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OIG Issues Unfavorable Opinion on Laboratory Specimen Collection Payments to Hospitals

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The US Department of Health and Human Services Office of Inspector General (OIG) has a long history of skepticism when reviewing financial arrangements between laboratories and referral sources, such as physicians and hospitals, under the Federal Anti-Kickback Statute (AKS). In its latest statement on this subject, OIG published Advisory Opinion (AO) 22-09, which analyzes arrangements between hospitals and clinical laboratories operated by the requestor (Requestor). OIG reached an unfavorable conclusion in this case, finding that the "per-patient encounter" fee structure could induce or reward referrals. This opinion is noteworthy because it raises unanswered questions given the representations made by the Requestor about the arrangement, and because of the Requestor's decision to move forward with obtaining an unfavorable opinion once it became aware of OIG's views.

IN DEPTH

OIG has a long history of scrutinizing laboratory arrangements because of the agency's view that these arrangements are particularly susceptible to fraud and abuse. Much of OIG's past guidance focused on laboratory arrangements with physicians. One of the first fraud alerts, published in 1994, dealt with a laboratory providing phlebotomists to a physician's office to collect samples for the laboratory (see OIG Special Fraud Alert, "Provision of Phlebotomy Services to Physicians" (Dec. 19, 1994) at 9). OIG has subsequently expressed concerns about provision of free specimen collection kits and per-patient payments for blood sample collections by laboratories (see OIG AO 05-08 (June 6, 2005)), laboratory payments of electronic medical record ordering processing fees that relieve ordering physicians of a financial obligation (see OIG AO 14-03 (Apr. 1, 2014)), and payments to physicians for specimen collection and registry arrangements (see OIG Special Fraud Alert, "Laboratory Payments to Referring Physicians" (June 25, 2014)). This past guidance has generally articulated OIG's concern with arrangements that may provide an improper incentive, such as above fair market value (FMV) payments or provision of free services, for a physician to order tests from a particular laboratory.

In AO 22-09, OIG turns to laboratory relationships with hospitals rather than physicians. The arrangement at issue involved a payment that the requestor-laboratory certified was FMV, but OIG

still issued a negative opinion. Read on for a discussion of OIG's rationale, the potential reasons for OIG's conclusion, and the implications for the laboratory industry.

THE PROPOSED ARRANGEMENT IN AO 22-09

The Requestor operates a network of clinical laboratories. Under the proposed arrangement, the Requestor would contract with hospitals (each a Contract Hospital) on a per-patient basis to collect, process, and handle specimens that would then be sent to the Requestor's clinical laboratories. The services would be performed by a Contract Hospital-employed or Contract Hospital-contracted phlebotomist at the Contract Hospital, and the per-patient payment encounter compensation rate would be consistent with FMV. Contract Hospitals would be compensated only for the services performed (i.e., collection, processing, and handling of specimens) in connection with individuals who presented with orders for testing and who were not currently inpatients or registered outpatients of the Contract Hospital. Services performed under the proposed arrangement would be limited to those that were "reasonable and necessary" to accomplish the "commercially reasonable business purpose." The Requestor would bill third-party payors for the testing—including federal health care programs. Contract Hospitals would not be permitted to bill any payor for patient services performed under the proposed arrangement. If the patient's test order did not specify a performing laboratory, the Contract Hospital would be able to choose the laboratory that would conduct the test. Each Contract Hospital would be required to represent and warrant that none of its employed physicians, contracted physicians, or affiliated practices would be required or directed to refer to the Requestor, and that such physicians or practices would not receive any remuneration from the Contract Hospital for any referrals to the Requestor. The Requestor expressly certified all of these facts to OIG under penalty of law as part of the AO process. However, because no Contract Hospital was a party to the AO request, OIG did not have before it a factual certification from a Contract Hospital as to how it would behave under the proposed arrangement.

OIG ANALYSIS

OIG found that the proposed arrangement would implicate the AKS because it would involve a laboratory providing remuneration to a party that was in a position to make referrals to the laboratory or "otherwise arrange for the laboratory to furnish[] items and services that may be paid for in whole or in part by a federal health care program." For example, under the proposed arrangement, if a patient presented to a Contract Hospital an order for laboratory services that did not specify the laboratory to which the specimen was to be referred, the Contract Hospital would have authority to choose the testing laboratory. OIG specifically took issue with the per-patient payment structure, concluding that it could create an incentive for a Contract Hospital to direct specimens to Requestor's laboratories.

