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Client Briefing

Life Sciences Health Industry

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OIG Finalizes Expanded Exclusion Authorities under ACA

On January 12, 2017, the Office of Inspector General (OIG) of the Department of Health and Human Services issued the final rule implementing its statutory authority under the Affordable Care Act (ACA) to expand the exclusion regulations applicable to persons or entities receiving funds, directly or indirectly, from federal health care programs (Final Rule).[1] *The Final Rule was issued with an effective date of February 13, 2017; however, the Final Rule is subject to a temporary postponement of its effective date, until approximately March 21, 2017, pursuant to a memorandum issued by the Trump administration delaying implementation of pending regulations to allow the new administration time for review.*

Overview

The Final Rule expands the OIG's exclusion authority in order to protect the federal health care programs and their beneficiaries from payments to potentially "untrustworthy" health care providers. Specifically, the Final Rule expands OIG's permissive exclusion regulations to reach individuals and entities convicted of interfering with or obstructing investigations and audits, failing to provide payment information, and making false statements and misrepresentations of material facts in applications to participate in the federal health care programs. Further, the Final Rule implements a 10-year limitations period, grounded in the False Claims Act limitations period, within which OIG must bring an exclusion action. Additionally, the Final Rule clarifies certain definitions and implements several changes to the aggravating and mitigating factors the OIG considers when determining whether to increase or decrease the length of a violator's exclusion period. Ultimately, the Final Rule significantly strengthens OIG's exclusion authority by expanding the grounds for exclusion and the depth of its reach to individuals and entities.

This Client Alert provides an overview of the Final Rule, with a focus on substantive changes from the OIG's proposal in 2014, including:

- Expanded exclusion authorities

- New statute of limitations period
- Changes to existing exclusion authorities
- The early reinstatement procedures
- Various procedural changes related to the OIG's exclusion authorities
- Revisions to certain definitions

Given the heightened discussion among various members of Congress with regard to the potential repeal of, or significant alteration to, the ACA, and the potential for substantive regulatory changes from the Trump administration, we note that there may be additional changes to the OIG's exclusion authority.

Background

On May 9, 2014, the OIG proposed to expand the exclusion regulations applicable to persons or entities that receive, directly or indirectly, funds from federal health care programs (the Proposed Rule).[2] OIG cited statutory authority in the ACA, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), as a basis for the expansion of its exclusion authority. Of note, the OIG identified the protection of the federal health care programs and their beneficiaries from "untrustworthy health care providers" (i.e., individuals and entities who pose a risk to beneficiaries or the integrity of the programs) as the underlying purpose of its expanded exclusion authorities in the Proposed Rule.

By delegation from the Secretary of the Department of Health and Human Services, the OIG has been granted authority to exclude individuals and entities from participation in the federal health care programs in certain instances under section 1128 of the Social Security Act (the Act). The Act provides the OIG with two mechanisms for exclusion authority—mandatory and permissive:

1. ***Mandatory exclusions*** (section 1128(a) of the Act) are required for any individual or entity convicted of a "program-related crime," such as patient abuse or neglect, and certain felonies related to health care delivery, governmental programs, and controlled substances. Mandatory exclusions last at least five years, and can result in permanent exclusion.

2. ***Permissive exclusions*** (section 1128(b) of the Act) permit the OIG to exclude individuals and entities for a broad range of conduct. Permissive exclusions, in turn, consist of two types: (1) "derivative" exclusions, i.e., those that are based on actions previously taken by a court or other law enforcement or regulatory agency; and (2) "affirmative" exclusions, which are based on the OIG's own initiative and administrative action for misconduct, such as poor quality care, kickbacks, submission of false claims, and other program integrity matters. Permissive exclusions have no five-year minimum, and can vary in duration. Importantly, an excluded person is not permitted to participate in federal health care programs until the excluded person is officially reinstated.

While OIG's exclusion authority relates to conduct affecting the federal health care programs, it provides guidance for individuals and entities not participating in such programs, because the conduct leading to OIG exclusion generally also can form the basis for a suspension or debarment (although such suspension or debarment is subject to different formal criteria). Suspension and debarment are much broader government-wide actions and are not just limited to federal health care programs. When a contractor is suspended, proposed for debarment, or debarred, the contractor cannot receive new contract awards. Further, for existing contracts, the government cannot make new orders (beyond minimum ordering thresholds), add new work, or otherwise extend the contract.

Expanded Exclusion Authority

The ACA drastically expanded OIG's permissive exclusion authority to include and cover the following situations: (1) obstruction of audits or investigations; (2) failure to provide payment information; and (3) making false statements or misrepresenting material facts.

