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Laboratory Phlebotomists in Physician Offices? States Increasingly Saying 'No'

A common practice among clinical laboratories is to place laboratory employees, such as phlebotomists, in physicians' offices for the purpose of collecting lab samples. This practice has been allowed, with some restrictions, under federal regulations. Increasingly, however, states are prohibiting this practice through their own anti-kickback and fraud regulations. Because of the far-reaching nature of these provisions, clinical laboratories should be mindful of state regulations before placing phlebotomists in physicians' offices.

Federal Regulations

Federal regulations, including the anti-kickback statute (42 U.S.C. §1320a-7b), the Stark law (42 U.S.C. §1395nn), and Clinical Laboratory Improvement Amendments (CLIA, 42 U.S.C. §263a), have been interpreted to allow clinical laboratories to place phlebotomists in physicians' offices under certain, limited circumstances. In the absence of state regulation, clinical laboratories placing phlebotomists in physician offices must pay fair market value rent for any space the phlebotomist uses and must ensure that the phlebotomist does not perform any additional tasks that are normally the responsibility of the physician's office staff.



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The anti-kickback statute prohibits the exchange of anything of value made to induce or reward the referral of federal health care program business. The Office of Inspector General (OIG) in a special fraud alert considered whether the federal anti-kickback statute prohibited the placement of phlebotomists in physicians' offices and gave limited approval to the practice (59 Fed. Reg. 65372, 65377, Dec. 19, 1994). The OIG cautioned, however, that the practice must be permitted by state law and that the anti-kickback statute might be implicated if the phlebotomist also performed tasks that normally were the responsibility of the physician's office staff. The OIG also commented that a contract between the laboratory and the physician prohibiting the phlebotomist from performing additional services alone was in itself insufficient to show compliance; rather, laboratories must carefully monitor the phlebotomist's activities to ensure no usual physician office staff services were performed.

Laboratories renting space from physicians for laboratory phlebotomists also must comply with the requirements of the Stark law since laboratory services are designated health services. The Stark law prohibits physician referrals of designated health services for Medicare and Medicaid patients if the physician has a financial relationship with that entity, including compensation arrangements. An exception to the Stark law exists for the rental of office space. To meet this exception, the parties must enter into a written lease identifying the premises to be occupied by the tenant, lasting at least one year, and setting rent at fair market value. The space must be exclusive to the tenant when being used by the tenant and the lease must be commercially reasonable. To be commercially reasonable, the phlebotomist placement must satisfy the same business standards that a clinical laboratory would apply to

any other phlebotomist placement, including performing a sufficient number of draws a day necessary to justify the placement.

CLIA regulations apply to virtually all clinical laboratories, with the exception of those in certain states such as New York that have regulatory programs as stringent as CLIA. The CLIA program, operated by the Centers for Medicare and Medicaid Services, sets standards and issues certifications for clinical laboratory testing. While CLIA is a comprehensive regulatory scheme, it only imposes a duty on laboratories to oversee the proper collection of laboratory samples and does not prohibit placement of phlebotomists in physician offices.

State Regulations

Certain states have prohibited or severely curtailed the practice of placing phlebotomists in physicians' offices. Some of these states have created broad prohibitions through legislation, while other states have limited the practice through administrative agency efforts, including regulations and advisory opinions.

Pennsylvania and Florida

Both Pennsylvania and Florida have enacted legislation in the past two years to explicitly prohibit the placement of paid or unpaid clinical laboratory personnel in physi-

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cians' offices. Pennsylvania's 2013 Senate Bill 1042, which amended its Clinical Laboratory Act, and Florida's 2012 Senate Bill 1929, which amended Fla. Stat. §483.245(1), prohibit clinical laboratories from placing in a physician's office paid or unpaid personnel to perform services, regardless of whether fair market value is paid. Similarly, both of these states prohibit clinical laboratories from leasing any space within physicians' offices for any purpose, including establishing a collection station. Pennsylvania also prohibits physicians from procuring clinical laboratory staff to perform any functions, even if the payment

is at fair market value. As a result of the recent legislation, clinical laboratories can no longer place their phlebotomists in physicians' offices in either of these states.

The scope of the prohibition in both states is also similar and impacts all clinical laboratories seeking to do business in these states. Senate Bill 1042 applies to clinical laboratories operating in Pennsylvania or testing a specimen collected or accepted in Pennsylvania. Fla. Stat. §483.245 provides for penalties both for clinical laboratories licensed in Florida and clinical laboratories licensed in other states but doing business in Florida. Penalties for clinical laboratories not licensed by the Florida Agency for Health Care Administration (AHCA) include a fine capped at \$1,000 for violations of this statute and a recommendation from AHCA to the appropriate licensing board that disciplinary action be taken. Therefore, clinical laboratories operating in neighboring states should be mindful of the recent statutory changes. Clinical laboratories with a national presence should consider enacting compliance procedures to ensure that no phlebotomists are placed with Pennsylvanian or Floridian physicians.

New York

New York regulates the behavior of clinical laboratories operating within its borders through regulations issued by the Wadsworth Center. The Wadsworth Center prohibits placing clinical laboratory collection stations within any part of the practice,

administrative area (as distinct from the office area), office or waiting area of any health services purveyor that refers specimens to the clinical laboratory (10 NYCRR, §34-2.6(c)). Similarly, the Wadsworth Center prohibits clinical laboratories from supplying employees or agents to a referring physician to perform functions and duties in the office of that physician (10 NYCRR, §34-2.7).

