

Insights

OIG Post New Advisory Opinion on Laboratory Services

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On December 5, 2016, the OIG posted Advisory Opinion No. 16-12 concerning a laboratory's proposal to provide the labeling of test tubes and specimens free of charge to dialysis facilities. One of the stated purposes of offering this free service was to "obtain or retain the business of a particular dialysis facility." The laboratory also noted that this was a practice being undertaken by its competitors.

The OIG discussed that although the OIG has issued a previous opinion on a similar issue (Advisory Opinion 08-06), CMS has implemented a new prospective payment system to reimburse facilities for furnishing renal dialysis service to patients with end-stage renal disease (the "ESRD PPS"). This instituted a bundled payment system and recognized that there may be times when a physician will order a laboratory tests that is unrelated to the patient's ESRD. Due to this, CMS allows for a separate payment for certain tests ordered in an ESRD facility when such tests are not ordered for treatment of ESRD.

The OIG held that despite the change in the payment structure for ESRD, the proposed arrangement may be a violation of the Federal anti-kickback statute, 42 C.F.R. § 1128(B)b, and that the arrangement did not fit into the safe harbor exception for personal services and management contracts found at 42 C.F.R. § 1001.952(d). In analyzing this issue, the OIG referenced its 1994 Special Fraud Alert whereby the OIG held that when a lab offers an item or service for free or less than fair market value to a referral service, there is an inference that such is being offered to induce the referral of business. Normally, the cost of the labeling services would be a service that the dialysis facility would perform at its own expense as it is not a service reimbursed by Medicare. Here, the lab would pay for that unreimbursed costs as opposed to the facility. Therefore, the OIG inferred that providing the services was intended to influence the dialysis facilities selection of a laboratory. This would allow the lab to generate substantial revenue due to the ongoing lab services required by dialysis patients, especially since labs can be reimbursed separately for test ordered for purposes other than ESRD under the ESRD PPS.

Any time a laboratory, facility or provider is analyzing whether to enter into an arrangement that offers items or services for free or for below-market costs, it is critical to carefully analyze whether such arrangement is in violation of the anti-kickback statute. Such analysis is very fact-specific and must take into account the intent of the parties as well as any applicable safe harbors. The OIG Advisory Opinion No. 16-12 can be found [here](#).

If you have any questions or would like to discuss this topic, please contact Stephanie T. Eckerle