Conviction related to obstruction of an audit or investigation

The Final Rule implements the ACA's statutory expansion of the OIG's exclusion authority to permit exclusion (1) when the conviction involves either the obstruction of an investigation or *the obstruction of an audit* related to any criminal offense that is a basis for mandatory exclusion or permissive exclusion, or (2) when the investigation or *audit* relates to the use of federal health care program funds received by the individual or entity, either directly or indirectly. In the Final Rule, OIG declined to define "audit," but instead stated that the term would be given its "general, common sense meaning," including inspections and examinations by government entities or contractors "verifying compliance with Government program standards."[3] The practical effect of these changes is that an audit, which could be relatively informal in nature, will be considered on par with a formal investigation for exclusion purposes. This significantly expands the OIG's exclusion authority.

The Final Rule implements all revisions as proposed by the OIG for exclusion relating to the obstruction of an investigation or audit, except that the amount of financial loss that will be regarded as an aggravating factor in determining the length of an exclusion was increased to $50,000, from the proposed amount of $15,000. The OIG stated that this increased amount "better reflects the threshold amount"[4] that should be considered for when the length of an exclusion should be increased.

Failure to provide payment information

Under the pre-ACA regulations, the OIG had the authority to exclude "any individual or entity that furnishes items or services for which payment may be made" under Medicare or Medicaid, who fails to provide certain payment information related to those services. The ACA significantly expanded the OIG's

authority to apply this basis for exclusion, not only to the provider or entity *directly furnishing* the services, but also to any individual or entity "ordering, referring for furnishing, or certifying the need for" items or services.

The Final Rule codifies this authority at 42 C.F.R. section 1001.1201, as proposed. The practical effect of the change is to expand dramatically the number of providers and/or entities that are subject to exclusion for failure to provide certain payment information. In addition to the actual provider of services being subject to possible exclusion, other upstream providers and/or entities that did not actually render the services may face scrutiny. Taken to the logical conclusion, the OIG now can seek to exclude the referring physician who did not bill for the items or services in question.

Making false statements or misrepresentation of material facts

The ACA also established a new basis for permissive exclusion for 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 health care program.

Although proposed as new regulation 42 C.F.R. section 1001.1751, OIG codified the new authority at 42 C.F.R. section 1001.1552 with some changes to the Proposed Rule. OIG finalized the proposed definition of "material," while clarifying that the OIG does not intend to pursue exclusion under section 1128(b)(16) of the Act based on inadvertent errors and minor oversights.

However, in response to several comments, the OIG revised the factors to be considered when determining the length of exclusion. Namely, because of concerns that vague factors could lead to arbitrary results, commenters suggested that the applicable factors be more specific than the vague two-factor list that the OIG proposed. The OIG agreed with commenters that more specific factors would be appropriate and, as such, replaced one factor[5] with two factors in the Final Rule: (1) the nature and circumstances of the false statement; and (2) whether and to what extent payments were requested or received from the federal health care programs under the application, agreement, bid, or contract on which the false statement was made.

Statute-of-Limitations Period

In response to extensive comments objecting to the OIG's Proposed Rule that there be no time limitations within which to impose affirmative exclusions for false claims, kickbacks, and other prohibited activities under section 1128(b)(7) of the Act, the OIG adopted a 10-year statute-of-limitations period for exclusion actions.

Initially, the OIG proposed that an exclusion would be neither time-barred nor subject to any statute-of-limitations period, even when the exclusion is based on violations of another statute that might have a specific limitations period. However, the Final Rule instead codifies a 10-year limitations period for exclusion actions for several reasons.

First, the OIG recognized that older conduct is less pertinent to current trustworthiness and, consequently, a limitations period for such exclusion actions would better protect the federal health care programs and beneficiaries.

Second, there is a palpable intersection between section 1128 of the Act and the False Claims Act (FCA), according to the OIG. The FCA, which is the federal government's primary civil remedy for health care fraud, authorizes exclusions as potential remedial actions to protect federal health care programs and beneficiaries. A majority of federal health care program fraud actionable under the FCA also may serve as a basis for exclusion under section 1128(b)(7) of the Act. Notably, the FCA allows for complaints to be filed up to 10 years after the alleged conduct.

Lastly, the OIG acknowledged that many FCA cases are not resolved until years after the claim is issued, and therefore there is a potential overlap of section 1128(b)(7) exclusion actions and FCA matters that are already in progress. Although inevitable under some circumstances, such overlap should become less frequent with a 10-year statute-of-limitations period in place. In effect, the 10-year statute of limitations allows the OIG to consider all relevant factors before making an exclusion decision, while providing individuals and entities with some certainty regarding an outside limit for potential exclusion actions.

