OIG PROPOSES SUBSTANTIAL CHANGES TO ITS CIVIL MONETARY PENALTY RULES

EXECUTIVE SUMMARY

On May 12, 2014, the Office of Inspector General ("OIG") issued proposed rules to substantially revise its Civil Monetary Penalty Rules ("Proposed Rules"). The Patient Protection and Affordable Care Act ("ACA") and the Medicare Prescription Drug, Improvement and Modernization Act enhanced OIG's statutory authority to exclude persons from participating in federal health care programs and impose civil monetary penalties ("CMPs") for violations of applicable program requirements. OIG now seeks to revamp the exclusion and CMP regulatory framework to adopt these changes. In particular, OIG proposes a new CMP for a provider's perceived failure to timely return identified program overpayments, puts forth aggravating and mitigating factors that impact OIG's assessment of CMPs, introduces new CMPs for certain Emergency Medical Treatment and Labor Act ("EMTALA") violations and codifies its methodologies for calculating damages and fines for the employment of, or contracting with, excluded individuals. The Proposed Rules apparently will be part of a series of new regulations that OIG plans to promulgate to clarify the existing CMP regulations as OIG acknowledges in the commentary that the current regulatory framework is "cumbersome and potentially confusing for the reader." A copy of the Proposed Rules is available here.

HIGHLIGHT OF PROPOSED CHANGES

While the Proposed Rules introduce several new instances in which OIG may impose a CMP, perhaps one of the most significant of these is the proposed CMP for failing to report and return an overpayment within 60 days of identification. Currently, CMPs are tied to each item or service found to be in violation of applicable requirements and are not imposed on a per-day basis. OIG now proposes that a penalty of $10,000 should apply to each day a provider fails to return and report an overpayment after expiration of the 60-day refund period set forth in Section 1128J(d) of the Social Security Act. OIG further suggests in the commentary that this CMP may apply "to each claim for which the supplier or supplier identified an overpayment" but specifically requests comments on this interpretation.

The Proposed Rules provide more insight as to the factors OIG considers when assessing the imposition of CMPs. For example, OIG considers the following aggravating factors in assessing the gravity of the alleged offense for CMP purposes:

- The time period of the misconduct;
- Whether the misconduct was a one-time event or if there was a pattern of misconduct;
- The magnitude of the misconduct;
- The materiality or significance of a false statement, including omissions;
- The number of people involved in the misconduct;
- The number of victims;
- Whether any patients were harmed; and
- The level of intent of the individuals involved in the misconduct.

OIG further proposes that in the claims context, any conduct that results in a loss greater than $15,000 to federal health care programs will be categorized as a "serious misconduct." In the past, OIG declined to attribute a specific dollar figure in assessing the seriousness of a claim-based violation and merely referred to a "substantial loss" to federal health care programs as an aggravating factor. OIG now suggests instead that referring to a specific dollar amount "increases transparency and provides better guidance to the provider community on OIG's evaluation of this factor." OIG does not elaborate on how this standard may apply in instances when there may be multiple overpaid claims that together may exceed this threshold.

Interestingly, OIG proposes to consider provider level of intent to commit a violation as a potential aggravating, but not a mitigating, factor in determining the appropriate CMP. That is, OIG will consider a situation in which the provider had a higher level of intent, such as actual knowledge, to commit the violation as an aggravating factor. On the other hand, OIG makes it clear that ignorance of the law is no excuse,

and possessing a lower level of intent to commit a violation will not be considered "a defense against liability, a mitigating factor, or a justification for a less serious remedy."

From a mitigation standpoint, the Proposed Rules express OIG's expectation that to receive "credit" as a mitigating factor for taking corrective action, providers must actually disclose the underlying violation to OIG through its Self-Disclosure Protocol. The Proposed Rules make no mention in this regard of self-disclosures made to the CMS Self-Referral Disclosure Protocol or voluntary refunds to Medicare Administrative Contractors.

The Proposed Rules also recognize other conduct set forth in the ACA that may create CMP exposure. These new CMP scenarios include the following:

- Failing to grant OIG timely access to records;
- Ordering or prescribing while excluded;
- Making false statements or misrepresentations in the provider enrollment process; and
- Making or using a material false record or statement to support a fraudulent claim.

Further, the Proposed Rules clarify OIG's authority to impose CMPs against physicians and hospitals for EMTALA violations. Under the Proposed Rules, both the hospital on-call physician and the hospital itself may be subject to CMP liability of up to $50,000 ($25,000 for hospitals with fewer than 100 Medicare-certified beds) for each violation of their respective EMTALA obligations, even if such violation is based in negligence. Such on-call physicians are further subject to exclusion if they commit flagrant or repeated EMTALA violations.

Finally, the Proposed Rules codify OIG's long-standing damage or "assessment" calculations for employing excluded individuals. One methodology applies to the situation in which an excluded person provides separately billable items or services, such as an excluded physician ordering covered services or an excluded pharmacist filling program prescriptions. The second approach addresses those situations in which services of the excluded person are not subject to separate payment under federal health care programs as would likely be the case, for example, with excluded provider support personnel. These damages methodologies were included in OIG's *Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health* Care Programs, which was published last year. (See Hall Render's article on this topic here). In addition to the damages or "assessments" described above, the Proposed Rules allow OIG to further impose a CMP of not more than $10,000 for each day that a provider employs or contracts with an excluded individual when the individual's services are not separately billable to federal health care programs. For individuals who provide separately billable items or services, the CMP will continue to apply to each item or service in violation of the applicable requirements.

PRACTICAL TAKEAWAYS

Providers should closely monitor the development of these Proposed Rules and others likely to follow regarding the enhancement of OIG's CMP authority. As OIG suggests, these Proposed Rules will likely mean CMP enforcement and collections will likely intensify in the future. In particular, providers should be aware of the potential impact that the Proposed Rules could have on them if they do not promptly return program overpayments. Providers should also carefully consider whether OIG will view potential violations as being more serious offenses based on the aggravating factors set forth in the Proposed Rules. In addition, providers should assess the impact of self-disclosure as a mitigating factor based on the Proposed Rules. With the new penalty options available under the Proposed Rules, the presence of mitigating factors may be more important to providers in a CMP enforcement setting than ever before.

Providers that wish to submit comments on the Proposed Rules have until 5:00 PM EST on July 11, 2014. If you are interested in submitting comments or if you have any questions regarding the Proposed Rules or CMPs please contact:

- Scott W. Taebel at staebel@hallrender.com or 414-721-0445;
- Nicholas A. Gonzales at ngonzales@hallrender.com or 414-721-0486; or
- Your regular Hall Render attorney.

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