NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

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

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

August 14, 2015

Dear Laboratory Director:

You recently received a letter that described some upcoming changes in the New York State Proficiency Testing (PT) policies. This letter contains further information about these changes and describes what your laboratory must do to remain in compliance with New York State (NYS) and CLIA PT requirements.

PT requirements as of January 1, 2016

As a result of these changes, tests offered by the permitted laboratories or laboratories applying for a permit fall into one of three categories in terms of PT requirements:

1. Tests for which NYS offers PT
2. Tests for which NYS does NOT offer PT but that are included in 42 CFR 493 Subpart I
3. Tests for which NYS does NOT offer PT and that are NOT included in 42 CFR 493 Subpart I

1. Tests for which NYS offers PT

Currently, NYS Clinical Laboratory Proficiency Testing Sustaining Standard of Practice 1 (PT S1): Participation requires permitted laboratories or laboratories applying for a permit to participate in NYS PT, if available, for each category or test for which the laboratory seeks or currently holds a permit, and for which proficiency testing is offered. This requirement applies whether or not the test/analyte is described in 42 CFR 493 Subpart I.

Beginning January 1, 2016, laboratories must enroll in:

- The appropriate NYS PT program OR
- The appropriate PT module(s) from another CMS-approved PT provider(s). The non-NYS PT module must be designated by the NYS Department of Health (Department) as equivalent to NYS PT. Please see the attached list of acceptable PT modules for each NYS PT program.

In addition to enrolling in appropriate PT with a CMS-approved PT provider, your laboratory must inform the Department of its PT selections for 2016 during the NYS PT events scheduled for August to November of 2015. The Event Page in the Electronic Proficiency Test Reporting System (EPTRS) for each PT event will include a dropdown menu for each test or analyte that lists the acceptable PT modules. The laboratory director or EPTRS delegated submitter must select a NYS PT or equivalent module from another CMS-approved PT provider for each test/analyte. The PT results for an event cannot be submitted until the 2016 PT selections have been made.

These PT selections will be binding for the entire calendar year 2016. Your laboratory will have the opportunity in late 2016 to make selections for calendar year 2017.

2. Tests for which NYS does NOT offer PT but that ARE included in 42 CFR 493 Subpart I

A number of NYS PT programs will be discontinued as a result of the change in PT policies. Some of the discontinued programs satisfy CLIA PT requirements described in 42 CFR 493 Subpart I.

Beginning January 1, 2016, laboratories that are currently enrolled in these NYS PT programs must be enrolled in another CMS-approved PT program that satisfies the same CLIA PT requirements.

In addition to enrolling in appropriate PT with a CMS-approved PT provider, your laboratory must inform the Department of its PT selections for 2016 during the NYS PT events scheduled for August to November of 2015. The Event Page screen in EPTRS for each PT event will include a dropdown menu for each test or analyte that lists the PT modules that satisfy the PT requirements in 42 CFR 493 Subpart I. The laboratory director or EPTRS delegated submitter must select a PT module for each test/analyte. The PT results for an event cannot be submitted until the 2016 PT selections have been made.

These PT selections will be binding for the calendar year 2016. Your laboratory will have the opportunity in late 2016 to make selections for calendar year 2017.

3. Tests for which NYS does NOT offer PT and that are NOT included in 42 CFR 493 Subpart I

Some of the discontinued NYS PT programs (for example, Oncology – Molecular and Cellular Tumor Markers) do NOT include tests/analytes described in 42 CFR 493 Subpart I. Therefore, there is neither a NYS nor a CLIA PT requirement for these tests/analytes.

Beginning January 1, 2016, laboratories currently enrolled in these programs are NOT required to enroll in another PT program. However, NYS Clinical Laboratory Quality Assessment Sustaining Standard of Practice 3 (QA S3): Ongoing Verification of Examination Accuracy requires biannual verification of test accuracy. Appropriate mechanisms for satisfying QA S3 include, but are not limited to, re-testing blinded samples, parallel testing with another laboratory, and participation in external PT.

