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The lab rental space sham

By Darrell W. Contreras, Esq., CHC-F, CHPC, CHRC

In February 2000, the U.S. Department of Health and Human Services Office of Inspector General (OIG) published a Special Fraud Alert, "Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer" (Rental Space SFA).[1] This Special Fraud Alert built on the Space Rental exception (Rental Space Safe Harbor) to the Anti-Kickback Statute (AKS). Twenty-four years later, too many labs continue to engage in rental space arrangements that are nothing more than an inducement to pay a physician or practice to refer more specimens to the lab. Moreover, physicians and practices have been drawn to the allure of an income stream from the lab based solely on the hollow assurance that they are safe from liability because the lab has included reference to the Rental Space Safe Harbor in the rental agreement. However, a settlement announcement released by the U.S. Department of Justice (DOJ) on April 29, 2024—in which three physicians and a contracted sales representative agreed to pay more than $1.3 million—should serve as a wakeup call for labs and physicians that engage in rental space agreements.[2]

The legal foundation

The AKS prohibits offering, paying, soliciting, or receiving remuneration to induce referrals of items or services covered by Medicare, Medicaid, and other federally funded healthcare programs unless a specific exception—safe harbor—is met. Civil and criminal liability can attach to AKS violations for both the party offering and the party receiving the kickback.

Some laboratories may attempt to justify the payment of rent to referring providers or practices by citing the Rental Space Safe Harbor which excludes rental payments from the definition of "remuneration" provided that six requirements are met.[3] The fifth requirement is central to this discussion because the aggregate rental charge must be set in advance and "not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties."

The primary issue with rental space agreements is that they completely depend on the physician or practice continuing to send specimens to the lab. Typically, labs will refute this by pointing to the language in the rental space agreement, specifically the statement that the agreement is not conditioned on the value or volume of past, current, or future business or referrals ("safe harbor language"). The attorneys who draft these agreements genuinely believe the agreement is not conditioned on referrals, but, unfortunately, the language in the agreement typically does not match the practical use of the rental space agreement.

If the practice stopped sending specimens to the lab, would the lab continue to make those rental payments? Has the lab ever made an express statement to a physician or a practice that there is no obligation to send specimens

to the lab that is renting the office space? In the sham rental arrangement—notwithstanding the safe harbor language in the agreement—the physicians and practices know that if they stop sending specimens to the lab, they will terminate the lease and stop making the office space rental payment. Put another way, the person receiving the benefit of the rental space payment believes that the payments for the rental space would stop if the person stopped referring specimens to the lab. As such, there is no avoiding the conclusion that as a practical matter and in the mind of the recipient, the rental space payment is conditioned upon the continued referral of specimens from the physician or practice to the lab. Therefore, the rental space arrangement does not comply with safe harbor requirement five and is entirely dependent upon the continuation of referred specimens to the lab. Even when the lab attempts to justify its rationale for renting space from a physician or a practice, there is no avoiding the fact that the lab is making a payment to a referral source and receiving specimens from that referral source.[4]

The Stark Law

To add yet another wrinkle to the rental space sham, consider the practices owned by physicians or where a physician financially benefits from the rental payment from the lab. These arrangements implicate the Physician Self-Referral Law, also known as the Stark Law.[5] The Stark Law prohibits a physician from referring Medicare patients for "designated health services" to entities with which the physician has a financial relationship unless a specific exception is satisfied.[6] One exception to this prohibition is the rental of office space, but to satisfy the office space rental exception: "The lease [must] be commercially reasonable even if no referrals [are] made between the parties."[7] In other words, if the physician, or the practice owned by the physician, did not refer any specimens to the lab, the lab must still have a legitimate business reason to pay for the rented space. In these sham rental space arrangements, all, or substantially all, of the specimens processed in the rented space are referred by the physician receiving the rental payment. Absent the specimens referred by the physician who receives the rental payment, there would be no business justification for paying for the space because little or no work is performed. As such, the Stark Law rental space exception is not met, and the lease payments from the lab to the physician would violate the Stark Law.[8]

The solution

Any proposed or existing lease arrangement between a laboratory and a referring entity should be diligently reviewed. The following questions can help attorneys and compliance professionals dig beneath the language of proposed or existing rental space agreements:[9]

1. Do the recipients of the rental space payments, or their agents, refer specimens to the lab that pays for the rental space?
2. For each space rental location, what percentage of specimens sent to the lab come from the practice/provider that is receiving the rental payment?[10]
3. If the rental agreement is with a physician or provides a financial benefit for a physician, would the agreement be commercially reasonable if the physician did not send any specimens to the lab?
4. Does the provider believe the rental agreement would be terminated if the physician or practice stopped sending specimens to the lab?
5. If the rental space payment stopped, would the physician or practice continue to send specimens to the lab?

