NY cuts labs loose from requirement to use state's PT

Anne Paxton

October 2015—With the New Year approaching, many laboratories that test New York state specimens can look forward to breathing a sigh of relief. Regulatory relief, that is. Thanks to a policy change by the state's Clinical Laboratory Evaluation Program (CLEP), beginning Jan. 1, 2016, laboratories will still have to be inspected by the state, but can fill New York's proficiency requirement with the proficiency tests of any organization to which the CMS has granted deemed status under CLIA.

As a result, laboratories that employ the CAP's proficiency testing program will no longer be required to use the PT program of the New York CLEP as well.

Dr. Lifshitz

For hundreds of laboratories in New York, the change will mean lower costs and a lighter staff burden because they will be able to go from paying for two PT programs to paying for one. "I think the state has taken a very positive step forward to help labs," says Mark Lifshitz, MD, clinical professor of pathology and director of clinical laboratories for NYU Langone Medical Center.

He welcomes the ability to scale back to one PT program, and in NYU's case, that will be the CAP's program. "It means fewer surveys to perform, less recordkeeping, and you're not duplicating the surveys you're already performing," he says.

New York state has always had a robust laboratory oversight system and was the first state to have an exemption from CLIA, Dr. Lifshitz notes. "A lot of labs in New York state do a whole lot of PT. The CAP Surveys tend to be more comprehensive in the sense that they cover more analytes, but the state's surveys are excellent and very thorough. They probably cover almost everything—if not everything—that a small hospital laboratory does."

But the policy change reflects the "reality in health care and diagnostics, and trying to make PT as efficient as possible, the same way we're trying to make testing in general as efficient as possible."

Laboratories already participating in the proficiency testing programs of other providers "potentially have the immediate flexibility to choose only one PT provider and so they are probably the most affected," Victoria Derbyshire, PhD, deputy director of the New York State Department of Health's Wadsworth Center (which administers CLEP), said in an email to CAP TODAY.

This category of laboratories includes not only those based in New York. National commercial laboratories and specialty labs like Mayo Medical and ARUP laboratories, even though their headquarters are out of state, have also been required to use New York state proficiency testing in order to perform testing on any specimen originating in New York.

The PT policy change is one that laboratories in the state have long been advocating. "This is something we've been after for a few years, and it stemmed from concerns within the lab community that laboratories were paying twice for proficiency testing inspections," says Tom Rafalsky, president of the New York State Clinical Laboratory Association.

Rafalsky

“Many labs had to get PT done by CAP or some other entity for various reasons, but if they did, New York state did not recognize it. But PT is expensive,” Rafalsky says. “For some labs it runs in the six figures. It also took a lot of staff time to do the PT, and that was almost as big a concern as the financial concern.”

One factor in turning the tide may have been New York governor Andrew Cuomo’s preference for more business-friendly regulation, Rafalsky notes. “Finally, after years of discussion with the Department of Health—and the governor’s office got involved with this—the DOH determined in 2015 that they had enough confidence in the PT performed by other CMS-approved vendors that, going forward, they would accept their PT results.” The Hospital Association of New York State also was involved in advocating for the plan, he adds.

As the New York CLEP noted in its announcement to laboratories, several months ago the agency had convened focus groups to look at how to reduce costs and improve quality, and eliminating the PT requirement was raised as a possibility. “Several people representing the clinical laboratory community have asked for this change in policy for a few years,” Dr. Derbyshire says. “A number of factors—feedback from labs, long-term changes in lab testing, and availability of other PT programs that we feel satisfy our requirements—converged to lead us to look at our PT program as a whole and to implement this new policy change.”

Some of New York state’s PT programs have already been marked for discontinuation. CLEP recently announced that the PT scheduled for Oct. 26 will be the last one provided by CLEP for urinalysis, urine pregnancy, and urine chemistry. Also as of Jan. 1, the program will drop several other proficiency tests that satisfy PT requirements under CLIA, such as gonorrhea and chlamydia, mycobacteriology identification and drug susceptibility, comprehensive parasitology, toxicology blood lead, and comprehensive virology. Others being canceled (for example, human papillomavirus and fetal defect markers) are proficiency tests that are not required under CLIA. All the discontinued New York PT modules are available PT modules under the CAP Surveys program.

