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Arrangements between Laboratories and Referring Physicians Involving “Registries”

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The United States Office of Inspector General (“OIG”) recently issued a “Special Fraud Alert” focusing on two potentially illegal trends that it has detected in arrangements between laboratories and their referring physicians: Specimen Processing Arrangements and Registry Payments. Specimen processing arrangements were the subject of an earlier blog post,“Laboratory Payments to Physicians for Specimen Processing Present Substantial Risk of Fraud and Abuse” (8/14/14). This blog post focuses on the OIG’s concerns regarding registry payments from laboratories to their referring physicians.

The “registries” which are the subject of the Special Fraud Alert are databases established, coordinated or maintained by clinical laboratories (or an agent of the lab) which collect data on patients who have undergone or may undergo tests performed by the lab. Typically, the tests are specialized and expensive, and paid for by Medicare and other Federal health care programs. According to the OIG, stated purposes for these registries include advancement of clinical research and providing physicians with additional clinical knowledge.

The “Registry Arrangements” that concern the OIG involves payments from labs to physicians for certain specified duties such as submitting patient data to be incorporated into the Registry, answering patient questions about the Registry and reviewing Registry reports. The OIG’s primary concern is that the arrangements may induce physicians to order medically unnecessary or duplicative tests from such offering labs in lieu of from other potentially superior laboratories.

Described below are types of practices relating to Registry Arrangements that should be avoided by the physicians and laboratories involved in such arrangements. These practices are based on the elements identified by the OIG in the Special Fraud Alert, and categorized below as either relating to “Physician Compensation” or “Registry Collection and Billing Practices”:

Physician Compensation

- The physician’s compensation should not be tied to the physician’s frequency of performance of the tests, nor should it be set as a per-patient or other basis that takes into account the value or volume of referrals.

- Compensation should be fair market value for the physician’s efforts in collecting and reporting data.

- The laboratory should not pay or collect data for its Registry from only physicians who were selected on the basis of their prior or anticipated referral volume, rather than their specialty, sub-specialty, or other relevant attribute.

- Physicians should support all compensation paid pursuant to Registry Arrangements with documentation, submitted in a timely manner, memorializing their efforts.

Registry Collection and Billing Practices

- The laboratory should not collect comparative data for the Registry from, and bill 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.

- The Registry Arrangements should not be offered only for tests (or disease states associated with tests) for which the lab has obtained patents or that the lab exclusively performs.

- The lab should not collect data only from tests it performs if such tests are performed by multiple labs.

- Tests associated with the Registry Arrangement should not be 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).

Physicians and laboratories involved in a Registry Arrangement should review the descriptions of potentially unlawful arrangements set forth above and ensure that they do not engage in actions that the OIG could consider “suspect” under the Special Fraud Alert.

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