

Physicians, Medical Groups Beware Recent OIG Special Fraud Alert Targets Lab Payments for Blood Specimens & Patient Data

The U.S. Department of Health and Human Services, Office of Inspector General



(OIG) recently issued a Special Fraud Alert based on a concern that laboratory payments to referring physicians and physician group practices for blood specimen collection, processing, and packaging, and for submitting patient data to a registry or database could constitute illegal remuneration under the anti-kickback statute. In following with OIG's prior statements and alerts, OIG issued this new Special Fraud Alert to address two new trends it has identified as potential violations of the anti-kickback statute. **Payments for Blood Specimen Collection, Processing, and Packaging** The anti-kickback statute may be violated when a payment for blood specimen collection, processing, and packaging is made, but it depends on the intent of the parties. Specifically, if any portion of the reason the payment is made is to "induce or reward referrals of Federal health care program business" then a violation is likely, even if the payment is fair market value. And if the payment is above fair market value, the likelihood of a violation is even greater. And because the anti-kickback statute creates criminal liability for both parties involved, both the lab making the payment and the physician or group receiving it may be held liable for the violation. **Submission of Patient Data to a Registry or Database** OIG's concern with the submission of patient data to registries and databases is in part due to the increased likelihood that such submission will result in unnecessary or duplicative tests, including "duplicative tests performed for the purpose of obtaining comparative data." Here too, OIG is concerned that payments for these services may include a purpose of seeking increased "referrals of Federal health care program business." If that is the case, a violation is likely to have occurred here as well. **Likely Violations** The Special Fraud Alert lists many examples of when a violation is likely, including those listed below. If you need assistance maintaining your compliance, be sure to contact one of our health care attorneys today! Likely Violations for Specimen Processing Arrangements:

- 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 (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.
- 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.

Likely Violations for Registry Arrangements:

- 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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