"Dear OIG": The Newest Way to Attain Kickback Guidance

Article By:

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The Office of Inspector General (OIG) recently unveiled a quicker process to answer the healthcare industry's most pressing questions on the Anti-Kickback Statute (AKS), allowing healthcare stakeholders to attain more timely guidance at less cost.

OIG has <u>expanded</u> its Frequently Asked Questions (FAQ) program to cover new topics such as AKS enforcement, civil monetary penalties, and general compliance. Previously, OIG opined on these topics only through formal advisory opinions — a slower-moving process that resulted in only a few opinions annually. The new FAQ program allows OIG to issue more guidance at a quicker rate.

This expansion stems from OIG's Modernization Initiative, which seeks to enhance the usefulness, timeliness, and accessibility of OIG's resources. OIG decided to expand the FAQ program after successfully utilizing FAQs to answer enforcement questions about COVID-19 during the pandemic.

Submitting parties may wonder which avenue is best to receive guidance: the traditional advisory opinion process or the new FAQ program. The below considerations should be weighed when making such decisions:

Benefits of Using the FAQ Process

- 1. The FAQ process is quick. It is designed to deliver faster guidance that addresses a submitting party's current realities. If time is of the essence, the FAQ process is the way to go.
- 2. The FAQ process is free, whereas the advisory opinion process could prove costly. OIG <u>estimates</u> that the least complex advisory opinions cost between \$5,000 to \$8,000, while more complex requests cost over \$10,000. The FAQ process provides more accessibility to stakeholders with leaner budgets.
- 3. The FAQ process is informal and allows stakeholders to receive reasonably tailored guidance or additional clarification in circumstances where a formal advisory opinion might not be appropriate.

Drawbacks of Using the FAQ Process

- 1. Any guidance issued through the FAQ process is non-binding. FAQ answers do not obligate OIG, the Department of Health and Human Services, the Department of Justice, or any other governmental agency to follow the guidance when making enforcement decisions. This contrasts with advisory opinions, which are binding legal opinions that could immunize the requesting party from administrative sanctions by OIG. If the requesting party is seeking stronger protection against enforcement, then the advisory opinion process may be the better path. However, even a non-binding statement from OIG blessing a party's conduct could be key when trying to disprove that a party acted willfully under the AKS or in reckless disregard under the False Claims Act.
- 2. Because FAQ guidance is non-binding, courts may ascribe it less precedential value than advisory opinions. It remains to be seen how courts will treat this new type of guidance. However, if precedential weight is a key factor, then advisory opinions offer more value.
- 3. OIG states that it will not disclose identifying information about the submitting party in any FAQ answer. However, OIG concedes that information submitted through the FAQ process could become publicly available through other means, such as the Freedom of Information Act. Stakeholders should weigh this risk of public exposure when submitting FAQs, especially with would-be whistleblowers scouting for new claims.
- 4. OIG expressly reserves the right not to answer certain questions through the FAQ process. It also reserves the right to modify questions to provide more meaningful responses to the public. As such, parties that submit questions through the FAQ process should be prepared to not receive an answer, or to receive an answer that does not directly address their specific concerns. This contrasts with the advisory opinion process, which guarantees a response to the narrow circumstances at hand.

Parties who are interested in submitting FAQ requests can do so by emailing <u>OIGComplianceSuggestions@oig.hhs.gov</u>. Each submission should include sufficient background information, including the specified type of arrangement, the types of parties involved, and the compensation structure at issue.

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