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OIG Publishes Special Fraud Alert Regarding Laboratory Payments Ro Referring Physicians - Some Arrangements May Violate the Anti-Kickback Statute

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The laboratory market has become quite competitive in recent years, raising compliance concerns and investigations into lab relationships with referring physicians. Accordingly, on June 25, 2014, the OIG released a Special Fraud Alert (the "Fraud Alert") which provides guidance about two different types of suspect arrangements: (1) Blood-Specimen Collection; and (2) Registry Payments. The concerns raised here by the OIG involve referring physicians receiving payments from laboratories who may not even be aware that these arrangements are violating the Anti-Kickback Statute due to their complicated nature.

The OIG explained that it is concerned about arrangements in which a lab pays a physician more than fair market value ("FMV") for the physician's services or for services the lab does not actually need or for which the physician is compensated. The four major concerns typically associated with kickbacks involving labs include: (1) corruption of medical judgment; (2) overutilization; (3) increased costs to the Federal health care programs and beneficiaries; and (4) unfair competition. These concerns arise because arrangements with labs could induce physicians to order tests from a lab that provides them with payment, rather than utilizing laboratories that provide the best, most clinically appropriate service. Indeed, the choice of which laboratory to use and whether to even order lab tests are decided by or at least strongly influenced by the physician.

Notably, the OIG points out that the Anti-Kickback Statute prohibits the knowing and willful payment of compensation, even if such payments may be reasonable in certain limited circumstances if "one purpose of the payment is to induce or reward referrals of Federal health care program business." However, the OIG also recognized that the Anti-Kickback Statute is an intent-based statute and the legality of any arrangement will depend on the parties' intent.

1. Blood-Specimen Collection, Processing, and Packaging Arrangements

The first arrangement discussed by the OIG involves payment to physicians to collect, process, and package patients' blood specimens. The OIG notes that the same concepts discussed in the Fraud Alert also apply to similar arrangement in which labs pay physicians to collect and package patients' buccal swabs or urine specimens or provide free or below-market point of care urine testing cups to health care providers who use the cups to perform billable in-office testing.

Typically, payments under Specimen Processing Arrangements are made on a per-specimen or per-patient encounter basis and involve expensive or specialized tests. A nominal specimen collection fee is permitted under certain circumstances, but only if it is the accepted and prevailing practice for physicians to make a separate charge for the drawing or collection of a specimen, and if it is customary to bill separate charges for the drawing or collecting of the specimen. Further, only one collection fee is allowed for each patient encounter, regardless of the number of specimens drawn.

The OIG identified the following characteristics of Specimen Processing Arrangements that may be suspect of a kickback:

· 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 especially if the panel includes duplicative or clinically unnecessary tests.

· Payment is made to the physician or the physician's group practice, even if the specimen processing is actually performed by a in-office phlebotomist provided by the laboratory or a third party.

The OIG also noted that arrangements involving a "carve out" of Federal health care program beneficiaries or business can still be problematic and implicate the Anti-Kickback Statute by disguising those payments as being purportedly related to non-Federal healthcare care program business.

2. Registry Payments

The second arrangement discussed by the OIG involves payments for registry maintenance and observational outcomes databases. These databases are used to collect data on patients who have undergone, or who may undergo, certain tests performed by the laboratories. Labs typically claim that the registry arrangements are intended to be used for research purposes. However, these arrangements become suspect when the labs offer physicians payment for certain specified duties, such as submitting patient data to be incorporated into the registry, answering patient questions about the database and reviewing registry reports. These payments may induce physicians to order medically unnecessary or duplicative tests and could be found to be kickbacks.

The OIG identified the following characteristics of registry arrangements that may be suspect of a kickback:

· The laboratory requires, encourages, or recommends that physicians who enter into registry arrangements perform the tests with a stated frequency to be eligible to receive, or to not receive a reduction in, compensation.

· The laboratory collects comparative data for the registry from, and bills for, multiple tests that may be duplicative or unnecessary.

· Ordering physicians are paid pursuant to registry arrangements on a per-patient or other basis that takes into account the value or volume of referrals.

· Compensation paid to physicians pursuant to registry arrangements is not FMV for the physicians' efforts in collecting and reporting patient data.

· Compensation paid to physicians pursuant to registry arrangements is not supported by documentation, submitted by the physicians in a timely manner, memorializing the physicians' efforts.

· The laboratory offers registry arrangements only for tests it performs or for which it has obtained patents.

· 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 tests are part of panels that make it difficult for the ordering physician to make an independent medical necessity decision to only order the tests he or she needs

· The tests associated with the registry arrangements are presented on the offering laboratory's requisition 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 also noted that that it would be problematic if the lab were to pay and collect data for its registry from physicians selected on the basis of their prior or anticipated referral volume, rather than their specialty, sub-specialty or other relevant attribute. Lastly, the OIG pointed out that even if the registries are intended to promote clinical research and treatment, this is not sufficient to disprove the suspect intent. "Even legitimate actions taken to substantiate such claims, including, for example, retaining an independent Institutional Review Board to develop study protocols and participation guidelines, will not protect a Registry Arrangement if one purpose of the arrangement is to induce or reward referrals."

While the OIG targeted its description of the above problematic registry arrangements towards relationships between laboratories and referring physicians, it could also be applied to other ancillary arrangements such a with drug and device manufacturers if suspect motivations can be found.

For more information on ancillary arrangements between physicians and laboratories or other vendors, the Anti-Kickback Statute, or related fraud and abuse issues, please feel free to contact Daniel Meier or any member of our health care practice group for a further discussion.