



Alerts

OIG Vetoes Proposed Lab Fee Waiver Arrangement

April 2, 2015

Health Law Alert

On March 18, 2015, the Office of Inspector General (OIG) issued an opinion advising against a laboratory's proposed agreement with physician practices under which it would provide all lab services for the practices' patients and waive fees for those patients whose insurance plans would otherwise require them to use a different lab. The OIG determined that the proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute and lead to OIG sanctions. In addition, the OIG concluded that the proposed arrangement could constitute a violation of the Social Security Act.

Background

The entity requesting the opinion, which we'll call "Lab X," was a multi-regional medical laboratory that provides services to physician practices. Typically, when Lab X's physician practice clients order lab tests, their patients go to a patient service center where a sample is collected, and then is tested at a lab site. According to Lab X, some physician practices have expressed a desire to work with a single lab for ease of communication and consistency in the reporting of test results. For example, different labs use different reference ranges in reporting test results, and each lab requires a different interface for transmitting test reports electronically.

Lab X certified that 70% of its physician practice clients have patients who are enrolled in insurance plans that require their enrollees to use a particular lab. None of these exclusive plans include individuals with Federal health care program coverage as their primary insurance, but some exclusive plan enrollees could have Federal health care program coverage as their secondary insurance. If Lab X is not the exclusive plan's designated lab, the plan does not pay it for any testing performed on the plan's enrollees.

Under the proposed arrangement, Lab X would have provided free services to certain patients to secure all business, including Federal health care program business, from physician practices. It would not have billed the patients with exclusive plans that require the use of a different lab. Under the proposed agreement, physicians would be required to represent that neither the physician nor the practice would receive any financial benefit from Lab X's provision of lab services at no charge to exclusive plan enrollees.

OIG Opinion

The OIG determined that the proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute. Although physicians and physician practices would not receive direct payments under the proposed arrangement, the OIG determined that reducing administrative and possibly financial burdens associated with using multiple labs could constitute remuneration. For those reasons, the OIG could not rule out that the proposed arrangement would not involve Lab X offering remuneration to induce the referral of Federal health care program beneficiaries. A definitive conclusion regarding anti-kickback violations requires a determination of the parties' intent, which is beyond the scope of the advisory opinion process.

In addition, the OIG concluded that the proposed arrangement could constitute grounds for permissive exclusion under the exclusion authority at section 1128(b)(6)(A) of the Social Security Act. Particularly, the arrangement could violate the "substantially in excess" provision, which is designed to prevent individuals and entities from charging Federal healthcare



programs substantially more than their usual charges to other payors for the same items or services. The proposed arrangement would allow for free services to patients who are insured and whose services could be covered if they were to use the lab designated by their insurance plan. Under these facts, it is possible that some of the agreements could cause Lab X to provide free services to a large portion of the business referred to it. Lab X noted that 70% of its physician practice clients have indicated that 10 to 40% of their patients are enrollees of exclusive plans. With percentages that high, it is plausible that more than half of the non-Medicare or non-Medicaid patients would be receiving free services, while Medicare and Medicaid would be charged at the regular rate. The OIG concluded that the proposed arrangement poses too high of a risk of violating the provision to grant Lab X prospective immunity.

As with any OIG advisory opinion, the opinion is not to be cited as precedent and was only issued to the entity requesting it, but it can be used as guidance for how the OIG will analyze similar arrangements.

For further information, contact your regular [Hinshaw attorney](#).

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