Other New York state-run PT programs could be eliminated later. “I expect that they’re waiting to see how many people want to continue with New York state before they determine if they’re going to drop any additional areas next year,” Rafalsky says. CLEP says it will proceed on the basis of which PT providers laboratories choose for 2016.

Analytes for some of the PT programs that CLEP has discontinued—for example, Oncology-Molecular and Cellular Tumor Markers—are not subject to either a NY state or CLIA PT requirement. Laboratories currently enrolled in those PT programs are therefore not required to find a replacement program.

But CLEP notes that under its Quality Assessment Sustaining Standard of Practice 3 (QA 3), Ongoing Verification of Examination Accuracy, laboratories must have a system to verify every six months the reliability and accuracy of each test for which no New York state PT is offered. And participation in external PT is one mechanism that can be used to satisfy QA 3. (Others include re-testing blinded samples and parallel testing with another laboratory.)

Rafalsky says the state has long required some kind of validation of test results even for non-regulated analytes. “They tried to cover as many areas as they could” with their own PT—“if there were enough labs wanting it to create a big enough pool so there would be scientific validity and it would cover its costs.”

The rationale for having such an extensive PT program is that the purpose of CLEP goes beyond CLIA-regulated analytes, Dr. Derbyshire explains. “More broadly, the purpose of the PT program, of course, is to maintain lab quality. That mission cannot be limited to the narrow set of tests and analytes listed in the CLIA regulations.”

CLEP considers it likely that some labs will continue participating in more than one PT module for a given test or analyte, even after Jan. 1. “Some of the permitted labs do this because PT is a valuable component of quality management,” Dr. Derbyshire notes. “Others do it because they have to participate in PT from a given provider to maintain accreditation, but prefer the format or support associated with a different provider. We have had multiple labs ask us whether they could participate in both NYS and non-NYS PT.”

Dr. Derbyshire

Virtually all the larger labs in New York are using an additional PT vendor now, Rafalsky says, but with New York’s new PT rules, “now they can mix and match—they can do some with CAP, some with New York state—they just have to have all the different CLIA-regulated analytes covered by somebody’s PT.”

CLEP deserves credit for working with the clinical laboratories to get this change made, Rafalsky says. “It’s a big deal, because they had no mechanism to recognize other PT vendors, so they had to figure that out. The big thing was how do you get information from the private vendor to CLEP, because when the private vendor does the PT, it still has to report results to CLEP.” In fact, CLEP will require all PT providers, whether or not the PT for a particular analyte is required by NY state or CLIA, to submit enrollment and performance data.

Rafalsky hopes laboratories are realizing they will now need to specify their PT provider. “CLEP has been trying to warn labs that this decision is coming up, but you can say something and for some labs it won’t register until push comes to shove. And then a lab will not be able to register its PT results for the rest of the year until they choose a provider in 2016.”

When labs get up to speed on the new PT policy, he sees increased competition as a positive outcome. “Now labs that want to operate in New York no longer have to have redundant PT testing. They can choose PT based upon the qualifications of the provider, on value-added, on cost, and on the areas offered, and they’re not mandated by the government to go with the government program. The government has to compete.”

New York’s shift in PT policy was preceded by extensive advocacy from the CAP, says Mary Fowkes, MD, PhD, president of the New York State Society of Pathology.

New York is probably the most heavily regulated state for labs, she says, pointing to the state’s recent adoption of a requirement for histology technicians to be state-licensed as an example. In the case of PT, “New York state regulators finally recognized that the state PT didn’t provide anything unique or different from what CAP PT already gave, and that we needed regulatory relief on this issue.”

