

Missing transcripts, diplomas snag labs

Anne Paxton

April 2013—The paperless office may be just around the corner, and virtual reality may lie ahead too. But for the time being, when it comes to demonstrating that personnel have the required educational qualification to perform nonwaived point-of-care testing, the Centers for Medicare and Medicaid Services and the CAP have a message for laboratory directors: Primary documents are king. For accreditation under CLIA, it's not enough to know personnel are qualified because of their certificate or license; you have to prove it with copies of their transcripts and diplomas.

For nonwaived point-of-care testing, laboratories are inspected with two checklists containing personnel requirements: the laboratory general and the point-of-care testing checklists. Laboratory general requirement GEN.54400 addresses personnel records and what must be in each file, explains Deborah Perry, MD, director of pathology at Children's Hospital and Medical Center, Omaha, and pathologist at Omaha's Methodist Hospital. "There are nine things listed there, and items such as dates of employment, license or certification, continuing education, and other areas are usually covered. The one that laboratories often get held up on is the second item: copy of academic degree or transcript."

Last year, in fact, during on-site inspections it was one of the most common accreditation deficiencies, recorded 7.2 percent of the time, says Dr. Perry, who is chair of the CAP Point-of-Care Testing Committee. "It's a pretty high number when you look at all the checklist items we have." The point-of-care checklist item, POC.06850, says labs must have records demonstrating "there is documentation that all staff have satisfactorily completed initial training on all instruments/methods applicable to their designated job." Records of training must be available in their personnel files.



Dr. Perry

The CMS requires the laboratory to have the diploma or transcript of anyone performing laboratory testing, whether inside or outside the laboratory. An entire list has to be maintained, together with documentation that the people have been trained on whatever point-of-care device they're using, proof of competence assessed semiannually in the first year and annually thereafter, and academic degree or transcript. That can mean hundreds or even thousands of academic records. "We have around 100 people performing POC testing at Children's Hospital even though we're only a 120-bed hospital," Dr. Perry points out.

Although it's technically performed at the bedside, most point-of-care testing is under the direction and CLIA license of the laboratory and thus the lab director. Personnel requirements affect everyone, therefore, not just the medical technologists in the lab but also the nursing personnel and patient care personnel—whoever is performing the actual testing.

When an inspector comes in during a laboratory inspection and asks the laboratory manager or POC coordinator to show all the personnel records, a spot check may show records are missing. "They can randomly pick five or 10, and if the lab inspector pulls one out that doesn't have the degree or transcript, then you have failed that requirement." A rate of seven percent, Dr. Perry says, means this happens not infrequently.

But a glance at the AACC listserv for point-of-care testing coordinators shows that within the hospital, there is

sometimes a distinct lack of understanding about the possibility of being cited. Says one commenter: "It was extremely hard to convince my Human Resources office that they could not use 3rd party verification and had to have a diploma or transcript." Another: "The nursing exec team feel that the diploma/transcript requirement may not be realistic." A rationale that is frequently heard: "Licensed personnel have to have a degree in order to be licensed, at least in our state, so why do we have to have their diploma?"

It's been at least a year since the CMS stepped up its scrutiny of the actual personnel file documents, says Gerald A. Hoeltge, MD, former chair of the CAP Laboratory Accreditation Program Checklists Committee.

"In the lab testing personnel area there was a discovery at CMS' end that some of the third-party credentialing agencies have had imperfect records. They've credentialed people who didn't do the training appropriately. With certificates that should only be awarded to an individual with a bachelor's degree, CMS discovered some of those certificates were invalid."

"It was spotty, but it was a real gap. That means the CAP inspection program now has to look to primary documentation, and not take a third-party credential to prove educational qualifications. Personnel documentation is a real focus of the CMS, so the Laboratory Accreditation Program has to be consistent in the way it looks at personnel records," Dr. Hoeltge says.

That need was underlined when CMS' own validation surveys started citing laboratories for missing records where CAP inspectors had not. The CAP checklist contains requirements associated with phase one and phase two deficiencies, while the CMS inspections use a different nomenclature for deficiencies, says Amy Daniels, MT(ASCP), CAP's manager of investigations in the accreditation program. "They call them 'standard level,' which are less severe, and 'condition level,' which are more severe."

The CMS does a small portion of simultaneous validations the same day as CAP inspections, but only about five per year. "We usually have about 100 to 120 validations a year, and most are within the 90 days following our inspection. Any time CMS cites a condition level deficiency, CAP needs to show a comparable deficiency in that area," Daniels explains.

Part of her job is to analyze the disparity report from the CMS that arrives every year in August, Daniels says. "If CMS cites a specific condition for lab testing personnel and it was because they lacked education documentation, and the CAP inspection team also cited the specific question about personnel qualification, that would be a match. It would not be a disparity. But if CMS cited that and the CAP team did not cite it, that would be seen as a disparity against the College."

