PUBLICATION

OIG Special Fraud Alert Questions Laboratory Payments to Physicians [Ober|Kaler]

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On June 25, 2014, the Office of the Inspector General (OIG) issued a Special Fraud Alert addressing the issue of remuneration offered and paid by laboratories to referring physicians. The Special Fraud Alert expands upon previous guidance released by the OIG on the matter, including its 1994 Special Fraud Alert on Arrangements for the Provision of Clinical Laboratory Services, the OIG Compliance Program Guidance for Clinical Laboratories, and OIG Advisory Opinion No. 05-08.

The OIG's well-established position is that the federal antikickback statute (AKS) may be violated when a laboratory provides referring physicians with free or below-market goods or services or with payments that are not commercially reasonable. According to the OIG, such arrangements may raise kickback-related concerns, including the corruption of medical judgment, overutilization, unfair competition, and increased costs to the federal health care programs and beneficiaries. The recent Special Fraud Alert addresses these concerns while focusing on two specific types of payment arrangements: (1) blood-specimen collection, processing, and packaging arrangements (specimen processing arrangements); and (2) registry arrangements.

Specimen Processing Arrangements

The OIG defined specimen processing arrangements as involving direct or indirect payments from laboratories to referring physicians for certain specified duties, such as blood specimen collection, centrifuging, maintenance, and packaging. These payments are usually made to physicians on a per-specimen or per-patient-encounter basis and are often associated with expensive or specialized tests. The Special Fraud Alert states that when paying physicians for specified services, laboratories should consider whether the physicians are eligible to receive reimbursement from Medicare or any other third party for the services. In the event that a physician is already receiving third-party reimbursement for a service, a laboratory's payment may constitute double payment. The OIG noted that while the AKS may be implicated regardless of whether a payment is fair market value, the probability that a payment is illegitimate is increased if it exceeds fair market value or is for a service already covered by a third-party payor.

The Special Fraud Alert identifies the following as indicia of an unlawful specimen processing arrangement:

- Payment exceeds fair market value for services actually rendered by the party receiving the payment.
- Payment is for services for which payment is also made by a third party, such as Medicare.
- Payment is made directly to the ordering physician rather than to the ordering physician's group practice, which may bear the cost of collecting and processing the specimen.
- Payment is made on a per-specimen basis for more than one specimen collected during a single patient encounter or on a per-test, per-patient, or other basis that takes into account the volume or value of referrals.
- Payment is offered on the condition that the physician order either a specified volume or type of tests or test panel, especially if the panel includes duplicative tests (e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information), or tests that otherwise are not reasonable and necessary or reimbursable.

- Payment is made to the physician or the physician's group practice, despite the fact that the specimen processing is actually being performed by a phlebotomist placed in the physician's office by the laboratory or a third party.

The OIG warned that questionable arrangements between laboratories and physicians that "carve out" federal health care program beneficiaries nonetheless may violate the AKS should they involve disguised remuneration intended to generate federal health care business. Such remuneration may have the effect of influencing physicians' referrals of federal health care business because physicians often choose to refer their business to a limited number of laboratories.

Registry Arrangements

The Special Fraud Alert also addresses laboratory-physician arrangements involving "registries," which are laboratory-operated databases that are designed to collect data on patient characteristics and outcomes. In many of these arrangements, laboratories pay physicians to provide certain duties, such as submit patient data, answer patient questions, or review registry reports. Although laboratories have championed registries for benefitting clinical research and treatments, the OIG is concerned that registry payments may induce physicians to order medically unnecessary or duplicative tests or to prefer labs that offer registry payments over other labs that may otherwise be clinically superior.

The OIG noted that laboratory payments intended to compensate physicians for data collection and reporting services "may be reasonable in certain limited circumstances," but that registry arrangements that include any of the following characteristics may be unlawful under the AKS:

- The laboratory requires physicians to perform tests with a stated frequency to be eligible to receive compensation.
- The laboratory collects comparative data from multiple tests that are duplicative or otherwise not reasonable or necessary and bills for these tests.
- Physician compensation is based on a per-patient or other basis that accounts for the value or volume of referrals.
- Physician compensation is not fair market value for the physician's efforts in collecting and reporting patient data.
- Physician compensation is not supported by documentation, submitted by the physician, which memorializes the physician's efforts.
- The laboratory offers registry arrangements only for tests (or disease states associated with tests) for which it has obtained patents or that it exclusively performs.
- When a test is performed by multiple laboratories, the laboratory collects data only from the tests it performs.
- The laboratory's requisition displays tests in a manner that makes it more difficult for the ordering physician to make an independent medical necessity decision with regard to each test for which the laboratory will bill (e.g., disease-related panels).

The OIG emphasized that the above list is non-exhaustive and that other registry arrangement characteristics may raise fraud and abuse concerns. For instance, substantial fraud and abuse risk would arise if a laboratory paid or collected data only from physicians selected on the basis of their past or anticipated referral volume. The OIG noted that while the AKS does not prohibit laboratories from compensating physicians for legitimate research activities, registry arrangements—even those that exclude federal health care program business—will violate the AKS if even one purpose of the arrangement is to induce or reward referrals.

Laboratory Payments to Referring Physicians Must Withstand Strict Regulatory Scrutiny

In the Special Fraud Alert, the OIG reemphasized its strict regulatory stance on arrangements between laboratories and referring physicians that is largely consistent with its previous guidance. While focusing on two "specific trends" in these arrangements—involving specimen processing and registries—the OIG again emphasized its concerns that laboratory payments not exceed fair market value or otherwise serve as an inducement for physician referrals. Even arrangements that "carve out" federal health care beneficiaries or involve registries designed to foster beneficial clinical treatment data may raise fraud and abuse risks if they could be perceived as intended to influence physicians' referrals of federal health care program business. Laboratories and physicians—both of which may face liability risk under the AKS for impermissible kickback activities—should carefully reevaluate any existing arrangements to ensure compliance with the OIG's latest guidance.