On June 25, 2014, the United States Department of Health and Human Services, Office of the Inspector General ("OIG"), issued a Special Fraud Alert that addressed its concerns about compensation paid by clinical laboratories to referring physicians and physician group practices for blood specimen collection, processing and packaging and for submitting patient data to a registry or data base. The OIG believes these arrangements between clinical laboratories and physicians or physician groups are suspect under the Anti-Kickback Statute, which prohibits the payment of remuneration in exchange for referral of items or services (42 U.S.C. § 1320a-7b(b)).

The OIG believes that the Anti-Kickback Statute is implicated when a clinical laboratory pays a physician for services. Whether an actual violation has occurred depends on the intent of the parties (if one purpose of the payment is to induce or reward for referrals, the OIG believes that the Anti-Kickback Statute has been violated). The probability that the payment is for an illegitimate purpose is increased if the payment exceeds the fair market value of the services provided by the physician or physician group.

When a clinical laboratory is determining the fair market value of a physician's services under a specimen processing arrangement, the laboratory should consider whether the services provided by the physician may have been paid by Medicare or another third party, including under a bundled payment arrangement. Any duplicate payment could be evidence of unlawful intent under the Anti-Kickback Statute. Other factors that may indicate improper intent include the following:

- Payment is made directly to the ordering physician, rather than the practice bearing the overhead.
- Payment is made on a basis that would indicate that the payment takes into account the volume or value of referrals.
- Payment is made to the physician or the group practice despite the fact that the work is being performed by a phlebotomist placed in the office by the laboratory or a third party.

The OIG also identified arrangements where laboratories are establishing, coordinating and maintaining data bases to collect data on patients who have undergone tests performed by the laboratory and paying physicians to enter data into them. The payments from a laboratory to a physician to compensate the physician for data collection and reporting may be reasonable under certain circumstances. Characteristics of suspect arrangements include the following:

- Compensation is paid on a per-patient basis or other basis that takes into account the volume or value of referrals.
- Compensation paid exceeds the fair market value of the services provided.
- No documentation is maintained or submitted of the physician's efforts in performing the services.

The Special Fraud Alert outlines the risks the OIG believes are present with Specimen Processing Arrangements and Registry Payments under the Anti-Kickback Statute. Moreover, it underscores the OIG's long-standing concern about payments by clinical laboratories to physicians in excess of the fair market value of the services provided and payments that reflect the volume or value of referrals. The Special Fraud Alert is available here.
As always, should you have any questions regarding this or any health care matters, please feel free to contact David Lewis or any other member of our Health Care Practice Group.

The opinions expressed in this bulletin are intended for general guidance only. They are not intended as recommendations for specific situations. As always, readers should consult a qualified attorney for specific legal guidance. Should you need assistance from a Miller & Martin attorney, please call 1-800-275-7303.

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