Changes to Existing Exclusion Authority

Exclusion Based on Certain Types of Convictions – The OIG had proposed to narrow the scope of providers excluded under sections 1128(a)(4) and (b)(3) of the Act for convictions related to controlled substances to those who were convicted for offenses that occurred during the time they were employed in the health care industry. The OIG did not adopt this proposal because it concluded that the proposal would have caused beneficiaries to lose protection from violators who left the health care industry before committing the relevant offense, and then re-entered the industry post-conviction.

Aggravating and Mitigating Factors – The Final Rule modifies a variety of factors the OIG considers when determining the appropriate length of an exclusion. As a general rule, the OIG can extend an exclusion period if the aggravating factors justify the extension. OIG also considers any mitigating factors that justify shortening the exclusion period. Below are several aggravating and mitigating factors that the OIG modified in its Final Rule:

(i) *Derivative exclusions for license revocation/suspension.* The OIG reconsidered and did not adopt its proposal to remove consideration of the aggravating and mitigating factors for a derivative exclusion based on a license revocation/suspension. The OIG explained that its reconsideration was because it is appropriate in certain instances to have the authority to impose longer or shorter periods of exclusion than those imposed by licensing boards.

(ii) *Monetary thresholds.* The Final Rule increases the financial loss threshold necessary to trigger an aggravating factor to: (1) $15,000 for excessive

claims or furnishing of necessary or substandard items or services; and (2) $50,000 for mandatory and permissive exclusions involving health care fraud or obstruction. The OIG explained that these increases reflect the OIG's experience resolving health care fraud matters, and better serve the purpose of aggravating factors—i.e., to provide for an additional period of exclusion for those cases that involve high losses.

Early Reinstatement

The Final Rule implements an early reinstatement process for individuals excluded because of actions taken against their health care license for professional competence, performance reasons, or financial integrity. The OIG finalized certain aspects of its proposal and clarified other portions. Specifically, the OIG listed several factors that it will consider when determining whether to grant an individual's or entity's request for early reinstatement where the exclusion was based on loss of a license and, after full disclosure to a second licensing authority, the second licensing authority grants a license to the individual or entity, or decided not to take any adverse action as to a currently held license:

1. The circumstances that formed the basis for the exclusion
2. Whether the second licensing authority is in a state that is not the individual's primary place of practice
3. Evidence that the second licensing authority was aware of the circumstances surrounding the action that formed the basis for the exclusion
4. Whether the individual has demonstrated that he or she has satisfactorily resolved any underlying problem that caused or contributed to the basis for the initial licensing action
5. The benefits to the federal health care programs and program beneficiaries of early reinstatement
6. The risks to the federal health care programs and program beneficiaries of early reinstatement
7. Any additional or pending license actions in any state
8. Any ongoing investigations involving the individual
9. All the factors used by the OIG generally to consider reinstatement of excluded persons, set forth in 42 C.F.R. section 1001.3002(b)

In the Final Rule, the OIG also explained that it will retain discretion in determining which factors are most relevant to, and to consider the relative weight of each factor on, any individual case. The OIG confirmed that it also will consider a broad range of investigations (by private insurers or third parties) even if those investigations do not directly impact federal health care programs.

The OIG additionally clarified that the Final Rule does not make early reinstatement available to individuals who lost their licenses for reasons related to patient abuse or neglect. These individuals will be required to obtain the license that they lost, in the state where they lost it, before the OIG will consider a reinstatement application.

Procedural Changes

The Final Rule implements a number of procedural changes impacting the OIG's exclusion process in order to codify recent statutory directives contained in the Medicare Modernization Act (MMA) and the ACA. As a result, the Final Rule provides greater consistency between the OIG's statutory authority and its implementing regulations.

Significantly, the OIG declined to implement its proposed changes to the regulations addressing the scope and effect of an exclusion, found at 42 C.F.R. section 1001.1901(c), in order to expand application of the current regulations to Medicare Parts C and D (Medicare Advantage and Prescription Drug Plans, respectively). As a result of its decision not to implement those revisions, the OIG also declined to create its proposed limited exception to the general prohibition against paying for items or services ordered by an excluded physician, where the enrollee and the pharmacy did not know that the prescribing physician was excluded.

The Final Rule also provides an additional opportunity for individuals and entities subject to exclusion to request and present oral argument to OIG. Previously, OIG heard oral argument for exclusions because of excessive charges or unnecessary services, or failure to furnish medically necessary services. Now the OIG can hear oral arguments for exclusions as a result of false statements or misrepresentations of material facts in documents related to a federal health care program. OIG clarified that such hearings would be before an OIG official prior to exclusion, not presented as an appeal before the Departmental Appeals Board.

