Proficiency tests on multiple instruments: CMS clarifies regs

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March 2016—If a laboratory does not perform its proficiency testing in accordance with a recently reiterated CMS directive regarding PT on multiple instruments, its standing with the Centers for Medicare and Medicaid Services could be at stake. In fact, "You could be sanctioned directly by the CMS," says Thomas Long, MPH, CAP director of biostatistics.

The July 2015 directive—which states that laboratories are not permitted to test PT samples on multiple instruments unless that is how they routinely test patient specimens—is not exactly new. Under CLIA regulations, a laboratory must treat a PT specimen just as it does a patient specimen. "It's always been around," says Linda Palicki, MT(ASCP), CAP director of continuous compliance. "It's just that in July, CMS clarified that this restriction applies also to nonregulated analytes and to analytes categorized as waived under CLIA." For CLIA-regulated analytes, PT providers in 2014 removed from PT result forms the option to report secondary instruments or methods.

Since last fall, Palicki and other CAP staff have received questions from laboratories that are concerned about inadvertently violating the directive. "We are still hearing from laboratories asking, 'What do I need to do? I have multiple departments that are under one CLIA and CAP number, so how will I approach my PT? And if I want to check my other analyzers, what are my best options?'"

Dr. Killeen

Palicki expects those questions will only increase as laboratories learn of the reporting change in the CAP's revised whole blood glucose proficiency test, which, she says, has been "significantly impacted by the CMS reiteration." Thus she, Long, and CAP Council on Scientific Affairs member Anthony A. Killeen, MD, PhD, spoke with CAP TODAY about the reiterated directive, in hopes of clearing confusion and easing anxiety among laboratories.

Palicki offers a straightforward summary of the directive and its context. "In the past," she says, "I don't think proficiency testing providers understood that laboratories were not able to test more than one kit of the same PT materials if they had multiple analyzers. I think they thought that laboratories did have the ability to test on more than one analyzer to verify the accuracy of those analyzers, and what CMS is saying is the CLIA regulations don't allow that, because that's not how laboratories are actually performing patient testing. With CMS clarifying that for us, we want to make sure our laboratories understand this also."

Or as Dr. Killeen sums it up: "In the past, everybody understood you couldn't run PT more than once on the same instrument unless that's what you did with patient samples. This reiterated directive clarifies that you can't run PT more than once on different instruments." Dr. Killeen is director of clinical laboratories, professor and vice chair for clinical affairs in the Department of Laboratory Medicine and Pathology, and director of the Advanced Research and Diagnostics Laboratory, University of Minnesota Medical Center in Minneapolis.

One proficiency test result per analyte per specimen is allowed for each individual CLIA-licensed laboratory during the PT event—that is, before the result submission due date. Materials from different PT programs can be ordered to test the same analyte as long as the programs have different specimen formulations or specimen designations. Large laboratories with multiple testing sites or locations under one CLIA license should order only one PT program kit, the CMS says, unless they are testing multiple instruments with different analytes. If a laboratory routinely uses more than one primary method or instrument to report the same analyte, PT can be rotated among the primary methods or instruments during different PT events.

In response to the CMS directive, the CAP eliminated secondary instrument reporting options from all of its proficiency testing programs. "Now here's an important piece," Long says. "Many people think, 'Oh, therefore, the CAP must have also restricted labs from ordering multiple kits under the same CLIA number.' But the CAP has not. Why? Because we know that laboratories use our materials for QA purposes, and we still allow that. So a laboratory can still order multiple kits under the same CLIA number, but the responsibility is then on the laboratory to make sure it doesn't run the same PT material on any other instrumentation during the PT period." Once the PT due date has passed, then they can use it for quality assurance purposes, Long says, because at that point they already will have had to submit their PT results.

"To say, 'You can only order one kit of a PT product' would not be an accurate statement," Palicki agrees. "If I'm a laboratory, and I have two different chemistry analyzers that are doing two totally different sets of analytes, I could order two PT kits, because I may do these five analytes on this analyzer and 10 different analytes on that analyzer. That's perfectly legal. That's not against CLIA."

Also permitted, she adds, would be using two PT products that are totally different but test for the same analytes. "For example, if I had a chemistry analyzer that runs basic chemistries, like sodium, potassium, and glucose, and then in my point-of-care area I had an i-Stat that also runs sodium, potassium, and glucose, in that case it would actually be okay for me to run PT on both instruments because the PT material is different. There's no way I could look at the PT results on my chemistry analyzer and the PT results I got on my i-Stat and try to compare them. They're totally different materials." In that case, it is acceptable for a laboratory to order two PT products for the same analytes. "So it gets complicated for the laboratories, knowing how to navigate this issue."

Another reason the CAP has not prevented laboratories from ordering multiple kits under the same CLIA number is that not all laboratories are subject to U.S. CLIA regulations. "Examples are international laboratories or other U.S. entities not subject to CMS interpretation," Long says. "If they want to run PT on multiple instruments during the PT period, and if they are not subject to a CLIA license, then this doesn't apply."

To make life easier for laboratories, the CAP has introduced its Quality Cross Check programs, which are designed to allow labs to monitor the performance of multiple instruments. "They're designed particularly for this application, and they're not just chemistry. They apply to hematology, coagulation, any kind of situation where you might be running different instruments for the same analyte," Dr. Killeen explains. (The full list of QCC programs available this year: automated hematology, B-type natriuretic peptides, clinical microscopy, coagulation, critical care aqueous blood gas chemistry, general chemistry and therapeutic drugs, special chemistry, and virology.)

With a QCC program, participants receive three challenges in each of two mailings a year that span the reportable range, and participants can report up to three instruments for each challenge. One evaluation uses peer group comparisons, which include peer group assignment, targets, acceptability limits, graphical summary of deviation, and summary statistics for each reported instrument and specimen. A second evaluation uses instrument comparisons, which include absolute and percent pairwise differences between reported instruments and specimens.

However, using a QCC program is just one option. "Laboratories can do other things themselves," Long says. "They can keep PT material after its due date has passed and run their own study of instrument comparisons. Or they can do their own instrument comparison study and assessment to meet the Laboratory Accreditation Program

requirement, and there are ways they can do that on other materials, including doing it on fresh patient samples." In both cases, there must be established acceptability criteria, and performance must take place twice yearly.

There has been a change to the CAP's whole blood glucose proficiency test, effective with the PT mailing this month, to accommodate the CMS directive. In the past, laboratories could report results for up to 20 different whole blood glucose instruments. "Because of the directive, now they can technically report a result on only one," Palicki says. For 2016 only, after the due date laboratories will be able to access a results form online and report up to 19 additional glucose results. "And that's different from all the other PT products we have," Palicki says. "This is going to be a big change for a lot of laboratories because it's one of the biggest products we sell. When someone sees the result field, and there's a result field for only one glucometer, they're going to wonder, 'Where are my 19 additional fields?' So we want to make sure laboratories understand they are going to have an opportunity to report those additional glucometers. It's just that you won't be able to access another report form until after the PT due date of the first meter has passed."

This is an interim solution. In 2017 the CAP will introduce a new QCC product that will be a comprehensive solution for whole blood glucose.

"All these issues are complex," Palicki says. She advises reviewing the list of frequently asked questions on the CAP website (under e-Lab Solutions Suite), and if that doesn't answer a question, then calling the CAP (800-323-4040 option 1). "We don't want to put laboratories at any kind of regulatory risk," she says, "but yet we want them to have a process to ensure their instruments and analyses are as accurate as possible by performing PT when appropriate and within regulatory confines."
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