Health Alert
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See note below about Hogan Lovells

**OIG Issues Special Fraud Alert Targeting Lab Payments for Specimen Collection and Registry Participation**

Expanding on its longstanding concerns about payments by clinical laboratories to referring physicians, the Office of Inspector General (OIG) released last week a Special Fraud Alert identifying lab payments to physicians for specimen collection and for participation in patient registries as presenting “a substantial risk of fraud and abuse under the anti-kickback statute [AKS].”

Although OIG guidance documents dating back to the mid-1990s have warned that payments from labs to referring physicians may entail significant risk under the AKS, the issuance of this Special Fraud Alert reflects the OIG’s apparent recognition of a renewed trend among certain labs to engage in arrangements with referring physicians that are suspect under the AKS. The Special Fraud Alert also represents the OIG’s most detailed analysis yet of the particular factors that may indicate an unlawful intent to induce referrals, so labs and physicians should consider carefully the risk factors identified by the OIG before entering into arrangements where physicians are paid for collecting and processing specimens or for contributing to patient registries.

**Payments for Specimen Collection, Processing, and Packaging**

The Special Fraud Alert first addresses arrangements in which labs pay physicians, either directly or through an agent, to collect and/or process patient blood specimens, including tasks such as collecting and centrifuging the specimens, maintaining the specimens at temperature, and packaging the specimens for transport. The OIG adds that the principles described in the Special Fraud Alert apply equally to “analogous” arrangements, such as paying physicians to collect and package patients’ buccal swabs or urine specimens.

The Special Fraud Alert reiterates the OIG’s traditional concern about payments to referral sources for services where the payment exceeds fair market value for the services. In addition, the OIG goes on to warn labs that they “should consider whether payment is appropriate at all” where specimen collection services are “paid for by a third party through other means.” On this point, the OIG notes that venipuncture is directly billable by physicians to Medicare under certain circumstances, and that Medicare considers the handling and conveyance of specimen services to be bundled into the payments physicians receive for office visits and other professional services under the physician fee schedule, thus implying, at least for Medicare patients, that lab payments for the same services may be considered...
inappropriate or in excess of fair market value. According to the OIG, where specimen collection, processing, and packaging services are included in a bundled payment or otherwise paid for by a third party, “any payment by the laboratory to the physician may constitute double payment for the physician’s services and, consequently, provide evidence of unlawful intent.”

The Special Fraud Alert identifies several other specific characteristics of a specimen collection or packaging arrangement that may be evidence of an unlawful intent to induce referrals:

- Payment is made directly to the ordering physician instead of to the physician’s group practice
- Payment is made on a per-specimen basis for more than one specimen collected during a single encounter, or on a per-test, per-patient, or other basis that takes into account the volume or value of referrals.
- Payment is conditioned on the physician ordering a specified volume of tests or a test panel, especially where the panel includes duplicative tests.
- Payment is made to the physician or group practice, but the specimen processing is actually done by a lab-provided phlebotomist.

Provision of Urine Drug-Testing Cups to Perform Billable Testing

The Special Fraud Alert also calls out the “analogous” practice of arrangements under which clinical laboratories provide free or below-market point-of-care urine drug-testing cups to healthcare providers who use the cups to perform billable in-office testing. Here, the OIG is reasserting its long-standing position that when a physician uses something provided by a clinical laboratory to seek reimbursement from Medicare, the AKS is implicated. This guidance suggests that point-of-care drug-testing cups furnished for specimen collection may be provided without charge to physicians only when that portion of the testing is not billed to Medicare.

Payments for Patient Registry Participation

The Special Fraud Alert also identifies substantial AKS risk in labs paying physicians to participate in or contribute to databases that have been set up purportedly to collect information about the demographics, presentation, diagnosis, treatment, or outcomes of patients who undergo tests performed by the lab. The OIG explains that these “registries” typically cover specialized and expensive tests paid for by federal healthcare programs, with the sponsoring labs paying physicians for services such as submitting patient data, answering patient questions about the databases, or reviewing registry reports. The OIG’s fundamental concern with such arrangements is that they may induce physicians to order unnecessary and duplicative tests or to choose the lab that made registry payments over a clinically superior lab. The Special Fraud Alert again identifies several specific characteristics of a registry arrangement that may be evidence of an unlawful intent to induce referrals:

- The lab requires or encourages physicians to perform tests with a stated frequency to be eligible to receive payment.
- The lab collects data for the registry from (and bills for) multiple tests that may be duplicative or that are otherwise not reasonable and necessary.
- Payment is made on a per-patient basis or other basis that takes into account the volume and value of referrals.
- Payment is not fair market value for the services rendered or is not supported by documentation of the physician’s work.
- The lab offers registry arrangements only for its own lab tests or disease states.
The lab does not collect or use data in the registry based on tests performed by other labs.

Tests associated with the registry are presented in disease-related panels so that physicians cannot make independent medical necessity decisions for each test in the panel.

The OIG adds that labs may not disprove unlawful intent simply by claiming that a registry is intended to promote and support clinical research and treatment, or by retaining an independent Institutional Review Board and developing study protocols.

Federal Program Carve Outs May Not Avoid Scrutiny

The Special Fraud Alert cautions that carving out federal healthcare program business does not cure an otherwise suspect payment for specimen collection and processing or for registry participation. Because physicians generally prefer to use a limited number of labs, the OIG recognizes that payment arrangements that carve out federal healthcare program business nevertheless may be intended to influence physicians’ referrals of Medicare or Medicaid patients to the offering lab. In addition, the OIG warns that physicians who accept suspect payments also may be at risk under the AKS.

In sum, the OIG’s Special Fraud Alert reveals a heightened level of federal scrutiny under the AKS of financial relationships between clinical laboratories and referring physicians. Such arrangements also might violate state anti-kickback laws, thereby subjecting the parties to enforcement scrutiny at the state level, too.

The OIG Special Fraud Alert is available at: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf

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If you have any questions about this Special Fraud Alert or arrangements between labs and physicians, please contact one of the lawyers listed in the “Contacts” section or another Hogan Lovells lawyer with whom you work.

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Atlantic House, Holborn Viaduct, London EC1A 2FG, United Kingdom
Columbia Square, 555 Thirteenth Street, NW, Washington, D.C. 20004, United States of America

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