Status of NYS PT programs

The enclosed list gives the status of each NYS PT program, the CLIA PT requirements they satisfy where applicable, and PT modules from other CMS-approved providers that satisfy the same NYS or CLIA PT requirements. There will also be a link to this list in EPTRS.

PT participation and performance

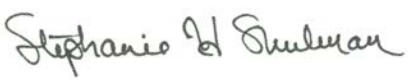
CMS requires NYS to collect and review PT enrollment and performance data for permitted laboratories. This requirement applies to all tests/analytes, regardless of whether the PT satisfies a NYS or CLIA PT requirement. Therefore, the Department will require PT providers to submit enrollment and performance data. Failure to participate or poor performance in PT, regardless of the PT provider, may impact the laboratory's permit.

As the Department transitions to accepting other PT providers, the impact on its PT programs will be better understood. The Department will keep affected laboratories informed.

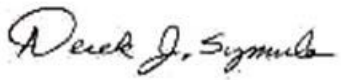
Please contact Derek Symula, Ph.D. by email at: derek.symula@health.ny.gov or Vicky Derbyshire at: victoria.derbyshire@health.ny.gov, if you have questions or need further information.

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,



Stephanie Shulman, M.P.H., M.S., M.T. (ASCP)
Director, Clinical Laboratory Evaluation Program
Wadsworth Center



Derek J. Symula, Ph.D.
Director, Wadsworth Center PT Program

Enclosure

Frequently Asked Questions

If I select a non-NYS PT module in EPTRS, will NYS forward my PT selection to the PT provider?

No. Your laboratory must enroll directly with the PT provider for the PT modules selected in EPTRS. DOH will not forward your selections to the PT providers. Note that PT providers generally have enrollment deadlines no later than December 1, 2015 for calendar year 2016. See sections 1 and 2 regarding PT selection and enrollment.

My laboratory performs waived testing. Am I required to participate in PT for these tests?

If your laboratory offers the test on NYS specimens and performs the test in a permitted clinical laboratory, the PT requirements are the same as for non-waived testing. See sections 1 through 3. If the waived testing is performed at the patient bedside under a Limited Service Laboratory registration, then PT is not required.

Several PT providers offer modules that would satisfy PT requirements for the tests my laboratory offers on NYS specimens. May my laboratory enroll in PT from different providers for these tests?

Each lab may choose any of the CMS-approved PT modules listed in the dropdown menus in EPTRS.

Do I have to authorize my PT provider(s) to release my laboratory's PT results to NYS?

DOH requires PT providers to release PT results to NYS.

May my laboratory participate in more than one PT module for a given test or analyte?

Some laboratories may want to participate in more than one PT module for a test. Other laboratories may participate in PT modules that have tests/analytes in common to satisfy PT requirements. Your selections in EPTRS will be used to satisfy PT requirements for NYS and/or CMS, as applicable. Your laboratory may participate in additional PT. However, poor performance on these additional PT challenges also may impact your laboratory's permit.

What happens if my laboratory has Unsatisfactory performance on a non-NYS PT challenge?

Per NYS Clinical Laboratory Proficiency Testing Sustaining Standard of Practice 10 (PT S10): Performance Review – Unsatisfactory Performance, unsatisfactory PT performance for tests offered on NYS specimens must be investigated and appropriate corrective actions implemented. The laboratory may be required to submit material for review, including the

results of the investigation and documentation of corrective action. Poor PT performance may impact your laboratory's permit. This applies to all external PT, whether or not there is a NYS or CLIA PT requirement for the test(s) in question.

Will surveyors review PT results during inspections?

Surveyors will review results for external PT from providers that are not CMS-approved and other mechanisms used to satisfy standard QA S3. PT results from CMS-approved providers generally will be reviewed centrally in Albany.

Will DOH provide samples to use in remediating an unsatisfactory or unsuccessful PT score?

DOH will not provide remediation samples for tests/analytes not included in our PT program. Individual PT programs may be able to provide samples under certain circumstances.