OIG RELEASES SPECIAL FRAUD ALERT REVISITING LABORATORY PAYMENTS TO REFERRING PHYSICIANS

EXECUTIVE SUMMARY

On June 25, 2014, the U.S. Department of Health and Human Services Office of the Inspector General ("OIG") released a Special Fraud Alert (the "Alert") addressing Laboratory Payments to Referring Physicians. The Alert supplements previous guidance and is the latest in a series of advisories, dating back to 1994, discussing the fraud and abuse implications of arrangements where laboratories "pay" referring physicians. Specifically, the Alert focuses on blood-specimen collection, processing and packaging arrangements ("Specimen Processing Arrangements") and "Registry Arrangements," which typically involve payments from a lab to a physician to compensate the physician for data collection and reporting services. The OIG Alert lists characteristics of these two types of arrangements that would be suspect under the federal Anti-Kickback Statute ("AKS"). The Alert can be found here.

BACKGROUND

The AKS makes it a criminal offense to knowingly and willfully offer, pay, solicit or receive any remuneration to induce or reward referrals of items or services payable by a federal health care program. Even if only one purpose of an arrangement is to "pay for referrals," the AKS is violated. Labs offering free or below-market items or services to physicians (e.g., free specimen collection containers) or offering payments to physicians that are not "commercially reasonable in the absence of [f]ederal health care program referrals, potentially raise four major concerns typically associated with kickbacks - corruption of medical judgment, overutilization, increased costs to the [f]ederal health care programs and beneficiaries, and unfair competition." The concern is that physicians will do business with the lab that pays, rather than the best lab, and that physicians will order tests that are not medically necessary, particularly if the payment arrangement is tied to the number of referred tests.

SPECIMEN PROCESSING ARRANGEMENTS

Specimen Processing Arrangements characteristically provide for lab payments to physicians for collecting blood specimens, centrifuging specimens, storing the specimens at an appropriate temperature and packaging the specimens for transport. The fee arrangement often involves a "per-specimen" or "per-patient-encounter" payment. Suspect Specimen Processing Arrangements may feature one or more of the following characteristics:

- 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 (e.g., in certain instances, physicians may bill Medicare a specimen collection fee; Medicare also reimburses for processing and packaging specimens through a bundled payment);
- 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 (when Medicare does reimburse a specimen collection fee, only one fee is permitted per specimen type, regardless of the number of specimens drawn, suggesting payments "per specimen" may be abusive by comparison);
- 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; or
- 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.

In addition to the suspect practices outlined above, OIG reiterated its concerns with Medicare "carve out" arrangements, noting that

payments for only non-federal health care program referrals may still influence the physicians' referrals of commercial pay business.

REGISTRY ARRANGEMENTS

Some labs establish, maintain or coordinate databases or registries for the purpose of collecting clinical and demographic data on patients who have undergone or may undergo lab tests offered by the lab. Labs ostensibly participate in Registry Arrangements to support clinical research and to provide physicians with patient population disease profile information. Typically, labs pay physicians to submit patient data, answer patient questions about the Registry and review Registry reports. OIG is concerned that physicians may choose Registry Arrangement-offering labs over clinically superior labs. The following characteristics may signal questionable Registry Arrangements:

- The lab 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 lab 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 is on a per-patient or other basis that takes into account the value or volume of referrals;
- Compensation paid to physicians is not fair market value for the physicians' efforts in collecting and reporting patient data;
- Compensation paid to physicians is not supported by documentation, submitted by the physicians in a timely manner, memorializing the physicians' efforts;
- The lab 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 lab'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); and
- The lab pays and collects data for its Registry only from past or anticipated high-referring physicians.

OIG reiterated that Registry Arrangement federal health care program "carve-outs" do not insulate these Arrangements from scrutiny. And while paying for "legitimate research activities" is not prohibited, a claim that a Registry Arrangement promotes and supports clinical research - even a claim supported by the existence of an IRB - will not insulate the Registry if one purpose of the Arrangement is to induce referrals.

PRACTICAL TAKEAWAYS

While the Alert does not break any new ground, it restates OIG's long-standing suspicion of arrangements where labs pay referring physicians. The Alert identifies a number of Arrangement features that could invite investigation. Labs and physicians desiring to enter into Specimen Processing Arrangements and Registry Arrangements must be very certain that they have no intent to pay for referrals, even if the payments are for bona fide services and are set at fair market value. Further, these Arrangements should be structured to avoid the identified suspect attributes. For example, Specimen Processing Arrangements can be set up to provide for a fair market value set-in-advance *fixed fee* that does not take into account individual patients, encounters or specimens. Payment programs should be offered to physicians regardless of their past or anticipated pattern of referrals. Finally, labs and physicians should carefully review any existing arrangements in light of the new guidance announcing a zero-tolerance position.

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