PUBLICATION

Despite Uncertain Future of ACA, OIG Issues Final Rule Revising Permissive Exclusion Authority

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On January 12, 2017, the Department of Health and Human Services (HHS), Office of Inspector General (OIG) published a final rule expanding its permissive exclusion authority while also codifying certain statutory changes made by the Accountable Care Act (ACA). The final rule comes almost three years after the OIG issued its proposed rule, which was published in May 2014.

The rule's stated effective date is February 13, 2017. In the meantime, however, the new administration issued a memorandum on January 20, 2017, instituting a regulatory freeze that allows the administration additional time to review all pending regulations and determine whether to initiate rulemaking to modify or rescind any of those regulations. As a result, the OIG's final rule may be further delayed.

Of further note, in light of the new administration's focused efforts to repeal the ACA, those provisions of the final rule with authority based in the ACA are at risk and may be impacted in the event of a repeal.

Highlights of the final rule are outlined below. For a more detailed discussion of the provisions as they were proposed, please see our *Health Law Alert* article, "OIG Proposes Updates to Exclusion and CMP Authority."

Ten-Year Statute of Limitations

The OIG is adopting a ten-year limitations period for permissive exclusions initiated under 42 CFR 1001.901(false or improper claims) or 42 CFR 1001.951 (fraud and kickbacks and other prohibited activities). The ten-year period is intended to align with the False Claims Act statute of limitation.

The ten-year limitations period marks a reversal from the proposed rule, under which the OIG had sought to bar the application of any statute of limitations to such exclusion actions. The reversal comes in response to public comments and reflects the OIG's efforts to provide "certainty to the industry" while also preserving the OIG's ability to "protect the programs and individuals from untrustworthy persons identified in FCA cases or otherwise."

Accountable Care Act, Permissive Exclusion Authorities

With this final rule, the OIG seeks to codify, and provide context for, certain ACA provisions expanding the OIG's permissive exclusion authority.

- *Obstruction of audits*: The ACA expanded the application of the OIG's permissive exclusion authority to include obstruction of audits. The OIG declined to define *audit*, but noted that the term *audit* would include both official inspections and examinations by government entities or contractors for the purpose of "verifying compliance with Government program standards."
- *Failure to supply payment information*: Current regulations provide for exclusion of certain individuals and entities that fail to provide payment information to HHS. With the ACA, the pool of individuals and entities to which this provision may apply was expanded – encompassing not only those that furnish or order Medicare or Medicaid items/services, but also those individuals or entities that *refer for furnishing* or *certify the need* for such items or services.

- *False statement in a participation application*: The ACA added a permissive exclusion authority for knowingly making or causing to be made any false statement, omission or misrepresentation of material fact in any application, agreement, bid or contract to participate or enroll as a provider of services or supplier under a federal health care program. In codifying this expanded authority and discussing its application, the OIG noted that it would not be limited to pursuing only those cases in which a false statement influenced the decision to deny or approve enrollment.

Ownership or Control Interest in Excluded Entities

Current regulation allows for the OIG to exclude any individual who has a "direct or indirect ownership or control interest in a sanctioned entity" and knew or should have known of the conduct at issue. With this final rule, the OIG seeks to clarify that an individual who has been excluded under such circumstances will be excluded for the same period as the entity, regardless of whether the individual terminates his or her relationship with the entity after he or she has been excluded.

Financial Harm, Aggravating Factors

The OIG finalized, with modification, its proposal to update the aggravating factor, financial loss levels for certain permissive exclusions. It maintained its proposed $15,000 financial threshold with respect to exclusions based on the provision of substandard care, while increasing to $50,000 the financial threshold for exclusions on the basis of convictions relating to program or health care fraud, or obstruction of an investigation or audit.

Testimonial Subpoenas

Consistent with its new authority under the ACA, the OIG finalized its proposed regulation allowing the agency to issue testimonial subpoenas in investigations of potential cases involving the exclusions statute. (Previously, the OIG's power to issue testimonial subpoenas had extended only to CMP claims and did not reach exclusion cases.)

Early Reinstatement

The OIG finalized, with modification, a process for early reinstatement for those individuals excluded as a result of the loss, suspension or revocation of their state license. In the final rule, the OIG sets forth several factors it will consider in determining whether early reinstatement is appropriate. In doing so, the OIG emphasizes that it retains its discretion in how it evaluates and applies those factors specific to individual cases.

The final rule sets the presumption against reinstatement at three years for individuals who are seeking reinstatement without a health care license (in contrast to five years in the proposed rule). However, there are exceptions. To the extent the term of the license revocation or suspension assigned by the licensing board exceeds three years, the licensing board's term will control and early reinstatement will not be available. In addition, early reinstatement will not be available where the basis for license loss, suspension or revocation related to patient abuse or neglect.