CORPORATE COMPLIANCE ALERT

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Department of Health and Human Services Issues a Special Fraud Alert on Laboratory Payments to Referring Physicians

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On June 25, 2014, the Department of Health and Human Services (HHS) Office of Inspector General (OIG) issued the "Special Fraud Alert: Laboratory Payments to Referring Physicians." Specifically, this Special Fraud Alert supplements prior guidance documents and advisory opinions and describes two specific trends OIG has identified involving transfers of value from laboratories to physicians that OIG believes present a substantial risk of fraud and abuse under the anti-kickback statute:

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

OIG warns that it has become aware of arrangements under which clinical laboratories are providing remuneration to physicians to collect, process, and package patient specimens. The Special Fraud Alert addresses arrangements under which laboratories pay physicians, either directly or indirectly (such as through an arrangement with a marketing or other agent) to collect, process, and package patients' blood specimens (Specimen Processing Arrangements). Specimen Processing Arrangements typically involve payments from laboratories to physicians for certain specified duties, which may include collecting blood specimens, centrifuging the specimens, maintaining the specimens at a particular temperature, and packaging the specimens so they are not damaged in transport.

Medicare allows the person who collects a specimen to bill Medicare for a nominal specimen collection fee in certain circumstances. The anti-kickback statute is implicated when a clinical laboratory pays a physician for services, and the anti-kickback statute is violated when the intent of the payment is to induce or reward referrals of Federal healthcare program business. OIG warns that the following characteristics of a Specimen Processing Arrangement, among others, may be evidence of an illegal kickback:

- Payment exceeds fair market value for services actually rendered by the party receiving the payment.
- Payment is for services 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 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, or tests that otherwise are not reasonable and necessary or reimbursable.
- Payment is made to the physician or 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.

B. Registry Payments

OIG also warns that it has become aware of arrangements under which clinical laboratories are establishing, coordinating, or maintaining databases, either directly or through an agent, purportedly to collect data on the demographics, presentation, diagnosis, treatment, outcomes, or other attributes patients have undergone, or

who may undergo, certain tests performed by the offering laboratories. These specialized and expensive tests are known as “Registry Arrangements” and are paid for by Federal healthcare programs.

Payments from a laboratory to a physician to compensate the physician for services-related data collection and reporting may be reasonable in certain limited circumstances; however, OIG warns that these payments violate the anti-kickback statute when the intent of the payment is to induce or reward referrals of Federal healthcare program business. OIG warns that the following characteristics of a Registry Arrangement, among others, may be evidence of an illegal kickback:

- The laboratory requires, encourages, or recommends that physicians who enter into Registry Arrangements perform the tests with a stated frequency (e.g., four times per year) 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 (e.g., two or more tests performed using different methodologies that are intended to provide the same clinical information) or that otherwise are not reasonable and necessary.
- Compensation paid to physicians pursuant to Registry Arrangements is 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 fair market value 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 (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 associated with the Registry Arrangement 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).

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