Dr. Fowkes expects the policy change to reduce burdensome and redundant testing at Mount Sinai Medical Center in New York City, where she is director of neuropathology and autopsy services.

Dr. Fowkes

But the policy shift does not affect the requirement for New York laboratories to be New York inspected, Dr. Fowkes emphasizes. “These are changes just for PT; everything else remains the same. The state is still going to inspect; you just don’t have to have two sets of proficiency surveys.” Most labs are happy with that outcome, she says. “A lot of labs prefer to do the CAP PT, and given that a very high percentage of labs want CAP accreditation, eliminating the state PT requirement is an economic relief to labs.”

The state should have a good idea soon of the direction in-state labs intend to take, because when labs submit their fall proficiency results between August and November, for each analyte they are required to indicate which survey they intend to use in 2016 to satisfy the PT requirement. “You can’t submit the current DOH survey results without doing so,” Dr. Lifshitz says.

And once laboratories decide on their survey providers, their choices will be locked in for 2016.

So far, Dr. Derbyshire says, “We have begun to receive notification from some labs. But it is too early to report” on how many labs will be using outside PT providers. She expects there to be cost savings for the Wadsworth Center as a result of the new policy. “But we do not know to what extent until we understand the impact on our programs as the permitted labs do or do not choose to participate in alternate PT programs.”

Stallone

Large health systems with many hospitals in New York, in particular, are likely to shift to just using CAP PT, says Robert Stallone, executive vice president, laboratories, Northwell Health (formerly Northshore-Long Island Jewish Health System), which has the largest laboratory network in New York. “As a large health system, we’re always concerned about expending our resources where they have value relative to patient care. For several years, we’ve had discussions with the state asking them to take a look at the PT program, which was redundant for many of us. As part of the state’s listening to its constituents, I think they heard our voice and agreed to do it.”

“So for us, this is terrific. The reduction in cost and effort in the laboratory will be achieved immediately within our own labs,” Stallone says. “I think it will be a little more work and challenge for those who are only using New York state proficiency testing, because the state will not be able to maintain all their proficiencies; they will have to go through and determine which ones they will need to get from another source. And there are several CMS-recognized providers of PT, not only CAP. So that gives laboratories a pretty wide field to choose from.” He hopes, if the change in PT policy works well, that the state will consider revising its laboratory surveillance program to allow use of private providers for inspection as well, sometime in the future.

Stallone has found laboratories to be upbeat about the impending policy change. “We had a meeting with the NYSCLA, and everyone was very pleased we were finally able to accomplish this. I think any time there is a change there is always a little concern. That’s the nature of lab people to be concerned about detail. And we have to be very careful with the transition, to make sure we get everything communicated to our staff at the hospitals and laboratories, and also stay in close communication with the state to clarify any questions.”

New York’s program is particularly visible and influential, Stallone notes. “It’s the state that requires labs outside the state to have a New York state lab permit if they do testing on New York patients, which is unique. And to have that permit you’d have to have, until now, New York state PT. So this was a big expense not only for labs in the

state but across the country."

By helping to stem that added expense, Stallone says, New York's new PT policy is reflecting the concept that "all segments of government and industry here in health care are doing what can be done to work together to reduce costs as we transition to value-based health care, because we just can't afford not to."

From the Wadsworth Center's viewpoint, Dr. Derbyshire says, "We want to emphasize that we are reviewing the PT program to maintain lab quality in response to long-term changes and trends in clinical lab testing. We believe quite strongly that the change in policy is an improvement in the program. We will have the ability to carry out a more systematic review of more PT results since we will be directly seeing and reviewing all PT events in which the permitted labs participate."

CLEP sees its primary role not specifically as a PT provider, she says, but as ensuring the overall quality of laboratory services in New York. "Our mission is to ensure lab quality. If providing PT is the best way at a given time to maintain lab quality, we'll provide PT. If monitoring other providers' results is the best way to maintain lab quality under other circumstances, that's what we'll do," she says.
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Anne Paxton is a writer in Seattle./em>