

NOTE: New Requirements in New Jersey for Arrangements Between Physicians, Physician Practices and Clinical Laboratories

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On July 19, 2010, new regulation N.J.A.C. 8:44-2.14 (the "Regulation"), promulgated by the New Jersey Department of Health and Human Services ("DHSS") became effective. The Regulation prohibits a clinical laboratory from paying remuneration to a physician or a physician practice for space in the practice's office in which the lab operates a collection station. **This means that a practice can no longer charge rent to a lab for such space.** Further, the Regulation set forth standards for collection stations and patient service centers that serve the general public.

Pursuant to the Regulation, a clinical laboratory that operates a collection station in a practice's office must be licensed and:

- o Not make any payment, direct or indirect, to the practice including rent or any other payment for use of the space for the station;
- o Only collect specimens from patients of the practice;
- o Not permit its staff to perform any services for the practice that are normally the duties of the practice's staff;
- o Not permit its staff to be shared with, jointly employed by, or contracted with, a physician or any other person affiliated with the practice in whose office the station is located;
- o Not offer office supplies, equipment, waste disposal services, test kits for the practice's use, electronic medical records systems or other goods or services to the practice;
- o Have a written agreement between the lab and the practice; and
- o Provide a copy of the signed agreement with the practice to DHSS upon request.

Additionally, a collection station or patient service center servicing the general public may **not** be located in a practice's office and must also abide by the following standards:

- o Be open to, and serve, the general public, and may not be limited to patients of specific medical practices;
- o Be located in a free standing building or use space in a publicly accessible building;
- o Be accessible through an exterior entrance or a publicly accessible hallway with clear identification of the laboratory's name and hours of operation;
- o Be identifiable to public through clear signage on the exterior of the building, a listing in the building's on-site directory and include its address and telephone number in all advertisements and other public notices;
- o Utilize only self-contained space for the waiting room, reception area, phlebotomy rooms, restroom facilities and storage areas except for a common area shared with all tenants of a building or floor of the building, but only if two or more tenants renting separate office space are not referring physicians or healthcare providers;
- o Have a written lease for the space; and
- o Provide a copy of the signed lease to DHSS upon request.

Importantly, you should be aware that although the Regulation does not permit a practice to receive rent from lab for the operation of a collection station in that practice's office, a physician or practice that owns an office building can receive fair market value rent from a laboratory for the lease of space in the building for a patient service center.

The DHSS believes that the payment of rent by a laboratory to a physician for the operation of a station in that physician's office creates an incentive for that physician to refer specimens to the laboratory. Such a referral violates N.J.S.A. 45:9-42.42d, which provides that a clinical laboratory may not directly, or through an agent, solicit referrals of specimens or contract to perform examinations of specimens in a manner which offers or implies an offer of rebates to a person submitting specimens, or fee-splitting inducements, participation in any fee-splitting arrangements or other unearned remuneration.

To conclude, to the extent that your practice has any arrangement with a clinical laboratory, the arrangement should be in writing and you should examine that relationship as soon as possible to ensure compliance with the Regulation.



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