Next, OIG concluded that the proposed arrangement would not meet the personal services and management contracts and outcomes-based payment arrangements safe harbor because the per-patient-encounter compensation methodology would take into account the volume or value of referrals or business otherwise generated for which payment may be made in whole or in part under a federal healthcare program.

Finally, OIG conducted a facts and circumstances analysis of the proposed arrangement. OIG came to an unfavorable conclusion because it believed the following:

- The proposed arrangement's per-patient-encounter fee structure would be a form of a "per-click" fee structure, which generally, by their nature, take into account the volume or value of

referrals or business otherwise generated between the parties.

- Laboratory services, in OIG's experience, are "particularly susceptible" to the risk of "steering" patients to a particular laboratory.

OIG noted that the proposed arrangement would contain three significant safeguards:

- An FMV payment.
- A prohibition against Contracted Hospitals billing payors or patients for the services performed under the proposed arrangement.
- Each Contract Hospital's representation and warranty that its employed physicians, contracted physicians and affiliated practices would not be required or directed to refer to the Requestor's laboratories.

However, OIG concluded that "because of the possibility that the per-patient-encounter fee would be used to induce or reward referrals to [the] Requestor and the corresponding risk of inappropriate steering to [the] Requestor," the proposed arrangement would "pose more than a minimal risk of fraud and abuse under the [f]ederal anti-kickback statute" (emphasis added).

TAKEAWAYS

AO 22-09 poses several interesting—and unanswered—questions. First, why did the Requestor proceed with an unfavorable opinion? This is a question one should ask whenever reading an unfavorable opinion. As part of the AO process, a requestor is generally made aware if OIG is heading towards an unfavorable conclusion (i.e., the arrangement is not low enough risk in OIG's eyes to receive a favorable opinion, which represents a very high bar) and has the opportunity to either withdraw the request or amend the arrangement to address OIG's concerns in order to obtain a favorable opinion. This means that whenever there is an unfavorable opinion, the requestor generally wanted to receive it. Here, it is not clear what motivated the Requestor to proceed with its request, because it is now effectively restricted in paying hospitals FMV fees for specimen collection services in the manner set out in AO 22-09. One possibility is that the Requestor, knowing that OIG had an unfavorable view, wanted AO 22-09 to function as a deterrent to other laboratories paying hospitals specimen collections fees since it would not be able to do so without some risk having learned OIG's view of the proposed arrangement. Another possibility is that the Requestor actually preferred not to pay hospital specimen collection fees and wanted the opinion to function as a shield against such requests from hospitals. However, these were not the only options available to the Requestor.

This leads to the second question: why didn't the requestor add a Contract Hospital to the request? It appears that one of the issues that OIG may have had with this request is the lack of a Contract Hospital as a co-requestor that could certify how it would behave under the arrangement. This gap may have led OIG to conclude that there was a "possibility" that the per-patient-encounter fee could induce referrals, which meant that it could not overcome OIG's very high standard for issuing a favorable opinion (i.e., that the arrangement "pose no more than minimal risk of fraud and abuse"). Perhaps OIG would have reached a different conclusion if it had a certification from a Contract Hospital to support that the Contract Hospital would behave in a manner consistent with the

contractual representations in the agreement—namely, that the Contract Hospital's employed physicians, contracted physicians, and affiliated practices would not be required or directed to refer to the Requestor and would not receive any remuneration from the Contract Hospital for any referrals to Requestor. OIG could have requested additional certifications from the Contract Hospital to make OIG more comfortable that the proposed arrangement was low-risk. For example, OIG could have requested certifications that the Contract Hospital would not take other actions to encourage physicians to select the Requestor or would otherwise ensure that physicians had several laboratories from which to choose.

The ultimate question remains: what are laboratories supposed to do now? Laboratories often are between a rock and a hard place when it comes to collecting specimens. Most laboratories depend on the provider to collect and process the specimen. However, past OIG guidance, AO 22-09, and recent enforcement actions show that the government has concerns about how payments from a laboratory to a provider can impact the provider's laboratory selection. As a result, laboratories and providers should carefully consider this guidance and construct arrangements that mitigate risks, for example by ensuring the payment is FMV and that the provider does not act in a way that could jeopardize an otherwise legally permissible and commercially reasonable arrangement.

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