OIG Issues Special Fraud Alert – Physicians and Laboratory Relationships

R. Michael Barry

On June 25, 2014, the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("DHHS") issued a Special Fraud Alert addressing arrangements between laboratories and physicians. OIG has addressed these arrangements in earlier fraud alerts, but the June 25 Alert focused on two scenarios OIG finds particularly suspect under the Anti-Kickback Statute: (1) Blood Specimen Collection; and (2) Registry Payments.[1]

If a laboratory compensates a physician for services related to the provision of laboratory testing, the arrangement may violate the federal Anti-Kickback Statute and expose both parties to civil and criminal liability. Of particular note are arrangements in which the physician is compensated at a rate in excess of fair market value for the service rendered; or arrangements in which the physician provides services that are not necessary. The Anti-Kickback Statute prohibits paying or receiving remunerations in exchange for referring items or services reimbursable by a federal health care program. A violation of the statute is a felony punishable by a fine of up to $25,000, a prison sentence up to five years, or both.

(1) Blood Specimen Collection

In specimen processing arrangements, laboratories may pay physicians a nominal fee for performing certain collection or processing tasks. These payments are usually associated with expensive or specialized tests and made on a per-specimen or per-patient-encounter basis. Sample services include: collecting the blood specimens, centrifuging the specimens, maintaining the specimens at a particular temperature, and packaging the specimens for transport. Though the Fraud Alert addresses blood specimens, the same principles apply to arrangements for collecting and packaging buccal swabs and urine specimens.

The person who collects a specimen sample can bill Medicare only in certain circumstances: (1) when making separate charges for drawing or collecting a specimen is the accepted and prevailing practice of physicians in the locality; and (2) it is the physician's customary practice to bill separate charges for drawing or collecting the specimen.[2] Only one collection fee is allowed for each type of specimen taken during a patient encounter, regardless of the number of specimens collected. Thus, a laboratory's payment to a physician for these tasks may constitute a prohibited double payment if the physician is also reimbursed by Medicare. The Anti-Kickback Statute prohibits such payments if even one purpose is to induce or reward referrals, and a double payment may provide evidence of this unlawful intent.

OIG identifies several characteristics of an arrangement that may indicate an unlawful purpose:

- 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.

1 OIG Special Fraud Alert, Laboratory Payments to Referring Physicians (June 25, 2014), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/OIG_SFA_Laboratory_Payments_06252014.pdf. See also OIG Special Fraud Alert (December 19, 1994), https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

2 *See Medicare Claims Processing Manual*, CMS Pub. 100-04, chapter 16, section 60.1.1.

- 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.

Importantly, arrangements that "carve out" federal health care program business are highly suspect and may violate the Anti-Kickback Statute. As it has done numerous times in the past, OIG notes in this Fraud Alert that such "carve out" arrangements may disguise illegal remunerations as payments for non-federal health care business.

(2) Registry Payments

Laboratories that establish and maintain patient information databases may violate the Anti-Kickback Statute by paying physicians for services associated with these databases. Registry arrangements may involve payments for physicians who submit patient data, review reports, or answer patient questions about the registry. Even if a laboratory characterizes a registry as a legitimate research activity, an agreement with a physician can be illegal if even one purpose is to induce or reward referrals. OIG explains that the risk of fraud or abuse would be particularly high if the laboratory paid and collected data from physicians who were selected because of their referral volume, rather than their specialty or other attribute that would yield useful data.

Other arrangement characteristics that may be evidence of an unlawful purpose include:

- 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 not to 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).

Importantly, OIG's examples of potentially unlawful arrangements are not the only ways laboratory-physician arrangements may violate the Anti-Kickback Statute. Physician-laboratory arrangements that involve compensation

payable to physicians for services rendered to the laboratories continue to be of particular concern to the OIG. We urge physicians and laboratories in these types of arrangements to reevaluate them in light of this recent enforcement guidance. Specifically:

1. Are the payments made to physicians within a fair market value range? Parties should ensure that any payments for services provided by physicians are within a validated fair market value range. Payments above fair market value or services provided at less than market value are suspect under the Anti-Kickback Statute. Providers should consider engaging a third party to determine the fair market value of the services provided.
2. Might the physician be compensated by federal health care programs for the services rendered? Compensating a physician for a service that is also reimburseable by a third party payor could lead to a prohibited double payment. Both parties should evaluate the arrangement to determine precisely what goods or services are the source of remuneration.
3. Why are the physicians selected to participate in the laboratory research activities? Safeguards put in place to legitimize registry arrangements cannot prevent these activities from violating the Anti-Kickback Statute if one purpose is to induce referrals. Research activities involving physicians are permissible, but laboratories should review the research protocol to ensure that physicians are selected without regard to prior or anticipated referral volume.

Mr. Barry acknowledges the assistance of Elizabeth Mulkey, a law student at Vanderbilt University Law School and summer associate at AGG, in the preparation of this article.

Authors and Contributors

R. Michael Barry
Partner, Atlanta Office
404.873.8698
michael.barry@agg.com

not *if*, but *how*.®

About Arnall Golden Gregory LLP

Arnall Golden Gregory, a law firm with more than 150 attorneys in Atlanta and Washington, DC, employs a "business sensibility" approach, developing a deep understanding of each client's industry and situation in order to find a customized, cost-sensitive solution, and then continuing to help them stay one step ahead. Selected for The National Law Journal's prestigious 2013 Midsize Hot List, the firm offers corporate, litigation and regulatory services for numerous industries, including healthcare, life sciences, global logistics and transportation, real estate, food distribution, financial services, franchising, consumer products and services, information services, energy and manufacturing. AGG subscribes to the belief "not if, but how.®" Visit www.agg.com.

Atlanta Office
171 17th Street NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Ave., NW,
Suite 1000
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: **http://www.agg.com/subscribe/**