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Is Project Labscam II On The Horizon?

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Law360, New York (August 15, 2014, 11:09 AM ET) -- Between its recent special fraud alert and a just-released study on 2010 clinical lab billing, the U.S. Department of Health and Human Services' Office of Inspector General has clinical labs in its sights. And if the past is any prediction of the future, relator's counsel and the U.S. Department of Justice will be following right behind.

There's a lot of money at stake. According to the OIG's recent billing study, as the largest payer of clinical lab services in the nation, Medicare payments for Part B lab services in 2010 alone totaled $8.2 billion. The OIG further cites statistics showing that from 2005-2010, spending for Part B lab services increased by 29 percent while Medicare Part B enrollment increased by only 10 percent.

As part of its study, the OIG highlights its prior work on this topic, most notably in a 2000 report, "Medicare Payments for Clinical Laboratory Services: Vulnerabilities and Controls," which identified a number of common Medicare fraud schemes involving clinical lab services. OIG described these schemes as including billing for services not performed, unbundling tests, falsifying diagnoses, providing kickbacks to physicians for patient referrals, double billing and billing for tests that were medically unnecessary.

OIG's study further claims that such practices were identified through Project Labscam, a nationwide law enforcement initiative the office claims identified fraudulent billing practices across all major clinical labs across the country, which resulted in large settlements. According to the OIG, the prevention, detection and correction of these problems were the result of investigations, audits, prosecutions and negotiations that involved the federal government.

To perform its more recent study, the OIG gathered and extrapolated Medicare claims for lab services from the Centers for Medicare & Medicaid Services. For each lab in its data set, the OIG looked at information from previous federal criminal and civil investigations involving lab services, among other sources, and developed a list of "13 measures of questionable billing." Applying these measures to 2010 Medicare Part B claims data led the OIG to conclude that more than 1,000 labs across the country — almost half located in just California and Florida — had what the office called "unusually high billing for five or more measures of questionable billing for Medicare lab services."

Although the OIG recognizes that some labs may have "legitimate reasons for exceeding certain thresholds" and that its analysis does not "confirm that a particular lab is engaging in fraudulent or abusive practices," it recommends further scrutiny by CMS. Specifically, the OIG recommends that CMS: (1) review the labs identified by OIG as having questionable billing and take appropriate action; (2) review existing program integrity strategies to determine whether these strategies are effectively identifying program vulnerabilities associated with lab services; and (3) ensure that existing edits prevent claims with invalid and ineligible ordering physician numbers from being paid. According to the OIG's study, "CMS concurred with all recommendations."

Both the DOJ and OIG have been talking about increased reliance on data to make cases rather than waiting for whistleblowers to come forward. While there is no way of knowing whether — and how many — lab investigations and sealed qui tams are proceeding in U.S. attorney's offices around the

country, there is a strong likelihood that law enforcement will be taking a closer look at the information in the OIG's recent study to see if there are any cases they consider worth pursuing. Indeed, the OIG recommends that CMS take action on the information in the study, including potential revocation of Medicare privileges and referral of cases to law enforcement for criminal investigation. We will likely see subpoenas issued in the near future as a result of this study.

Moreover, as mentioned above, OIG is no stranger to issues involving clinical lab services. In addition to potential billing issues identified in its recent study, the OIG has long been concerned with potential Anti-Kickback Statute violations. Almost 20 years ago, the OIG issued a special fraud alert on "Arrangements for the Provision of Clinical Laboratory Services," which identified "a number of practices engaged in by clinical laboratories and health care providers that implicate the Anti-Kickback Statute," including waiver of charges to managed care patients and free pick-up and disposal of biohazardous waste products unrelated to the collection of specimens for the outside laboratory.[1]

Thus, the OIG's recent special fraud alert is consistent with its well-established position that arrangements in which a clinical lab agrees to provide free, below-market or above-market goods or services to actual or potential referral sources are suspect and may violate the federal Anti-Kickback Statute — a criminal statute that prohibits the exchange or offer to exchange anything of value in an effort to induce or reward the referral of health care program business.[2] According to the OIG, such arrangements raise potential kickback concerns, including the corruption of medical judgment, overutilization, increased costs to federal health care programs and beneficiaries and unfair competition.

