



Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

SALLY DRESLIN, M.S., R.N.
Executive Deputy Commissioner

Date: April 1, 2016

Dear Director,

In New York State (NYS), two programs provide oversight of clinical laboratory testing; the Clinical Laboratory Evaluation Program (CLEP) and the Physician Office Laboratory Evaluation Program (POLEP). Section 579 of New York State Public Health Law (PHL) Article 5, Title 5 states that laboratories operated by a licensed physician, osteopath, dentist, midwife, nurse practitioner or podiatrist who performs laboratory tests or procedures, personally or through his or her employees, solely as an adjunct to the treatment of his or her own patients, are not subject to the requirements of Article 5, Title 5 of the Public Health Law. Accordingly, such activity is exempt from oversight by CLEP. However, this exemption does not mean that there is no oversight of these "exempt" laboratories, as they would be subject to oversight by the Centers for Medicare & Medicaid Services (CMS). CMS has established a contract with NYS to provide oversight of these laboratories, which are referred to as Physician Office Laboratories (POL's); these functions are carried out by POLEP.

Recent survey findings by POLEP have shown that many pathology laboratories are not meeting the exemption requirement described in Section 579 of NYS PHL and need to be permitted as a clinical laboratory by CLEP. This letter is being sent to provide guidance on requirements that need to be met by a pathology laboratory to be designated as a POL (i.e., exempt as described in Section 579 of NYS PHL) and, therefore, under the regulatory authority of POLEP.

These requirements are as follows:

1. A POL **MUST** be wholly owned and operated by physicians. All staff, including pathologists, must be employees of the practice and paid by the physician owner(s). Independently contracted pathologists are not allowed in the POL model. During surveys, the Director will be asked to show a recent pay stub to confirm employment. Any arrangement outside of this description does not qualify the laboratory to be a POL and the laboratory must be permitted by CLEP.
2. If a laboratory is using a technical component/professional component (TC/PC) split for pathology specimens (Distributive Model), the technical component **MUST** be performed by a laboratory permitted by CLEP in accordance with Federal Regulation 493.1101(c) that describes compliance with applicable Federal, State, and Local laboratory requirements. The CLEP technical component laboratory **MUST** return the slides directly to the POL where the specimens were collected for the professional component if the POL is to bill for the reading.
3. The professional component **MUST** be read on site at the POL. Slides cannot be read at pathologists' other places of employment or at their homes. **PLEASE NOTE:** This is not a specific NY POL requirement. This is a Center for Medicare/Medicaid Services (CMS)

Federal requirement. Section 493.43 of the CLIA regulations state that "except as specified in paragraph (b) of this section, all laboratories performing non-waived testing must file a separate application for each laboratory location." If someone is reading slides/images at a location other than the main laboratory, that location requires a separate CLIA certificate. If the lab fails to comply after being notified in writing, they are referred to the Office of Inspector General. If the other site where a pathologist is reading a POL's slides, has a CLIA number, then that laboratory must be credited with the test and the POL cannot bill for the professional component.

4. Specimens from an Ambulatory Surgical Center (ASC) are not allowed to be sent to a POL. Patient specimens collected at an ASC are considered patients of the ASC and not an individual physician who is performing the surgery. If an ASC wishes to perform the professional component then the ASC must have a CLEP permit for pathology and the slides must be read at the ASC. In an office based surgery situation, the patients are considered patients of the physician and slides may be read at the POL.

Please be advised the above noted items will be addressed routinely at survey by POLEP and CLEP. Laboratories that do not meet the requirements for a POL will be referred/transitioned to CLEP. If the activities listed in 2 through 4 above are found to continue after the date of this letter, the laboratory will be cited accordingly.

We also request that the laboratory director share this letter with the POL/ASC/CLEP owner(s) so that they are also aware of these requirements. If you have any questions, please contact POLEP at 518-485-5352 or email at clia@health.ny.gov or CLEP at 518-485-5378 or email at clep@health.ny.gov.

Sincerely,



Thomas L. Lipinski, MT
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Physician Office Laboratory
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TLL/jc