With just a week left before a new administration takes office, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) finalized changes to the regulations authorizing OIG to exclude individuals or entities from participation in federal health care programs. The final rule is the most substantial revision to the exclusion regulations in many years and reflects changes made by the Affordable Care Act (ACA) in 2010 and the Medicare Modernization Act (MMA) in 2003, as well as informal practices that OIG has now codified in regulations. The final rule eases OIG’s proposals slightly by adding a 10-year limitations period for exclusion actions and making other minor modifications, but many of the new exclusion rules are largely unchanged from the proposed rule (79 Fed. Reg. 26,809 (May 9, 2014)).

10-year limitations period for exclusion actions

Bowing to strong opposition, OIG finalized a 10-year limitations period for exclusion actions. OIG had proposed not to apply any limitations period to exclusion proceedings, even though OIG’s other administrative remedies are subject to a 6-year limitations period and, in many cases, exclusion is based on the violation of a statute that is subject to its own limitations period.

The final rule is particularly relevant to individuals and entities that are considering resolution of False Claims Act (FCA) investigations or litigation. FCA actions are subject to a 10-year limitations period. In the proposed rule, OIG had argued that the exclusion statute (Section 1128 of the Social Security Act) does not require a limitations period, and that limiting exclusion actions to the 6-year period governing OIG’s other remedies would prevent OIG from pursuing exclusion based on FCA cases that are resolved more than 6 years after the conduct at issue, or force OIG to act prematurely if the FCA case is not yet resolved. Commenters responded that imposing no limitations period would leave individuals or entities subject to exclusion long after the underlying violation was resolved or the statute of limitations for the underlying violation had expired, preventing the finality and efficient administration of justice that a limitations period is designed to provide.

OIG chose a middle ground by finalizing a 10-year limitations period. The 10-year period matches the FCA limitations period and provides a point of finality for individuals and entities
that decide to forgo administrative settlement with OIG when entering into a settlement with the Justice Department to resolve alleged FCA violations (or that are not facing FCA allegations). The 10-year period also may allow OIG more time to pursue exclusion actions after resolution of FCA liability in many instances. OIG considers this an important positive feature of the longer limitations period, arguing that with more time after an FCA case settles, OIG will be better able to consider the factors relevant to whether it should pursue exclusion, including “the defendant’s willingness to agree to appropriate compliance terms.”

Finally, OIG acknowledged comments asking OIG to consider a shorter limitations period with the option of tolling the period, for example, while FCA litigation is being resolved. OIG rejected this suggestion, arguing that it would be inefficient for the OIG to consider tolling the limitations period on exclusion actions on a case by case basis.

**Codification of permissive exclusions under the ACA**

The ACA expanded OIG's authority to exclude individuals or entities from participating in federal health care programs where OIG deems it appropriate to protect programs and beneficiaries from fraud and abuse. The final rule codifies OIG's authority to exclude based on the following:

- Convictions relating to obstruction of an investigation or audit;
- Failure to provide payment information, including by individuals who “order, refer for furnishing, or certify the need for” items or services paid for by Medicare or State healthcare programs; and
- Making false statements or misrepresenting material facts in applications to participate as a provider or supplier under a Federal healthcare program.

**Changes to exclusion of individuals with ownership interests in excluded entities**

The final rule amended 42 C.F.R. Section 1001.1051 (now redesignated as Section 1001.1551) to allow OIG to exclude individuals who hold ownership or control interests in excluded entities, but OIG agreed to eliminate ambiguous language from the proposed rule that could have been read to allow exclusion of individuals who terminated their ownership or control interest in an excluded entity before the individual was excluded. The proposed rule read: “The length of the individual's exclusion will be for the same period as that of the sanctioned entity with which the individual has or had the prohibited relationship” (emphasis added). The final rule states simply: “If the entity has been excluded, the length of the individual’s exclusion will be for the same period as that of the sanctioned entity.” Moreover, the key provision of the regulation remains unchanged and states that OIG may exclude any individual who “has a direct or indirect ownership or control interest in a sanctioned entity” (emphasis added).

**Changes to aggravating and mitigating factors**

OIG also finalized several changes to the aggravating and mitigating factors that the agency
considers in determining whether to increase the length of exclusion above the minimum required. Mitigating factors are only considered if OIG has established one or more aggravating factors. The finalized changes include:

- Updating the dollar amounts for aggravating and mitigating factors that consider the financial loss to Federal healthcare programs as a result of the misconduct (including by increasing the financial loss required to apply an aggravating factor from US$15,000 in the proposed rule to US$50,000 in the final rule, except with respect to exclusions that are based on providing substandard care rather than other convictions);

- Reworking the existing aggravating factors regarding other offenses into two new factors, one of which considers adverse actions based on offenses separate from those forming the basis of the exclusion and the other which considers adverse actions based on the same offenses; and

- Removing the mitigating factor related to availability of alternative sources of the type of healthcare items or services furnished by the person; note, however, OIG will still consider this factor in determining whether a permissive exclusion should be imposed at all.

Note that OIG did not finalize its proposal to remove all aggravating and mitigating factors that currently permit OIG to lengthen periods of exclusion where the exclusion derives from the loss of a healthcare license and exclusion or suspension from a federal or state health care program. OIG reasoned that it may be appropriate in some cases for OIG to impose longer or shorter periods of exclusion than the period of license suspension or revocation or health care program exclusion.

**Creation of early reinstatement procedures for exclusion related to the loss of a license**

The final rule creates a new process to allow early reinstatement of individuals who are excluded under SSA Section 1128(b)(4) because of the loss of their healthcare licenses for reasons related to their professional competence, professional performance, or financial integrity. Previously, such individuals were not eligible to be reinstated until the lost license is restored. Under the new rules, such individuals may apply for early reinstatement if they obtain, or are permitted to retain, a healthcare license in another state, or retain a different healthcare license in the same state, or if they do not have a valid healthcare license but can demonstrate that they would no longer pose a threat to Federal healthcare programs and beneficiaries of such programs. The final rule also includes factors OIG will consider in determining whether early reinstatement is appropriate, which are modified slightly from the proposed rule.

**Expansion of certain definitions**

The final rule also broadened certain definitions to clarify that a person or entity has “furnished” an item or service not only when the person or entity “submits a claim” to a federal health care program but also when the person or entity “requests or receives payment” by any other means. As OIG notes, this definition is intended to align with the broad definition of a “claim” under the
FCA and to reflect the various methodologies by which federal programs pay providers and suppliers. Note that, although the focus of the changes was on OIG’s exclusion authority, these revised definitions apply to the full set of regulations governing OIG authorities, including the regulations authorizing OIG to impose civil monetary penalties (CMPs) and the regulatory safe harbors under the federal anti-kickback statute.

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If you have any questions about the final exclusion rules, or any other questions related to federal fraud and abuse laws, please contact one of the Hogan Lovells lawyers listed below.

**Contacts**

Sheree R. Kanner
Partner

Thomas Beimers
Partner

Jonathan L. Diesenhaus
Partner

Helen R. Trilling
Senior Counsel

Ronald L. Wisor, Jr.
Partner

Eliza L. Andonova
Partner

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