



DHHS OIG Proposes New Rules That Could Expand Exclusion Authority and Increase Civil Monetary Penalties

BY PAUL A. GOMEZ

The Department of Health and Human Services Office of Inspector General (“OIG”) recently proposed new rules¹ related to its permissive exclusion and civil monetary penalty authority, respectively. If these proposed rules are finalized, it could result in a greater number of instances in which providers are excluded from participation in federal healthcare payor programs. It could also increase the frequency with which the OIG imposes civil monetary penalties for various conduct and the amounts involved. Some of the material proposed rule changes follow below.

Expansion of Permissive Exclusion Authority

No Statute of Limitations

Perhaps one of the most controversial aspects of the proposed rule changes is the OIG’s assertion that there is no statute of limitations upon its ability to exercise its exclusion authority under Section 1128(b)(7) of the Social Security Act (the “Act”) for false or improper claims. According to the OIG, no time bars should apply to this exclusion authority even when the exclusion would be based upon violation of another statute that has a specific limitations period. This would be a significant expansion of the OIG’s permissive exclusion authority and could potentially subject providers to exclusion for conduct that occurred several years in the past.

The OIG proposed a similar rule change more than ten years ago. Commenters at the time opined that if the exclusion is based upon the OIG’s determination that another law has been violated, the program exclusion period should be the same as the limitations period for the law that had been violated. Commenters expressed concern that an individual or entity could be excluded for activities that occurred years beforehand and that do not bear on their current trustworthiness or integrity. They expressed further that with the significant passage of time, evidence becomes difficult or impossible to gather in order to prepare a sufficient response and mount a solid defense. The comments and concerns led the OIG to drop that proposed expansion of permissive exclusion authority in 2002², but it has resurrected that proposal now, notwithstanding that the same concerns voiced by commenters when the expansion was initially proposed will likely resurface once again.

Potential Severe Consequences for Error in Applications for Participation and Enrollment

Building upon authority granted in the Affordable Care Act (“ACA”), the proposed rule reaffirms that the OIG may exclude any individual or entity that knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid or contract to participate or enroll as a provider of services or supplier under a federal healthcare program. Although one would hope that any enforcement under this rule would be limited only to those situations in which the fact that is misrepresented or omitted is truly material and the misrepresentation or omission was made knowingly, what is material or knowing may be subject to interpretation and misunderstanding. Moreover, as anyone who has had the experience of gathering information for and preparing Medicare enrollment applications (or other similar federal healthcare programs) can relate to, omission of certain information or an “inaccurate” response to requested information can easily result from confusion and miscommunication, rather than a knowing omission or misrepresentation, or intention to make a false statement. Providers will need to take great care in preparation of their Medicare (and other federal payor program) enrollment and participation applications and be mindful of the potentially severe consequences that may follow erroneous or incomplete responses.

Broadening the Scope

The OIG proposed to broaden the scope of its permissive exclusion authority to exclude any individual or entity furnishing, ordering, referring for furnishing or certifying need for items or services that does not provide necessary payment information as required to the government. Currently the language pertains to “furnishing” items or services for which payment may be made. The proposed rule would expand the language and authority to include individuals or entities that also order such items, refer such items for furnishing, or certify the need for such items.

Expansion of and Changes to Civil Monetary Penalty Law

Calculating Penalties for Failure to Report and Return Overpayments Within Sixty Days

The proposed rules attempt to clarify the penalty associated with Section 1128A of the Act (as amended by the ACA) for failure to report and return overpayments. Under the Act, overpayments must be reported and returned by the latter of sixty days after the date the overpayment was identified or the date any corresponding cost report is due, as applicable. No specific new penalty amount was set forth for this requirement, so the default penalty amount in the Civil Monetary Penalties Law (“CMPL”) of \$10,000 for each applicable item or service has generally been understood to apply. However, the OIG is proposing that it may be appropriate to interpret the CMPL default penalty as imposing up to \$10,000 for each day a person fails to report and return an overpayment after the sixty day deadline has passed. Notwithstanding the foregoing, the OIG acknowledged that Congress specified per day penalties in amending other sections of the Act, but did not specify a per day penalty for the particular Section pertaining to overpayments, and so is requesting comments about whether it should, instead, interpret the default penalty of \$10,000 referred to above as applying to each affected claim for which the provider or supplier identified an overpayment, and not on a per day basis.

