
SPECIAL BRIEFING & POLICY STATEMENT REGARDING SPECIMEN COLLECTORS (PARADIGM PLAs) IN FLORIDA

QUESTION: May a clinical laboratory doing business in Florida, place a specimen collector (also known as a Paradigm Laboratory Assistant (PLA)) in a Florida-based physician's office for the purpose of collecting/handling/processing specimens provided by the physician's patients?

SHORT ANSWER: No. Florida law prohibits clinical laboratories from placing a specimen collector in a physician's practice and leasing space from a physician, as further stated below.

DISCUSSION: Florida Statute 456.054(3)(b) states: It is unlawful for any clinical laboratory to:

1. **Provide personnel to perform any functions or duties in a health care practitioner's office** or dialysis facility **for any purpose, including for the collection or handling of specimens, directly or indirectly through an employee, contractor, independent staffing company, lease agreement, or otherwise, unless the laboratory and the practitioner's office, or dialysis facility, are wholly owned and operated by the same entity.**
2. **Lease space within any part of a health care practitioner's office** or dialysis facility for any purpose, **including for the purpose of establishing a collection station where materials or specimens are collected or drawn from patients.**

PENALTIES FOR VIOLATION: Violations of Florida Statute 456.054(3)(b) are punishable under Florida Statute 817.505, which is Florida's Patient Brokering Law. The penalties are steep and are set forth below:

817.505(4)(a) Any person, including an officer, partner, agent, attorney, or other representative of a firm, joint venture, partnership, business trust, syndicate, corporation, or other business entity, who violates any provision of this section commits **a felony of the third degree**, punishable as provided in s. 775.082 or s. 775.084, and shall be ordered to pay a fine of \$50,000.

817.505(4)(b) Any person, including an officer, partner, agent, attorney, or other representative of a firm, joint venture, partnership, business trust, syndicate, corporation, or other business entity, who violates any provision of this section, where the prohibited conduct involves 10 or more patients but fewer than 20 patients, commits **a felony of the second degree**, punishable as provided in s. 775.082 or s. 775.084, and shall be ordered to pay a fine of \$100,000.

817.505(4)(c) Any person, including an officer, partner, agent, attorney, or other representative of a firm, joint venture, partnership, business trust, syndicate, corporation, or other business entity, who violates any provision of this section, where the prohibited conduct involves 20 or more patients, commits **a felony of the first degree**, punishable as provided in s. 775.082 or s. 775.084, and shall be ordered to pay a fine of \$500,000.

817.505(5) Notwithstanding the existence or pursuit of any other remedy, the Attorney General or the state attorney of the judicial circuit in which any part of the offense occurred may maintain an action for injunctive or other process to enforce the provisions of this section.

817.505(6) The party bringing an action under this section may recover reasonable expenses in obtaining injunctive relief, including, but not limited to, investigative costs, court costs, reasonable attorney's fees, witness costs, and deposition expenses.

817.505(7) The provisions of this section are in addition to any other civil, administrative, or criminal actions provided by law and may be imposed against both corporate and individual defendants.

PARADIGM'S CORPORATE POLICY: **In the State of Florida, Paradigm WILL NOT permit its personnel to market or place specimen collectors (PLAs) in any healthcare facility, hospital, or medical practice, and Paradigm WILL NOT enter into any lease arrangements for space inside of a healthcare practitioner's facility/office-whether or not for specimen collection.** Paradigm monitors state laws and there may be narrow exceptions to rules, but these are the laws at the current time and each case must be evaluated on its own facts using Paradigm's protocol for placing PLAs or leasing space. **NOTE:** In other states, including AZ, GA, NC, and SC, Paradigm may agree to the placement of a specimen collector following a careful analysis of the proposed business arrangement that includes adherence to specific compliance protocols for the healthcare provider, the Paradigm Laboratory Assistant (PLA), and Paradigm Employees; All parties must participate in the analysis and governing compliance protocols to ensure Paradigm's compliant and sound business use of PLAs.

All laboratory representatives SHALL COMPLY with the guidance in this document. **If you have any questions on what activities are allowed or prohibited, please contact Cynthia Wentland, VP of Administration & Compliance Officer: cindyw@paradigm.healthcare.**

By signing below, you acknowledge that you have read and understand this policy.

Paradigm Healthcare Representative (printed)

Signature

Date Signed:

NOTE: Specimen Collectors are specifically **PROHIBITED BY LAW** in the following states: **California, Florida, New York, and Pennsylvania.** If you have any questions on whether a state allows the use of specimen collectors or "leasing" of space for the purpose of operating a specimen collection station, please contact Cindy Wentland.