

LEGAL ALERT

January 13, 2017

OIG Issues Advisory Opinion on Lab's Performance of Administrative Tasks for Dialysis Facilities

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On December 5, 2016, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued Advisory Opinion Number 16-12, in which it concluded that a laboratory's proposed performance of administrative tasks for dialysis facilities would potentially violate the anti-kickback statute.

The OIG analyzed a proposal by a laboratory to provide labeling of test tubes and specimen collection containers at no cost to dialysis facilities. The labeling was to be performed at the laboratory and by laboratory personnel. The laboratory, however, had sole discretion to determine which dialysis facilities would be offered the no cost labeling service.

Because dialysis facilities were already performing these labeling services themselves, without reimbursement from Medicare, the proposed labeling would be prohibited remuneration. The Centers for Medicare & Medicaid Services (CMS) already reimburses dialysis facilities for services associated with laboratory tests, and does not furnish payment for administrative tasks such as labeling containers. Medicare reimburses all services for end stage renal dialysis (ESRD) as part of a bundled payment. Non ESRD related lab tests can be paid by Medicare under a rate reimbursement system, but even when Medicare makes separate payment for laboratory tests, it does not reimburse for administrative tasks.

It has long been established that when a laboratory offers or gives services at less than fair market value, there is an inference that the laboratory is seeking to induce referrals. In December 1994, the OIG issued a prior Special Fraud Alert explaining that when laboratories offer services or goods as incentives for business, an inference arises that the offer violates the anti-kickback statute. The proposed labeling of the containers, at issue in the December 2016 Advisory Opinion, at no cost would be a tangible benefit to the dialysis facilities. Medicare makes no special payment for administrative tasks, and by the lab performing these tasks, the facilities are relieved of the burden of performing certain administrative tasks. An inference would therefore arise that the labeling services were being offered to obtain business and are prohibited remuneration under the anti-kickback statute.

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While the Advisory Opinion only addresses the labeling of containers by a lab, there are broader implications when health care facilities contract with laboratories. Any proposed arrangements in which the laboratory is providing some service or item to the medical facility could potentially implicate the anti-kickback statute. It is, therefore, important that any such proposed arrangement be analyzed to make certain that fair market value is being paid for any goods or services being provided by the laboratory, even those services that are as seemingly minor as labeling a specimen container.

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