Special OIG Anti-Kickback Fraud Alert Relating to Payments by Laboratories to Physicians

Legal Alert

July 2, 2014

The Office of Inspector General ("OIG") recently issued an anti-kickback statute Special Fraud Alert addressing compensation paid by laboratories to referring physicians for blood specimen collection, processing, and packaging ("Specimen Processing Arrangements"), and for submitting patient data to a registry or database. The release of the Special Fraud Alert suggests that clinical laboratories continue to have a target placed squarely on their backs by the OIG, and that in this situation referring physicians are also a target and also subject to potential civil and criminal penalties. This Fraud Alert reiterates the OIG's aggressive position towards payment relationships between labs and referring physicians, and reinforces the importance of such arrangements being carefully analyzed and documented to reduce the risk of violation of the anti-kickback law.

Specimen Processing Arrangements

The OIG describes Specimen Processing Arrangements as typically involving payments from laboratories to physicians for certain duties, which may include collecting a blood specimen, centrifuging the specimen, maintaining the specimen at a particular temperature, and packaging the specimen so that it is not damaged in transport. Payments are typically made on a per-specimen or per-patient-encounter basis.

Arrangements under which a clinical laboratory pays a physician for services raise potential issues under the anti-kickback statute. However, Specimen Processing Arrangements do not automatically violate the anti-kickback statute. A violation of the anti-kickback statute exists in the case of knowing and willful payment for such services if even one purpose of the payment is to induce or reward referrals of Federal health care program business, such as Medicare or Medicaid business, notwithstanding that the amount of the payment is at fair market value.

The Special Fraud Alert indicates that the following characteristics of a Specimen Processing Arrangement may be evidence of such an unlawful purpose:

- 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, 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.

Such arrangements will violate the anti-kickback statute even if patients participating in Federal health care programs, like Medicare, are not included in the arrangements.

The OIG notes that the same principles described in its Special Fraud Alert apply to arrangements that are similar or analogous to Specimen Processing Arrangements, such as arrangements under which clinical laboratories 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.

Registry Payments

The OIG stated that it has become aware of arrangements under which clinical laboratories are establishing, coordinating or maintaining databases, purportedly to collect data on the demographics, presentation, diagnosis, treatment, outcomes or other attributes of patients who have undergone, or may undergo, certain tests performed by the laboratories. These registry arrangements typically involve payments from laboratories to physicians for certain specified duties, including submitting patient data to be incorporated into the registry, answering questions about the registry and reviewing registry reports.

The OIG is concerned about such registry arrangements because they may induce physicians to order medically unnecessary or duplicative tests, and to order those tests from laboratories that offer registry arrangements in lieu of other laboratories.

As with Specimen Processing Arrangements, registry arrangements do not automatically violate the anti-kickback statute, as the intent of the parties will be evaluated to determine whether a violation exists. The OIG indicated that payments from a laboratory to a physician to compensate the physician for services related to data collection and reporting may be reasonable in certain limited circumstances. Again, however, such compensation is illegal if even one purpose of the payments is to induce or reward referrals of Federal health care program business.

If you would like more information about the information discussed in this alert, please contact a member of the Healthcare Practice Group at Flaster Greenberg PC.