



**LASHLY & BAER, P.C.**  
ATTORNEYS AT LAW

MISSOURI  
714 Locust Street  
St. Louis, MO 63101-1699  
TEL: 314 621.2939  
FAX: 314 621.6844  
[www.lashlybaer.com](http://www.lashlybaer.com)

ILLINOIS  
20 East Main Street  
Belleville, IL 62220-1602  
TEL: 618 233.5587  
By Appointment Only

**OIG Examines Lab Payments to Referring Physicians**  
**By**  
**Stuart J. Vogelsmeier, J.D. And Hannah M. Nelson, J.D.**  
**Lashly & Baer, P.C.**

The Office of Inspector General of the Department of Health and Human Services (“OIG”) has long expressed concern about compensation arrangements between laboratories and referring physicians. In past OIG Fraud Alerts and Advisory Opinions, the OIG has emphasized that providing free or below-market goods and services to a referring physician, or paying a referring physician more than fair market value for the physician’s services, could constitute illegal remuneration under the Anti-Kickback statute. The Anti-Kickback statute ascribes criminal liability to parties on both sides of impermissible “kickback” arrangements. The OIG’s four primary areas of concerns include: 1) corruption of medical judgment, 2) overutilization, 3) increased costs to Federal health care programs and beneficiaries, and 4) unfair competition. In a Special Fraud Alert issued on June 25, 2014, the OIG described two areas of concern regarding compensation and transfers from labs to physicians, which the OIG indicates represent a substantial risk of fraud and abuse under the Anti-Kickback statute.

**Blood-Specimen Collection, Processing and Packaging Arrangements**

Specimen processing arrangements typically involve payments from labs to physicians for duties such as collecting specimens, centrifuging the specimens, maintaining the specimens at a particular temperature, and packing the specimens so that they are not damaged in transport. Payments under these arrangements are typically made on a per-specimen or per-patient-encounter basis, and often are associated with a specialized or high-cost test. In some cases, Medicare reimburses physicians for collecting specimens either through a nominal specimen collection fee or through a bundled payment.

The Anti-Kickback statute may be triggered whenever a clinical laboratory pays a physician for services. In these situations, the OIG noted that the probability for a payment that is intended to compensate referrals to the lab is increased if the payment exceeds fair market value, or if the payment is for a service that the physician is already paid by a third party, including Medicare and Medicaid. The OIG also noted that limiting specimen processing payments to non-Medicare/Medicaid patients may be questionable, because this type of arrangement may actually disguise compensation for Medicare/Medicaid referrals through the payments of amounts purportedly related to non-Medicare/Medicaid referrals.

**Registry Payments:**

The OIG also examined arrangements under which labs establish, coordinate, or maintain databases to collect data on patients who have had tests performed by the offering labs. These are often referenced to as “Registries”. The OIG noted that labs often pay physicians for duties related to Registries such as submitting patient data to the Registry, answering patient questions

about the Registry, and reviewing Registry Reports.

Although payments for data collection and reporting may be reasonable under certain circumstances, the OIG highlighted potential problems, which include: inducing physicians to order medically unnecessary or duplicative tests; and inducing physicians to order those tests from labs that maintain Registries, in lieu of potentially clinically superior labs. The OIG noted characteristics of Registry arrangements with physicians that may be suspect:

- Encouraging physicians to order tests with a stated frequency in order to be eligible to receive compensation.
- Collecting duplicative tests that provide the same clinical information or that are otherwise not reasonable and necessary.
- Compensation paid to physicians that is on a per-patient basis.
- Compensation paid to physicians that exceeds fair market value for the physicians' efforts in collecting the data.
- Compensation paid to physicians that is not supported by physician documentation memorializing the physicians' efforts.
- Payments for Registry arrangements only for tests for which the lab has obtained patients or that it exclusively performs.
- Selection of physicians for participation on the basis of their prior or anticipated referral volume.

Labs and physicians that enter into arrangements under which the physicians are compensated must examine those relationships closely. Even if the arrangements have legitimate clinical purposes, if one purpose of the arrangement is to reward or induce referrals by the physicians to the labs, the arrangements are not protected.

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Stuart Vogelsmeier is a partner with the St. Louis law firm of Lashly & Baer, P.C. Mr. Vogelsmeier regularly counsels health care providers on issues such as Stark Law and Anti-Kickback Law compliance, corporate structure, employment agreements, joint ventures, adding ancillary services to practices, and asset protection. He can be contacted at (314) 436-8349 or at [sjvogels@lashlybaer.com](mailto:sjvogels@lashlybaer.com). Hannah M. Nelson practices in the firm's Health Care Group. Ms. Nelson counsels providers on compliance issues and health care transactions. She can be contacted at (314) 436-8359 or at [hnelson@lashlybaer.com](mailto:hnelson@lashlybaer.com). The firm's website is [www.lashlybaer.com](http://www.lashlybaer.com).

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