Assessing Penalties for Employing Excluded Providers

In the proposed rule, the OIG also addressed how to assess penalties related to the provision of items or services payable by federal healthcare 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 healthcare program, or that may not be separately billable. The OIG expressed that it is difficult to determine the appropriate penalty and assessment for claims that are not separately billable by the excluded individual. Moreover, the OIG discussed the increasing use and movement toward bundled payments and prospective payment systems and noted that when an excluded individual provides items or services that are not separately billable, but rather, are part of a comprehensive “package” of items or services that are billed and paid together, it may result in prohibition on the entire payment. The OIG acknowledged that such a prohibition could lead to a disproportionate assessment in relation to the harm to the applicable federal healthcare payor program. As result, the OIG proposed regulations to address how penalties and assessments for these two distinct types of scenarios should be determined – one for instances in which the items or services at issue are separately billable and one for instances in which the items or services at issue are not separately billable to a Federal healthcare program.³

In instances in which the items or services provided by the excluded person are separately billable, the employing or contracting person or 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 OIG proposed 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 OIG indicated that it believes this is a fair and reasonable way to assess penalties against employers or contractors who utilize excluded persons for applicable items or services, without imposing sanctions that are disproportionately harsh. Of note, however, is that the OIG’s proposal in this regard is somewhat different from the formula it set forth related to excluded persons in its Self-Disclosure Protocol (“SDP”). The main difference, which may be inadvertent, appears to be that the proposed rules do not include a further adjustment to the costs of the employed or contracted excluded person based upon the employer or contractor’s revenue that derives from a federal healthcare program. Under the SDP, one would look to the total cost of employing or contracting the excluded individual and then multiply that by the proportion of the employer or contracting party’s revenue that consists of payments from a federal healthcare program during the applicable time period. The proposed rule apparently looks at the entire cost of employing or contracting with the excluded person, with no such proportional adjustment. It remains to be seen whether comments will draw attention to this apparent discrepancy and how the OIG will respond.

Mitigating Factors in Assessing Penalties and Exclusions

The OIG expressed a desire to clarify the factors to be considered in determining penalties and exclusion periods. The OIG identified what it believed to be the most common issues among the applicable factors that are already listed in 42 C.F.R. Section 1003.106 and created a single, primary list of factors in a new proposed 42 C.F.R. Section 1003.140. The primary factors are: (1) the nature and circumstances of the violation, (2) the degree of culpability of the person, (3) the history of prior offenses, (4) other wrongful conduct, and (5) other matters as justice may require. The OIG views this as an illustrative, and not a comprehensive or exhaustive list. According to the OIG, these factors would apply to all CMPL violations, except as otherwise provided specifically by statute or regulation.⁴

Take Away

The proposed rules largely codify or attempt to clarify amendments to the CMPL that were set forth in the ACA. It may result in more intense enforcement activity on the part of the OIG, particularly with respect to overpayment-related penalties and excluded persons, and exercise of its permissive

exclusion authority several years after alleged underlying conduct occurred. However, certain proposed clarifications regarding mitigating factors may potentially serve to limit the severity of certain penalties, even as the overall level of enforcement intensifies. Healthcare providers and suppliers will need to wait for the final rule to be published after the comment period to learn where all of these proposals will land. The commenting period for the proposed rules expires in July of this year and we expect that the final rules will be issued later this year.

✧ ✧ ✧

If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings lawyers:

Atlanta

Craig Smith
1.404.815.2366
craigsmith@paulhastings.com

Phillip Street
1.404.815.2216
phillipstreet@paulhastings.com

Tara Ravi
1.404.815.2368
tararavi@paulhastings.com

Los Angeles

Paul A. Gomez
1.213.683.6132
paulgomez@paulhastings.com

Joshua Hill
1.213.683.6328
joshuahill@paulhastings.com

Tomer Konowiecki
1.213.683.6278
tomerkonowiecki@paulhastings.com

James F. Owens
1.213.683.6191
jamesowens@paulhastings.com

Jenny Wang
1.213.683.6119
jennywang@paulhastings.com

¹ 79 Fed. Reg. 27080 (May 12, 2014) (regarding Civil Monetary Penalties Law) and 79 Fed. Reg. 26810 (May 9, 2014) (regarding Exclusion Authority).

² 67 Fed. Reg. 11928, 11929 (March 19, 2002).

³ The OIG proposed new definitions for “non-separately-billable item or service” and “separately billable items or service”. *Id.* at 27093.

⁴ 79 Fed. Reg. 27080, 27082 (May 12, 2014)