

OIG warns against selective free labeling services

Ron Shinkman

February 2017—A laboratory's proposal to provide free labeling services to some of its dialysis center clients poses more than a minimal risk of fraud and abuse, according to an advisory opinion from the Office of Inspector General of the U.S. Department of Health and Human Services.

The OIG said in its Nov. 28, 2016 opinion that the laboratory may violate federal Medicare anti-kickback laws by generating prohibited remuneration under the anti-kickback statute. And that may have been exactly what the laboratory wanted to hear.

The circumstances presented to the OIG were straightforward: The unnamed laboratory proposed providing some of its clients with labeling services of test tubes and specimen collection containers. Employees of the laboratory at the lab's own facilities would do the labeling. No laboratory employees would be stationed at the dialysis facilities. The labeling services, which employees of the dialysis center are performing now, would be furnished free.



'Asking for an advisory opinion might have been the most effective way to address the problem.'

Jack Bierig

The laboratory "would retain sole discretion regarding the selection of which dialysis facilities would be offered the labeling services and, according to the lab, such selection would be based upon whether offering such services would be necessary to obtain or retain the business of a particular dialysis facility," says the OIG advisory opinion.

The key to this opinion is that the laboratory determines whether to offer the labeling services based on whether such services are "'necessary to obtain or retain the business of a particular dialysis facility,'" says Jack Bierig of the Chicago law firm Sidley Austin LLP, former general counsel of the CAP, and lecturer in health law and policy at the University of Chicago Law School. By selectively offering a service based on whether the service is needed to obtain a client's business, the laboratory would be seen as offering something of value to induce a referral. That would violate the Medicare anti-kickback law, which is designed, as Bierig puts it, "to stop a lab from greasing its way into referrals of items and services covered by Medicare."

The OIG concluded that the proposed arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that administrative sanctions could potentially be imposed on the lab. The agency's reasoning was clear: Providing the additional service without charge could be construed as an inducement or remuneration to obtain the business of a dialysis center or centers, a violation of the anti-kickback statute. Though

there may be myriad reasons to provide the services, if one of them is to obtain business, it constitutes a violation.

While there is a safe-harbor provision under the anti-kickback statute for management contracts, the OIG noted that this situation did not fit the definition because under the proposed structure, the dialysis center would be receiving remuneration from the laboratory. And while arrangements outside of the safe-harbor provision are not necessarily illegal, the free services that the dialysis center would receive from the laboratory would create an inference of illegality that cannot be dismissed, the OIG said. Although the intent of both parties would have to be evaluated for a prosecution, the OIG said a laboratory in such a business arrangement would likely face sanctions.

The OIG noted that it had reached a similar conclusion when it issued an advisory opinion in May 2008, when another laboratory also requested an opinion on providing free labeling services for dialysis centers. The agency concluded then that dialysis centers were already being paid for labeling services under the composite payment system in place at that time.

That rationale has not changed even though Medicare has, since the first advisory was issued nearly a decade ago, shifted dialysis from composite to bundled payments. The shift occurred in 2011 when Medicare began paying a flat rate of \$240 per dialysis treatment, or about \$37,000 per patient per year. That compares to the \$88,000 per year spent to treat the typical dialysis patient nationwide, according to the U.S. Renal Data System.

Under the bundled payment system, labeling services are not covered. They are also excluded when the center orders tests for the patient that are unrelated to dialysis services and reimbursed outside of the bundle.

The two largest dialysis center operators, Fresenius and DaVita HealthCare Partners, lose money on their Medicare patients and make their entire profit on those patients with private insurance. The two for-profit companies control about 70 percent of the U.S. dialysis market.

The OIG's answer to the most recent laboratory proposal may have been exactly what the requesting laboratory was looking for, Bierig says. Some of the laboratory's competitors were already offering similar services free to some of its dialysis center clients, according to the OIG.

"My guess," he says, "is that the requesting lab doesn't really want to offer free labeling services to dialysis centers but is facing competition from other labs that are providing the service. It probably wanted to get an opinion that would call into question the actions of its competitors and that would dissuade dialysis centers from asking for the free services."

"Now they can say to a potential customer, 'We would like to offer the free service, but it is unlawful for us to give it to you and unlawful for you to receive it,'" Bierig says.

The wording of the laboratory's request for the opinion appeared to be constructed to obtain the very response it received. "When they wrote this letter, they basically admitted a violation of the anti-kickback statute," he says. "They figured they had nothing to lose. If OIG said the practice was unlawful, it would provide a tool that could be used against the lab's competitors. If OIG said the practice was lawful, they could compete against other labs without concern that the conduct might lead to legal sanctions."

Although the laboratory that sought the opinion could have filed a complaint with the OIG about competitive laboratories offering free labeling services, the OIG might well not have done anything. "Whether the agency would take action depends on the often scant resources that are available and the agency's priorities," Bierig says. "Asking for an advisory opinion might have been the most effective way to address the problem."

The OIG opinion doesn't necessarily preclude laboratories from providing free labeling services to all dialysis centers. "If a service is provided to everyone, it may be viewed as part of the service rather than as an inducement for a referral," Bierig says. "Moreover, it is much harder for OIG to prove that the service was offered in order to obtain a referral."

If a laboratory is going to give free or discounted benefits to its clients, “it had better give it to all clients,” in Bierig’s opinion.

“If you selectively give the service, you are asking for problems. And before a lab offers any free or discounted service to clients,” he says, “it would be well advised to check with knowledgeable counsel on whether the offer raises issues under the anti-kickback statute or similar state law.”

[hr]

Ron Shinkman is a writer in Sherman Oaks, Calif.