: If the person's level of intent to commit the violation is greater than the minimum intent required to establish liability (having a lower level of intent will not be considered a mitigating factor though);
- Proposed mitigating factor – degree of culpability factor: Taking appropriate and timely corrective action in response to the violation. This proposed factor would require that the violation be disclosed to the OIG through its Self-Disclosure Protocol and full cooperation with the OIG through its review and resolution of the disclosure;
- Proposed aggravating factor – prior offenses or other wrongful conduct: The OIG's proposed rule clarifies that in determining the appropriate remedy against an entity, the OIG will consider not only the prior offenses of the entity itself, but also of any individual who had a direct or indirect ownership or control interest in the entity at the time the violation occurred and who knew or should have known of the violation, and any individual who was an officer or a managing employee of the entity at the time the violation occurred; and
- Clarifies that any consideration of a sanctioned person's financial condition in determining the amount of a CMP would only be considered after the OIG proposes the amount of the penalty, at which time the person may request consideration of his/her ability to pay.

Other significant changes in the proposed rule include:

Finally, the American Hospital Association (AHA) expressed concern about the proposed rule in a letter dated July 7, 2014, to OIG's Inspector General Daniel Levinson. In the letter, the AHA urged that (1) the OIG to maintain the current six-year limitation period for initiating an exclusion action and (2) the penalty for failing to meet the deadline for returning an overpayment should be applied on a per-item or service basis.

- Clarification that a principal's liability for the acts of its agent does not limit or extinguish the liability of the agent. Agents

remain liable for their own misconduct, as well. The proposed changes to the CMP regulations make that clear.

- New or revised definitions for the following terms: "claim," "item or service," "knowingly," "material," "overpayment," "reasonable request," "responsible official," "select agent program," "responsible physician," "separately billable item or service," and "non-separately billable item or service."
- Proposed new methodology for determining the amount of a CMP when the item or service provided by an excluded individual is not separately billable to a Federal health care program to permit a penalty based on the number of days the excluded person was employed, was contracted with, or otherwise arranged to provide non-separately billable items or services. Assessments (as opposed to penalties) would be based on the total costs to the employer or contractor of employing or contracting with the excluded individual during the exclusion, including salary, benefits, and other money or items of value.
- Revisions to CMPs for violating Section 1140 of the Social Security Act, which prohibits the use of words, letters, symbols, or emblems of the Department of Health and Human Services, The Centers For Medicare & Medicaid Services (CMS), Medicare, or Medicaid in an "advertisement, solicitation, circular, book, pamphlet, or other communication, or a play, motion picture, broadcast, telecast, or other production" in a manner that could reasonably be interpreted as conveying the false impression that HHS, CMS, Medicare, or Medicaid has approved, endorsed or authorized such use. The proposed revision would clarify the applicability of Section 1140 to telemarketing, internet and electronic mail solicitations. The OIG is also soliciting comments for how to interpret Section 1140 in the context of social media such as Facebook and Twitter.
- Add regulations providing for CMPs for tipping off a skilled nursing facility, nursing facility, home health agency or community care setting of the date or time of a survey. These facilities are subject to state compliance surveys without any prior notice. Federal law provides for a penalty of up to $2,000 against any individual who notifies an entity, or causes an entity to be notified, of the time or date on which a survey is scheduled to be conducted. The regulations reiterate the federal law prohibition and set forth the general factors to be considered when determining the amount of the CMP.
- Revisions to the Emergency Medical Treatment and Labor Act (EMTALA) CMP to:
    1. Clarify that on-call physicians at any participating hospital subject to EMTALA, including the hospital a patient initially presents to and the hospital with specialized capabilities or that has received a request to accept a transfer, face potential CMP and exclusion liability under EMTALA; and
    2. Revise the factors to clarify that aggravating circumstances include: a request for proof of insurance or payment prior to screening or treatment, patient harm, unnecessary risk of patient harm, premature discharge, or a need for additional services or subsequent hospital admission that resulted or could have resulted from the incident, and whether the individual presented with a medical condition that was an emergency medical condition.

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