Building on its prior guidance, the 2014 Special Fraud Alert focuses on two trends that OIG has observed and believes are suspect under the Anti Kickback Statute: (1) payments to referring physicians for patient specimen collection, processing and packaging; and (2) payments to referring physicians through registry payments.

Specimen Processing Arrangements

First, the OIG is concerned with arrangements in which clinical labs pay physicians for certain duties relating to the collection, processing and packaging of patient blood specimens, such as collecting and centrifuging the specimens, maintaining them at a particular temperature and packaging the specimens so that they are not damaged in transport. As the OIG describes, such payments are typically made on a per-specimen or per-patient-encounter basis and are often associated with expensive or specialized tests.

In determining whether such payments may be problematic, OIG considers the intent of the parties.[3] According to the OIG, the probability that payment is for an improper purpose is increased if the payment exceeds fair market value or is for a service for which the physician is paid by a third party, including Medicare.[4]

OIG identifies additional characteristics of specimen processing payments which it believes might be evidence of an unlawful purpose:

- payments made directly to the ordering physician rather than to the physician's group practice;
- payments made on a per-patient or per-specimen basis; and
- payments made on the condition that the physician order either a specified volume or type of test(s) that are otherwise not reasonable and necessary or reimbursable.

Registry Arrangements

Second, the OIG raised concerns about registry arrangements in which clinical labs agree to pay physicians for submitting patient data to a registry or database maintained by the lab. According to the OIG, clinical labs maintain such registries or databases to collect and track data (such as patient demographics, presentation, diagnosis and other attributes) on patients who have undergone, or who may undergo, certain tests by the offering lab.

While the OIG recognizes the position that such registries and databases advance clinical research and provide physicians with valuable clinical knowledge for patients with similar disease profiles, the office considers such registry arrangements may induce physicians to order medically unnecessary or duplicative tests. Additionally, although the OIG acknowledges that compensating a physician for services related to data collection may be reasonable in certain limited circumstances, it expresses concern that these payments may be improper remuneration to obtain federal health care business by inducing physicians to order unnecessary tests or to order tests from laboratories that make payments rather than those that do not make payments.

As with the specimen processing arrangement, the OIG identifies a number of characteristics it believes are evidence of such unlawful purpose, including most notably:

- requiring, encouraging or recommending that physicians perform tests with a certain frequency to be eligible to receive payment;
- payment to physicians based on a per-patient or other basis that takes into account the value or volume of referrals;
- payment to physicians that is not supported by timely submitted documentation from the physician memorializing his/her efforts; and
- payment provided to a subset of physicians selected based on their prior or anticipated volume rather than specialty or other relevant attribute.

The OIG notes that while the Anti-Kickback Statute does not prohibit labs from engaging in or paying compensation for legitimate research activities, the arrangement will not be protected if one purpose is to induce or reward referrals.

Conclusion

These recent publications should serve as notice that the OIG will once again be scrutinizing lab billing and compensation arrangements between clinical labs and ordering physicians. And we well know, where OIG goes, relators and the DOJ are likely to be right behind.

[1] Four years later, in August 1998, the OIG published compliance guidance for clinical laboratories setting forth the now familiar seven elements of an effective compliance program.
[2] For example, in June 2005, the OIG issued Advisory Opinion No. 05-08 opining that a clinical lab's provision of free blood collection supplies to physicians and payment to those physicians for the collection of blood samples potentially implicated the Anti-Kickback Statute.
[3] The Anti-Kickback Statute prohibits the knowing and willful payment of remuneration to induce or reward referrals of federal health care program business.
[4] The OIG noted the Medicare payment provisions for physicians to receive payment for specimen collection under certain circumstances, as well as bundled payments to physicians, which include processing and packaging specimens.

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