"The trend I'm noticing in these valuations and these disparity reports is that about half of our disparities are related to personnel standards. Our disparity rate is not that bad. But this has definitely brought to the forefront that we need to improve."

CAP inspectors generally are told to do a random check of a subset of personnel files. "We don't make them check every person," says Daniels, "but we do inspect all types of labs. For a small lab that has only a handful of personnel, they would probably check all of the files. But in some hospital or reference labs you can have hundreds of personnel."

The CAP accreditation program asks labs to submit a personnel roster every time they reapply for accreditation. "But that's only every two years, so laboratory directors need to remember to check and make sure they've updated that document and have those credential documents on site for those people."

Some lab directors have the misconception that they can know people are qualified even if they lack the paper. But be warned, Daniels says. "When CMS cites a condition deficiency for not having personnel documentation, they cite the issue but they also cite the lab director, because that is the person ultimately responsible for oversight. So I think the opportunity here is to make sure lab directors really understand that."

Many times lab directors are surprised that falling short on this requirement amounts to a condition level

deficiency. “That didn’t happen 10 years ago. But the regulation hasn’t changed. It’s just that CMS is now driving the point home. It’s crept into our world over the last few years, and we’re striving to make it right for all our labs. It’s very rare to find a person who’s actually not qualified. So it’s basically an exercise in making sure you’ve crossed the T’s and dotted the I’s,” Daniels says.

Inspection citations for lacking personnel transcripts or diplomas are not a widespread problem, but they are not rare either, says Earle Collum, MD, Region 6 commissioner for the CAP Laboratory Accreditation Program, and chairman and medical director of the Department of Pathology and Laboratory Medicine, St. Joseph’s Hospital, Phoenix, Ariz.

With the registry or temporary duty nurses on whom hospitals frequently rely, for example, “The registry will assure the hospital that these people are qualified to perform their duties as registered nurses, but the hospitals are still responsible for having information in their personnel files if that person is performing moderately complex testing. If the registry has that information and they want the person to do moderately complex testing, they can forward the credentials as well,” Dr. Collum says.



Dr. Collum

“It’s very much like when you want to qualify for a board exam after medical school. You wouldn’t have gone through a residency if you hadn’t gone to medical school. But they still want the medical school diploma as a matter of completeness,” he adds.

Dr. Collum has heard of instances in which a school has closed and the former student couldn’t get the transcript, and he says those have to be dealt with on a case-by-case basis. “Usually there is some way to do it. Either the school will provide some directions on how to get transcripts, or the person made an application that required the diploma 10 years ago and they may be able to get it that way. But one needs to show a conscientious effort and somehow assure that no rock has been left unturned to get the right documentation.”

The bigger problem, he points out, is that years ago, “we allowed nurses to use their nursing license as their credential, but, strictly speaking, that’s not acceptable, and I don’t think we’ve done enough to educate laboratory directors about this requirement.”

An additional issue can crop up with graduates of hospital diploma nursing programs, Dr. Hoeltge says. “I don’t know about all states, but I can tell you in my state of Ohio, a lot of nurses are non-baccalaureate nurses. They went to a hospital training program, they’re licensed in state, fully capable of doing everything an RN can do, but they don’t have a bachelor’s degree.”

“From a credentialing point of view, that’s an issue, because what the regulations mention is education from an accredited institution—so we’re talking about a bachelor’s degree or a transcript. Many of the hospital programs are combined with a college or university, so some of their credits are from college or university and others are from the hospital itself. As I read CLIA regulations, it may be that some hospital-based nurses do not have enough college education to meet the CLIA requirements.”

Dr. Perry says most laboratorians know they need the documents. The challenge is the nursing personnel do not understand it, and there may be difficulties getting the nursing staff to provide the documents to labs. “They may say, ‘I have the transcripts in Ohio and I live in Michigan, or it’s in my mom’s basement.’ So at some institutions they kind of hold the POC testing device hostage. We do that here. We will not allow a nurse or other personnel performing testing to have access to the POC device until they provide their transcript or diploma. That’s just one

way to make sure you have it.”

A related and common deficiency the CAP accreditation program sees is documentation of annual competency, Dr. Perry adds. “There’s a checklist requirement that the competency of each person performing testing needs to be assessed twice in the first year, then annually” (GEN.55500). During on-site inspections last year, this item was cited as a deficiency 17.6 percent of the time—“even more frequently than the absence of personnel documents,” she says. In December 2012, the CMS released a new brochure to help address the issue of competency, “What Do I Need to Do to Assess Personnel Competency?,” available at www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/CLIA_CompBrochure_508.pdf.

To protect the laboratory accreditation process, basic awareness of the personnel records requirement is key, Dr. Collum emphasizes. “We just need to make laboratories and CAP inspectors aware that personnel requirements do get special emphasis from other accrediting organizations and CMS, and to make sure our laboratories have provided those records.”□

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