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Alerts

Special Fraud Alert Released by OIG Regarding Laboratory Payments to Referring Physicians

July 9, 2014
Health Care Alert

On June 25, 2014, the Office of Inspector General of the Department of Health and Human Services (OIG) released a Special Fraud Alert ("Alert") addressing arrangements between clinical laboratories and referring physicians. The Alert provides insight into those payment arrangements which the OIG believes raise enforcement concerns under the federal Anti-Kickback Statute (AKS).

The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive *any remuneration* to induce or reward referrals of items or services payable by a federal health care program. Concerns about the AKS arise when a clinical laboratory pays a referring physician for services. Whether such an arrangement violates the AKS depends on the intent of the parties. Such intent may be inferred from a number of factors, including the legal structure of the arrangement, its operational safeguards and the conduct of the parties. If even one purpose of the arrangement is to induce or reward referrals, the arrangement violates the AKS. The OIG is particularly concerned about arrangements in which laboratories provide free or below-market goods or services to physicians; make payments to physicians that are not commercially reasonable in the absence of referrals; make payments for services that are duplicative or paid for by another source, such as Medicare; or, make payments as part of a bundled payment or overhead expense paid for by another source, even if that payment does not fully compensate the physician for his or her services.

The Alert highlights two types of arrangements that may be suspect under the AKS: (i) Specimen Collection, Processing and Packaging Arrangements; and (ii) Registry Payments.

Specimen Processing Arrangements

Specimen Processing Arrangements are arrangements in which the physician or his or her agent is paid for collecting, processing or packaging blood specimens. Payments are generally paid on a per-specimen or per-patient encounter basis and are associated with expensive or specialized tests. According to the OIG, Specimen Processing Arrangements may violate the AKS, if they include the following characteristics:

- Payment exceeds fair market value for services actually rendered by the party receiving the payment;

Service Areas

Regulatory Investigations and Compliance Counseling

- The laboratory is paying for services for which another third party, such as Medicare, also pays;
- The laboratory makes the payment directly to the ordering physician rather than to the 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 payment is made 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(s), 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 under a federal health care program; or
- 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.

Registry Arrangements

In these types of arrangements, the laboratory establishes, coordinates or maintains a database (directly or through an agent), purportedly to collect data on the attributes of patients who have undergone or may undergo certain laboratory tests performed by the laboratory. The laboratory pays the physician for gathering or submitting data, answering patient questions, or reviewing registry reports, generally on expensive or specialized tests paid for by federal health care programs. According to the OIG, Registry Arrangements that may provide evidence of an unlawful purpose may include the following:

- The laboratory requires or recommends that physicians perform the tests at specific time intervals (e.g., four times a year) to be eligible for compensation or to avoid a reduction in compensation;
- The laboratory collects comparative data for the Registry and bills for multiple tests that may be duplicative (e.g., two or more tests intended to provide the same clinical information) or for tests that are not reasonable and necessary;
- Physicians are paid on a per-patient basis or other basis that takes into account the volume or value of referrals;
- The physician compensation exceeds the fair market value of the services provided or is not supported by documentation of the physician's efforts;
- The laboratory offers registry arrangements only for tests (or disease states associated with tests) for patients that the laboratory has obtained or for tests that the particular laboratory exclusively performs;
- When a test is performed by multiple laboratories, the laboratory only collects data from the tests it performs; or
- The tests are presented on the offering laboratory's requisition in a manner that makes it more difficult for the ordering physician to make an independent determination of medical necessity with regard to each test for which the laboratory will bill (e.g., disease-related panels).

Additional Considerations

The OIG is concerned that physicians may be induced to order unnecessary or duplicative tests and to use laboratories that offer payment rather than choosing laboratories on the basis of quality. In reviewing arrangements between clinical laboratories and referring physicians, it is important to bear in mind the following general principles:

- First, payment arrangements, whether Specimen Processing Arrangements or Registry Arrangements, are not necessarily illegal, but they need to be scrutinized carefully by knowledgeable health care counsel. The OIG has had long-standing concerns about arrangements between laboratories and referring physicians and has issued prior guidance that remains in effect.
- Second, the probability that an arrangement between a clinical laboratory and a referring physician will be deemed to have an improper purpose is increased if: (a) the payment is above fair market value; (b) the payment is for a service for which the physician is paid by a third party in addition to the laboratory; (c) payments are made on a per-patient or per-specimen basis, or take into account the value or volume of referrals.
- Third, arrangements between laboratories and physicians, whether specimen processing arrangements, registry arrangements or other arrangements, are not protected from scrutiny even if they apply only to specimens collected from non-federal health care program patients. Arrangements that "carve out" federal health care program

beneficiaries from otherwise suspect arrangements may still be illegal if the purpose is to influence physicians to refer federal health care program business to a particular laboratory that offers payments to referring physicians.

- Fourth, the AKS is a criminal statute. If the arrangement violates the AKS, both parties to the transaction are criminally liable. An arrangement that violates the AKS may also violate the False Claims Act.
- Finally, the remuneration need not be cash to qualify as unlawful remuneration under the AKS. An arrangement could involve free or below-market supplies, such as urine cups, swabs, or other supplies or equipment.

This is a complex area, and we strongly urge that all arrangements be reviewed by knowledgeable health care counsel to ensure compliance with the AKS and any other fraud and abuse laws.

The OIG Special Fraud Alert can be found at: http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf

If you have any questions or wish to discuss a particular arrangement, please contact your regular Hinshaw attorney.

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