Additionally, OIG made clarifying revisions in the Final Rule related to its notice of intent to exclude and to the withdrawal of exclusions previously made. Specifically, the Final Rule removes the requirements for a notice of intent to exclude and notice of exclusion (42 C.F.R. sections 1001.2001 and 1001.2002), but retains the requirement that OIG issue a notice of proposal to excluded pursuant to 42 C.F.R. section 1001.2003, and clarifies that OIG will withdraw exclusions that are derivative of convictions reversed or vacated on appeal by the excluded individual or entity. OIG will provide notification of withdrawals and reinstatements to the same state agencies originally notified of the related exclusion, and will notify the public of such withdrawals through its monthly updates to the List of Excluded Individuals and Entities.

The Final Rule also implements the proposed changes to OIG's testimonial subpoena authority under 42 C.F.R. section 1006.1, which reflects the ACA's statutory expansion of OIG's authority to issue such subpoenas when the

OIG pursues exclusions for both permissive and mandatory exclusions under section 1128 of the Act.

Finally, the Final Rule expands without comment OIG's authority to grant waiver requests under 42 C.F.R. section 1001.1801, as proposed in the Proposed Rule.

Changes in Definitions

The Final Rule also included non-substantive "technical changes," such as reorganization of certain subparts of part 1001,[6] and expanded the definition of a number of key terms. Importantly, the Final Rule adopted the OIG's proposed changes to the definitions of "furnished," "directly," and "indirectly," as follows:

> **"Furnished"**
>
> Furnished refers to items or services provided or supplied, directly or indirectly, by any individual or entity. ~~This includes items and services manufactured, distributed or otherwise provided by individuals or entities that do not directly submit claims to Medicare, Medicaid or other Federal health care programs, but that supply items or services to providers, practitioners or suppliers who submit claims to these programs for such items or services.~~
>
> **"Directly"**
>
> Directly, as used in the definition of "furnished" in this section, means the provision or supply of items and services by individuals or entities (including items and services provided or supplied by them, but manufactured, ordered, or prescribed by another individual or entity) who ~~submit claims to~~ request or receive payment from Medicare, Medicaid, or other Federal health care programs.
>
> **"Indirectly"**
>
> Indirectly, as used in the definition of "furnished" in this section, means the provision or supply of items and services manufactured, distributed, supplied, or otherwise supplied provided by individuals or entities ~~who~~ that do not directly ~~submit claims to~~ request or receive payment from Medicare, Medicaid, or other Federal health care programs, but that provide items and services to providers, practitioners, or suppliers who ~~submit claims to~~ request or receive payment from these programs for such items and services. ~~This term does not include individuals and entities that submit claims directly to these programs for items and services ordered or prescribed by another individual or entity.~~

These new definitions update the regulations to account for new payment methodologies involving federal health care programs—i.e., methodologies other than traditional fee-for-service claims—that have emerged since the OIG's last revision to the regulations. Such new payment methodologies include, for

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example, “shared savings payments or performance-based payments,” “capitated payments,” and diagnosis resource groups that account for supplies a provider may not have used during that specific patient’s episode of care.

OIG also explains that these definitional changes are consistent with the broad definition of “claim” in the FCA. Because OIG views “the underlying conduct triggering an exclusion action [as] comparable to that pursued under the FCA,” it has expanded its exclusion authority to reach “newer fraud schemes.”

Finally, OIG adopted without comment its proposed revisions to establish new regulatory definitions for certain terms that are currently defined either by cross referencing the statute or in an explanatory clause, and to delete certain definitions that are not relevant to the OIG’s exclusion rules.

Conclusion

The Final Rule greatly expands and strengthens OIG permissive exclusion authority—that is, instances where OIG has the discretion to exclude—by expanding the grounds for exclusion and broadening the reach to additional entities, and for longer timeframes. Health care providers and suppliers, of all levels and specialties, should be cognizant of OIG’s new exclusion authorities, and should ensure compliance with the new requirements so as to avoid any potential issues that could arise and fall within the OIG’s new authority.

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1 82 Fed. Reg. 4100 (Jan. 12, 2017), available at https://www.gpo.gov/fdsys/pkg/FR-2017-01-12/pdf/2016-31390.pdf.

2 79 Fed. Reg. 26810 (May 9, 2014), available at http://www.gpo.gov/fdsys/pkg/FR-2014-05-09/pdf/2014-10390.pdf.

3 82 Fed. Reg. 4100, at 4104.

4 *Id*. at 4103.

5 This proposed factor read in pertinent part: “What were the actual or potential repercussions of the false statement, omission, or misrepresentation of a material fact.”

6 Specifically, the Final Rule moved 42 C.F.R. section 1001.1051, addressing the exclusion of individuals with an ownership or control interest in a sanctioned entity, to a new 42 C.F.R. section 1001.1551; moved the definition of “Federal health care program” from 42 C.F.R. section 1001.2 to 42 C.F.R. section 1000.10, with minor grammatical revisions; and revised “CMPs” to “civil monetary penalties” in 42 C.F.R. section 1001.1001(a)(2).

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