
SPECIAL BRIEFING & POLICY STATEMENT REGARDING SPECIMEN COLLECTORS (PARADIGM PLAS) IN GEORGIA

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

SHORT ANSWER: Yes. Georgia law permits clinical laboratories to place and use a specimen collector in a physician's office/practice. The laws are further subject to federal and state anti-kickback and unfair trade practices law. Paradigm has a business structure to guide its business arrangements with specimen referral sources.

DISCUSSION: Georgia Rules of Department of Community Health Healthcare Facility Regulation Amend Chapter 290-9-8 and Replace with New Chapter 111-8-10 Rules and Regulations for Licensure of Clinical Laboratories; 11-8-10-(f) Specimen Collectors and Phlebotomists. **A laboratory may employ specimen collectors and/or phlebotomists whose responsibilities are outlined in Rule 290-9-8111-8-10-.06(7). There are training and supervision requirements associated with this Rule and Paradigm follows these.**

PARADIGM'S CORPORATE POLICY: In the State of Georgia, Paradigm WILL permit its personnel to market or place specimen collectors (PLAs) in any healthcare facility, hospital, or medical practice ONL IF PARADIGM'S CORPORATE PLA POLICIES AND PROTOCOLS ARE FOLLOWED. In Georgia, 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.