Because New York requires any laboratory testing specimens originating in New York to hold a New York clinical laboratory license, the Wadsworth prohibitions will apply to any laboratory that tests New York specimens. Compliance with these regulations is important since operating a collection station or placing staff within a physician's office is deemed consideration for referral of specimens for the performance of clinical laboratory services and is, therefore, prohibited under New York's laboratory-specific anti-kickback statute (N.Y. Pub. Health Law §585-588).

New Jersey

New Jersey originally prohibited the placement of phlebotomists in physicians' offices through its Medicaid regulations. N.J. Admin. Code §10:61-2.4 prohibits the payment of rent by clinical laboratories to physicians as a condition of provider enrollment in Medicaid. Because federal regulations, including the Stark law and the federal anti-kickback statute, require that the clinical laboratory pay fair market value rent for space it uses in a physician's office, this regulation effectively prohibits a clinical laboratory from establishing a collection space in a Medicaid-enrolled physician's office. A ramification of this Medicaid-focused approach was that some providers stopped participating in Medicaid in order to continue to pay and receive rent for clinical laboratory collection stations placed in physicians' offices.

New Jersey has interpreted its state anti-kickback law, N.J. Stat. §45:9-42.42, to prohibit the placement of phlebotomists in non-Medicaid-affiliated physicians' offices. In May 2001 and January 2007, the Department of Health issued advisory opinions stating that the rental of office space by clinical laboratories in physicians' offices violated the state's laboratory anti-kickback law. Because these advisories were not effective in prohibiting clinical laboratories from placing phlebotomists in physicians' offices, the New Jersey Department of Health, in 2010, promulgated regulations prohibiting a laboratory from paying rent on physician office space (*see* N.J. Admin. Code §8:44-2.14). Any payment of monetary or nonmonetary remuneration to a physician to operate a collection station at the physician's office is considered a payment by the laboratory to solicit the physician's patients in violation of the state's laboratory anti-kickback statute.

The regulations provide an exception to the prohibition for freestanding collection stations. The N.J. Admin. Code §8:44-2.14, however, creates stringent requirements that collection stations must meet to be deemed freestanding, including that these stations (1) serve all members of the public, not just patients of one or more specific medical practice; and (2) be accessible through a public access entrance that clearly identifies the name of the laboratory and its days and hours of operation. As a result, it is impossible for a phlebotomist stationed in a physician's office to meet the requirements of a freestanding collection station.

The regulation allows for the placement of staff in physicians' offices so long as the physicians received no compensation. The Public Health and Environmental Laboratories Division of the New Jersey Department of Health explained that the intention was not to prohibit the operation of collection stations entirely but to instead allow in-office collection stations driven by patient need instead of financial incentives. Because N.J. Admin. Code §8:44-2.14 is written more narrowly than the Pennsylvania,

Florida, or New York statutes, laboratories may be able to place phlebotomists in a limited number of physicians' offices, provided that these physicians do not participate in federal health care programs and acquiesce to providing office space for free.

California

While California does not have explicit legislative prohibitions on the placements of phlebotomists in physicians' offices, the Physician Ownership and Referral Act (PORA), California's Stark law, and Cal. Bus. & Prof. Code §650, California's anti-kickback law, have been interpreted to prohibit laboratories from providing phlebotomists in physician offices. In 1980, the California attorney general interpreted

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these statutes to prohibit the provision of professional courtesy services by clinical laboratories provided as compensation or inducement for referrals to a physician, a physician's family, or patients. The opinion notes that even when there is no money changing hands there may still be improper consideration, which, if connected in any manner to the referral of patients, would violate Cal. Bus. & Prof. Code §650. The payment of rent


for collection station space in a physician's office violates Cal. Bus. & Prof. Code §650 as interpreted by the attorney general. Additionally, the attorney general interpreted the statute to prohibit the provision of staff in physicians' offices.

While attorney general advisory opinions are not binding on the courts, the Clinical Laboratory Technology Advisory Committee, the subagency that advises California's Department of Public Health on clinical laboratory matters, has adopted the attorney general's stance and even affirmatively stated that Cal. Bus. & Prof. Code §650 and PORA specifically prohibit the placement of laboratory phlebotomists in physicians' offices. Clinical laboratories operating in California thus should not assume that the absence of any legislative prohibition in California renders this practice permissible.

Conclusion

Clinical laboratories should be mindful of which state regulatory regimes prohibit the placement of phlebotomists in physicians' offices. As evidenced by Pennsylvania and Florida, prohibitions against placing phlebotomists in physicians' offices are generally written broadly. The scope of these regulations will be of particular concern to clinical laboratories located in one state but looking to expand across the border to other states and to clinical laboratories with a national presence.

Clinical laboratories also should consider the impact of regulatory risk on their provider relations. Physicians who run afoul of prohibitions against laboratory staff in their offices may face disciplinary action. Clinical laboratories thus should be mindful of the impact enforcement could have on their relationships with physicians.

Increasingly, states are not content to let federal guidance be the final word regarding placement of phlebotomists in physicians' offices. Concerns about the potential for abuse have sparked a number of recent statutes and regulations severely limiting or prohibiting the practice. Because of the broad scope of this legislation, all clinical laboratories — not just those licensed in these states — should be aware of state compliance requirements. 

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