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Healthcare Alert

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Substantial regulatory changes proposed for New York's clinical laboratories and blood banks

By Justin D. Pfeiffer

NY's Department of Health published proposed regulations changing the requirements governing clinical laboratories and blood banks—the public comment period is open.



What's the Impact?

- / The proposed regulations include new and/or revised duties, requirements, and qualifications for laboratory directors, assistant laboratory directors, and several other positions
- / Character and competence review proposed for laboratory directors and owners of clinical laboratories and blood banks
- / If adopted, the new regs would establish a "single use" permit type to authorize testing for a limited period of time and/or for a limited number of tests

After a long development cycle, the New York State Department of Health ("NYSDOH") has published [proposed regulations](#) that would make significant changes to the requirements governing clinical laboratories and blood banks. If adopted in their current form, the new regulations would:

- / Authorize NYSDOH to review, when processing clinical laboratory and blood bank permit applications, the character and competence of the laboratory director and all owners of the laboratory or blood bank. The regulations specify numerous review factors, along with any "other factor having a direct bearing on the laboratory director and/or owner's ability to provide high quality laboratory services."
- / Clarify and amend the processes related to the application, denial, and termination of provisional permits for categories of testing.
- / Establish a new "single use" permit that may be issued on a patient-specific or test-specific basis. Such permits may be issued for a limited period of time and/or for a limited number of tests, based on several criteria. Significantly, NYSDOH would be able to issue single use permits to laboratories that do not otherwise hold a clinical laboratory or blood bank permit.
- / Impose new responsibilities on any assistant laboratory director who possesses the sole certificate of qualification for a category of tests.
- / Expand the number of clinical laboratories or blood banks at which a person may serve as laboratory director or assistant director, from two (2) to five (5).
- / Require laboratory directors and assistant directors to be present on-site, at each laboratory where such person serves, at least eight (8) hours per week, and to be immediately available remotely at all other times. NYSDOH will consider requests to be present on-site for less than eight (8) hours at a particular location, and may require directors and assistant directors to be present for more than eight (8) hours, depending on several factors.
- / State that the laboratory director and all owners of a clinical laboratory or blood bank are "jointly and severally responsible" for the facility's operations, and responsible for a "quality management system for the delivery of services."
- / Provide that failure to notify NYSDOH of the resignation, termination, death, or physical or mental incapacitation of the laboratory director within 60 calendar days shall result in the voiding of the permit. Failure to provide such notifications with respect to a sole assistant director would void any specific testing category for which such assistant director is responsible.
- / Establish new or substantially revised duties and qualifications of laboratory supervisors, clinical laboratory technologists, clinical laboratory technicians, cytotechnologists, and histological technicians.
- / Establish new communicable disease reporting requirements.

The new character and competence requirements would be a significant change to NYSDOH's permitting process. However, NYSDOH said little about them in the regulatory paperwork, focusing more on the regulatory flexibilities that the regulations would provide.

Among other goals, NYSDOH stated that these regulations would enable the agency to more quickly issue limited permits in a public health emergency—in particular, by providing a process

for issuing provisional permits in the category of virology, as well as “single use” permits to laboratories not currently licensed by NYSDOH.

The new regulations also appear aimed at addressing the current shortage of laboratory director candidates—in particular, by allowing assistant directors to be treated as laboratory directors for certain categories of testing (“sole assistant directors”), and by increasing the number of directorships that may be held from two to five. At the same time, the regulations specify new on-site presence requirements for laboratory directors and sole assistant directors. Similarly, the regulations would expand the pool of laboratory supervisor candidates, by expanding the eligibility criteria.

The comment period for the regulations expires on May 23, 2022. For more information on the content of this alert, please contact your Nixon Peabody attorney or:

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