

PUBLICATION

8 Years and a New Reimbursement Methodology Later [Ober|Kaler]

2016

OIG Still Rejects Laboratory's Free Labeling Services for Dialysis Facilities in Advisory Opinion No. 16-12

On November 28, 2016, the U.S. Department of Health and Human Services, Office of Inspector General (OIG) issued an unfavorable advisory opinion, [No. 16-12 \[PDF\]](#), regarding a laboratory's proposal to provide selected dialysis facilities with free labeling of test tubes and specimen collection containers to send specimens to that laboratory for testing. The OIG concluded that the proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that it would potentially impose administrative sanctions, especially since the laboratory acknowledged it would select the dialysis facilities "based on whether offering such services would be necessary to obtain or retain the business of a particular dialysis facility."

Notably, the same laboratory sought (and received) a similar advisory opinion in 2008 ([No. 08-06 \[PDF\]](#)) based on virtually identical facts – with one exception. At the time of the 2008 opinion, Medicare employed a composite rate reimbursement system for the laboratory testing services at issue. Since then, the Centers for Medicare & Medicaid Services (CMS) has implemented a prospective payment system (which became effective January 1, 2011) to reimburse facilities for furnishing dialysis services to patients with end-stage renal disease (ESRD PPS), and has implemented a bundled payment system in which all ESRD-related laboratory tests are reimbursed as part of the ESRD PPS bundle. Nevertheless, CMS recognizes that while an ESRD patient is receiving his or her dialysis treatments, the patient's physician may order laboratory tests unrelated to the patient's ESRD that are separately reimbursed and paid to the ESRD facility. With that said, after consultation with CMS, the OIG concluded its analysis from 2008 remains the same.

The OIG first considered whether the proposed arrangement satisfied the safe harbor for personal services and management contracts, which requires payment to be consistent with fair market value. Since the dialysis facilities would not be paying *any* compensation to the laboratory for the labeling services even though such services are of value to them, the OIG quickly concluded this safe harbor was not satisfied. As noted below, the cost of the services would have otherwise been borne by the dialysis facilities since CMS does not make separate payment for administrative tasks, such as labelling test tubes and containers, under the ESRD PPS. Thus, providing such services free of cost provides value to the dialysis facilities.

Since the proposed arrangement would not be protected under a safe harbor, the OIG then conducted a factual analysis to determine whether the proposed arrangement potentially violated the anti-kickback statute. The OIG noted that the proposed arrangement was inherently suspect given its longstanding policy that a laboratory's provision of free or below-market items or services to actual or potential referral sources creates an inference "that the item or service is offered to induce the referral of business."¹ This inference was consistent with, and supported by, the laboratory's representation that the labeling services would be provided to facilities when necessary to retain or obtain their business. The OIG also referenced its 1994 caution against "swapping" arrangements between laboratories and dialysis facilities in which a laboratory offers discounts on the facility's composite rate tests in exchange for the facility's referrals for non-composite rate tests billable by the lab directly to Medicare or other federal health care programs.

The OIG concluded that despite the change in Medicare reimbursement methodology for dialysis services, the proposed arrangement still poses “more than a minimal risk” of fraud and abuse.

Ober|Kaler's Comments

Similar to OIG Advisory Opinion No. 08-06, it appears that the laboratory requesting this opinion may have been seeking a negative advisory opinion, particularly in light of the laboratory's acknowledgement that it would select dialysis facilities to receive labelling services “based upon whether offering such services would be necessary to obtain or retain the business of a particular dialysis facility.” The OIG has emphasized in its guidance that providing free or below-market goods or services to physicians and other sources of referrals could constitute prohibited remuneration under the anti-kickback statute depending on the circumstances.² Accordingly, laboratories should exercise caution when entering into such arrangements with referral sources and ensure that no remuneration or services are provided in exchange for referrals.

¹ See Special Fraud Alert, *Arrangements for the Provision of Clinical Lab Services*, 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994).

² See, e.g., Special Fraud Alert: *Laboratory Payments to Referring Physicians* [PDF] (June 25, 2014); OIG Advisory Opinion No. 05-08 [PDF] (concluding that an arrangement regarding a laboratory offering free blood-drawing kits and paying physicians a per-patient fee to collect blood samples may violate the anti-kickback statute).