6. Has the frequency of testing and test utilization (the number of tests ordered) increased since the rental space arrangement was established? If so, the lab should review the medical necessity documentation for the submitted test orders.

Conclusion

Labs that offer sham rental space agreements do so because they are either ignorant of the laws or are fooling themselves with a superficial analysis of the Rental Space Safe Harbor. In either case, the labs that engage in these sham rental space agreements risk civil and criminal enforcement by DOJ and the imposition of Civil Monetary Penalties by OIG, including the possibility of exclusion from participation in federal healthcare programs. Moreover, any physician or practice receiving payments under a sham rental space agreement is equally culpable and invites significant risk to the business, license, career, livelihood, and reputation. Rarely do labs consider the risk to the physicians or practices they lure into the sham rental arrangement. Lawyers and compliance professionals for labs who offer rental space agreements need to dig beneath the surface of the language of the agreement to document how the rental space agreement is marketed, implemented, and understood by the physicians and practices receiving the rental payment.

Takeaways

- In a lab rental space agreement, a provider receives payment in exchange for referral of specimens to the lab.
- Sham rental space arrangements may violate the Anti-Kickback Statute (AKS) and Physician Self-Referral Law (Stark Law).
- Many lab rental agreements are disguised as kickbacks to encourage the referral of specimens.
- Compliance with AKS's Rental Space Safe Harbor requires looking beyond the language of the rental space agreement.
- Labs should objectively evaluate how rental space arrangements are marketed, implemented, and understood.

1 U.S. Department of Health and Human Services, Office of Inspector General, "Special Fraud Alert: Rental of Space in Physician Offices By Persons or Entities to Which Physicians Refer," February 2000, https://oig.hhs.gov/documents/special-fraud-alerts/871/office_space.htm.html.
2 U.S. Department of Justice, Office of Public Affairs, "Laboratory Marketer and North Carolina Physicians Agree to Pay Over $1.3M to Settle Kickback Violations," news release, April 29, 2024, https://www.justice.gov/opa/pr/laboratory-marketer-and-north-carolina-physicians-agree-pay-over-13m-settle-kickback.
3 42 C.F.R. §1001.952(b).
4 Special Fraud Alert, "Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer," generally addresses this point with the following statement: "The threshold inquiry when examining rental payments is whether payment for rent is appropriate at all. Payments of 'rent' for space that traditionally has been provided for free or for a nominal charge as an accommodation between the parties for the benefit of the physicians' patients [. . .] may be disguised kickbacks."
5 42 U.S.C. § 1395nn (2023).
6 Clinical laboratory services are a designated health service. *See* 42 U.S.C. § 1395nn(h)(6)(A) (2023).
7 42 U.S.C. 1395nn(e)(1)(A); *see also*, 42 C.F.R. 411.357(a)(6).
8 In the Complaint-In-Intervention for U.S. v. Balance, the U.S. Department of Justice stated that to qualify for

the Rental Space Safe Harbor under the Anti-Kickback Statute, "the lease must be commercially reasonable in the absence of referrals." This standard is not included in the Rental Space Safe Harbor language; however, it indicates that the U.S. Department of Justice may apply the Stark Law "commercially reasonable" standard in the evaluation of whether a rental agreement satisfies the Rental Space Safe Harbor. U.S. v. Balance, 15 Civ. 2641 (VSB) S.D.N.Y. (May 10, 2024); *See* U.S. Department of Justice, U.S. Attorney's Office for the Southern District of New York, "U.S. Attorney Announces $2.5 Million False Claims Act Settlement With Diagnostic Testing Facility For Paying Kickbacks To Physicians For Patient Referrals," news release, May 15, 2024, https://www.justice.gov/usao-sdny/pr/us-attorney-announces-25-million-false-claims-act-settlement-diagnostic-testing-0.

9 The State of New York has a statute that prohibits the rental of office space by a clinical laboratory from a referring "health services purveyor" or family member except under very limited circumstances. N.Y. Comp. Codes R. & Regs. tit. 10 § 34-2.6. These criteria serve as useful guidance for labs legitimately attempting to rent space from a practice or physician without creating an illegal inducement.

10 A related issue is the number of "collection stations" that exist within proximity of one another. "Collection stations" that are disguised kickbacks receive a substantial majority of specimens from the physician or practice receiving the rental payment.