

ANDREW M. CUOMO Governor HOWARD A. ZUCKER, M.D., J.D. Commissioner

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

July 22, 2016

Dear Laboratory Director,

The New York State (NYS) Department of Health (DOH) recently implemented a new policy regarding required clinical laboratory proficiency testing (PT). Effective January 1, 2016, permitted laboratories were allowed to use other CMS-approved PT providers to satisfy NYS PT requirements. Many laboratories opted to enroll with other providers for 2016.

After evaluating the effects of the new policy for the first half of 2016, we will discontinue the remaining NYS clinical laboratory PT programs. Effective December 31, 2016, New York State will no longer provide clinical laboratory proficiency testing. Instead, we will expand our current process for reviewing results and scores from other PT providers, following a model similar to Washington state, the other CLIA-exempt state.

Note that all NYS PT requirements apply to PT offered by other providers. Requirements for permitted laboratories include but are not limited to:

- Enroll in PT for tests offered by the laboratory that are described in 42 CFR 493 subpart H and subpart I.
- Notify NYS of intended enrollment for required PT. There will be a notification process for 2017 in the fall of this year. Additional information about the notification process will be available in September, 2016.
- Maintain satisfactory and successful performance for any formal PT event, whether or not the PT is required.
- Perform corrective action and remediation for unsatisfactory and unsuccessful performance. Provide documentation to the Department when requested.

Your patience is appreciated as the Department transitions to a new PT model designed to be flexible in responding to the needs of permitted laboratories while continuing to maintain the quality of laboratory testing in New York.

Regards,

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