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OIG FINAL RULE SIGNIFICANTLY EXPANDS EXCLUSION AUTHORITY

On January 12, 2017, the Department of Health and Human Services Office of Inspector General ("OIG") published the "Health Care Programs: Fraud and Abuse; Revisions to the Office of Inspector General's Exclusion Authorities" Final Rule ("Final Rule") revising and expanding its authority to exclude individuals and entities from participation in federal health care programs. The Final Rule includes new and revised exclusion authorities implemented by the Affordable Care Act ("ACA"), as well as clarifications to existing regulatory provisions that reflect OIG's policies and practices. Given recent events designed to repeal the ACA, it is difficult to predict whether the exclusion expansion will remain. Below is a brief summary of the key regulatory changes contained in the Final Rule, which is effective February 13, 2017.

STATUTE OF LIMITATIONS FOR AFFIRMATIVE EXCLUSIONS

In response to extensive comments objecting to OIG's Proposed Rule dated May 9, 2014 ("Proposed Rule") that there be no time limitations to impose affirmative exclusions for false claims, kickbacks and other prohibited activities under 1128(b)(7) of the Social Security Act, OIG adopted a ten-year statute of limitations period for exclusion actions. OIG noted the ten-year time period is consistent with the False Claims Act ("FCA") statute of limitations and that "most section 1128(b)(7) exclusion matters considered by OIG are related to FCA cases." Because OIG and DOJ work closely together in FCA settlements, the Final Rule is designed to allow them to coordinate and resolve exclusions while at the same time reduce the risk of OIG initiating exclusion proceedings while FCA litigation is pending. OIG further acknowledged that in determining whether to seek exclusion, OIG often considers factors that cannot be determined until the case is resolved, including the individual's or entity's willingness to agree to appropriate compliance terms. The ten-year statute of limitations allows OIG to consider all relevant factors before making an exclusion decision while providing individuals and entities a point of finality.

NEW DEFINITIONS OF KEY TERMS

The Final Rule also included new expanded definitions for a number of key terms (i.e., "directly," "indirectly" and "furnished"). Specifically, OIG changed language in the definitions from "submit claims to" to "request or receive payment from" to convey that providers who request or receive federal health care program funds, whether directly or indirectly, through the submission of claims or other payment mechanisms, are still subject to exclusion. Similarly, OIG referenced the broad definition of "claim" under the FCA to recognize the various ways payment is requested from the federal government. These new definitions reflect amendments to the FCA to capture payments that ultimately come from the government, even when claims are not submitted directly to a government payor. They also capture a broader category of federal health care program payments and include evolving payment methodologies that are increasingly shifting away from traditional fee-for-service claims toward bundled and performance-based reimbursement models.

OBSTRUCTION OF AUDITS

The Final Rule implements the ACA's statutory expansion of OIG's permissive exclusion authority under 1128(b)(2) of the Act to include exclusion for the conviction of an offense in connection with the interference with or obstruction of an audit. Prior to the ACA, this exclusion authority was limited to obstruction of investigations. In response to objecting comments, OIG noted that not only was it required by statute to expand the authority, but that audits are "formal in nature" and compliance with such government audits "is integral to fraud prevention and detection." OIG also expressly noted the need for providers to devote resources to compliance with such audits. Whereas OIG declined to provide a formal definition of "audit," OIG provided examples of government audits to include inspections and examinations by government entities or contractors "verifying compliance with Government program standards." This is a significant expansion, as some providers have historically categorized responses to one-off audit requests as a routine compliance function, as compared to a government investigation, which typically involves the dedication of greater resources.

FAILURE TO PROVIDE PAYMENT INFORMATION

The regulation also reflects ACA's statutory expansion of OIG's permissive authority to exclude individuals and entities for failure to provide certain payment information when requested by the federal health care programs. This exclusion authority was previously limited to any individual or entity who "furnishes items or services." The Final Rule, however, broadened the scope of the exclusion to reach any individual or entity who "furnishes, orders, refers for furnishing, or certifies the need for items or services" payable under federal health care programs.

OIG rejected comments that suggested that expanding the authority to individuals who refer for furnishing or certify the need for services could result in providers being unfairly excluded.

FALSE STATEMENT OR MISREPRESENTATION OF MATERIAL FACT IN ENROLLMENT

The Final Rule implements the ACA's new permissive exclusion authority for making, or causing to be made, any false statement, omission or misrepresentation of a material fact in applications to participate or enroll as a provider or supplier under a federal health care program. OIG specifically rejected the proposition that in order to be material, false statements must in fact influence the decision to deny or approve enrollment. Importantly, OIG clarified it does not intend to pursue exclusion under section 1128(b)(16) of the Act based on inadvertent errors and minor oversights but will continue to evaluate the nature and circumstances of the conduct and exercise discretion in its decision whether to impose an exclusion remedy. In light of the Supreme Court decision in *United Health Services v. U.S. ex rel. Escobar*, which gave detailed direction on the definition and application of "materiality," it is likely that if OIG does not apply that same standard, the courts will.

INDIVIDUALS WITH OWNERSHIP IN EXCLUDED ENTITIES

The existing permissive authority under 1128(b)(15) provides for exclusion of individuals with ownership or control interest in excluded entities under certain circumstances. OIG clarified in the Final Rule that the length of an individual's exclusion would be the same term as the entity on which the individual's exclusion is based, regardless of whether the individual terminates his or her relationship with the entity.

AGGRAVATING AND MITIGATING FACTORS

The new regulation also increases the financial harm aggravating factor threshold under OIG's permissive exclusion authority from $5,000 to at least $15,000 and in several scenarios to $50,000. This allows OIG to increase the period of exclusion for cases involving financial loss of at least $15,000 or $50,000, depending on the authority. OIG decided to remove a proposed mitigating factor that served to reduce the length of an exclusion term if patient access to care was negatively impacted. OIG noted that it will continue to consider beneficiary access to care before implementing its permissive exclusion authorities. OIG stated "[i]t is more appropriate to consider whether exclusion will impact access to care in determining whether to impose a permissive exclusion, rather than to determine the length of exclusion."

EARLY REINSTATEMENT PROCESS

OIG also created an early reinstatement process in the Final Rule for individuals who have been excluded due to action taken against a health care license for reasons bearing on professional competence, professional performance or financial integrity. OIG listed several factors it will consider in determining whether a request for early reinstatement will be granted. For example, an individual may be eligible for early reinstatement if the individual obtains a new license and can demonstrate that any underlying issues that led to the initial licensing action have been resolved. Individuals who do not seek new licenses can also apply for early reinstatement, but they must overcome a presumption against early reinstatement during the first three years after exclusion under this authority. If, however, the license revocation or suspension on which the exclusion is based was for a set period of time longer than three years, the presumption against early reinstatement runs for the same period of time as the license revocation or suspension.

PRACTICAL TAKEAWAYS

The ACA significantly expanded OIG's already extensive permissive exclusion authority. This Final Rule provides additional guidance regarding the implementation of these new and revised regulatory provisions. The preamble to the Final Rule suggests OIG views its increased administrative enforcement oversight as mirroring the reach of the FCA. Providers and suppliers should be aware of the new policy changes and clarifications to existing OIG exclusion authorities in order to ensure regulatory compliance and avoid potential sanctions as a result of increased enforcement actions.

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