

OIG Issues Special Fraud Alert Regarding Laboratory Relationships With Physicians

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July 15, 2014

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On June 25, 2014, the U.S. Department of Health and Human Services' Office of Inspector General ("OIG") released a Special Fraud Alert addressing two increasingly common relationships between clinical laboratories and physicians that may raise fraud and abuse concerns—payments to referring physicians for (i) specimen collection and (ii) data submission/review for laboratory registries.¹

This Special Fraud Alert is likely a response to the increasingly competitive nature of the clinical laboratory industry as a result of downward pressure on reimbursement, new health reform delivery structures and the influx of small esoteric laboratories offering limited, specialized test menus. In this environment the OIG is concerned that some laboratories may be taking steps to win business from referring physicians in potential violation of the Federal Anti-Kickback Statute.

Payment for Specimen Processing

The Special Fraud Alert first addresses arrangements where laboratories, either directly or indirectly through marketing or other agents, pay physicians to collect, process and package patient specimens. Often this may involve expensive or specialized tests that require centrifuging or special storage/packaging efforts to ensure the integrity of the sample during transport.

The OIG's chief concern with such arrangements is one of double payment— if the physician already receives a payment for such services from a third party like Medicare, through receipt of either a direct specimen collection fee or a bundled payment for the service, intent to violate the Federal Anti-Kickback Statute may be found. This is so even if the laboratory's payment to the physician, standing alone, reflects fair market value. Other suspect factors include:

- Payments that exceed fair market value for services actually rendered;
- Payments conditioned on a physician ordering a specified volume or type of test/panel, especially if tests are duplicative or not reasonable and necessary;
- Payments made on a per-specimen basis when more than one specimen is 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;
- Payments made directly to the ordering physician, rather than the physician's group practice, which more likely bears the processing costs; and

- Payments made to the physician or group practice when the services are actually performed by a phlebotomist placed in the physician's office by a third party.

Registry Arrangements

The Special Fraud Alert next addresses payments by laboratories to physicians for the submission of patient data or for answering questions or reviewing registry reports. Laboratories, especially those performing specialized and expensive tests such as genetic and genomic tests, are increasingly establishing, coordinating and maintaining databases, directly or indirectly, to collect data on the demographics, presentation, diagnosis, treatment, outcomes or other attributes of patients who have or will undergo a particular test offered by the laboratory. These registries can serve legitimate purposes related to clinical research, treatment or management of chronic or genetic diseases, quality assessment or reimbursement analysis. Nonetheless, in the OIG's view, even registries established under the oversight of an independent Institutional Review Board will not protect payments to physicians if one purpose of the arrangement is to induce or reward referrals.

According to the OIG, such payments may induce physicians to order medically unnecessary or duplicative tests, or to order a test from the registry laboratory rather than "other, potentially clinically superior" laboratories. Suspect characteristics of such arrangements include:

Compensation arrangements that require a physician to perform tests with a stated frequency, that do not require appropriate documentation of the physician's services, that do not reflect fair market value or that pay on a per-patient or other basis that reflects the value or volume of referrals;

- Laboratories collecting comparative data (and billing) for tests that may be duplicative or are not reasonable and necessary;
- Laboratories limiting compensation only to tests for which the laboratory holds a patent or performs exclusively, or collecting data only for the tests it performs (when the same test is performed by multiple laboratories);
- Laboratories presenting registry-eligible tests on the requisition form in a manner that makes it more difficult for the ordering physician to make an independent medical necessity decision with regard to each individual test for which the laboratory will bill (e.g., disease-related panels); and
- Laboratories limiting data collection from (and thus paying) only a subset of physicians who are selected based on their prior or anticipated referral volume rather than relevant attributes (like physician specialty).

"Carving-out" FHCP Business May Not Reduce Risk

Notably, the OIG emphasizes that Anti-Kickback risk exists even if such specimen collection or data registry payments "carve out" Medicare, Medicaid and other Federal Health Care Program ("FHCP") beneficiaries primarily because physicians typically limit the number of laboratories to

which they refer for administrative and convenience reasons. Accordingly, compensation for specimen collection or data registry services for non-FHCP patients is viewed by the OIG as "disguised" remuneration for FHCP business, raising Anti-Kickback risk under the OIG's "swapping" theory (explained in numerous past OIG Advisory Opinions).

Footnote

1 OIG, Special Fraud Alert: Laboratory Payments to Referring Physicians (June 25, 2014), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf.

The content of this article is intended to provide a general guide to the subject matter. Specialist advice should be sought about your specific circumstances.