Laboratory accreditation program 2016 checklists: Less legwork, more clarity seen in personnel changes

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September 2016—For the CAP Laboratory Accreditation Program, inspection checklist requirements covering personnel are a perennial concern. They are the leading source of disparities between the findings of the program's inspectors and inspection audits done by the Centers for Medicare and Medicaid Services. Personnel is also high on the list of questions asked of Laboratory Accreditation Program staff. "Personnel is a hot topic for the College," says CAP Checklists Committee chair William W. West, MD.

Dr. West

Another round of revisions to the personnel checklist requirements may seem as routine as clockwork. But the 2016 edition of the checklists, released in August, "has the most significant personnel changes in several years," says Dr. West, who is a pathologist at Physicians Laboratory, PC, in Omaha, Neb. The 2016 personnel checklist changes are, in part, the result of a Commission on Laboratory Accreditation decision to form a personnel workgroup to consider revising the laboratory personnel roster to help respond to the inspection disparities. "The College really seems to have gone out of its way this year to help tackle this complex area," Dr. West says.
Members of the Checklists Committee believe the 2016 edition of the checklists will streamline inspections and pull more labs into compliance with CLIA personnel regulations, while relieving a major headache of labs by allowing independent verification of credentials to replace firsthand collection of documents.

Foremost among the changes: a new checklist requirement for the Personnel Evaluation Roster to ensure that the roster is current, accurate, and audited at least annually by the laboratory; added information on the qualifications and responsibilities of supervisors and consultants; and provisions for primary source verification reports, long sought by the CAP and recently approved by the CMS.

Getting on track with the CMS expectations was one goal of the 2016 changes because the number of discrepancies between the CAP inspections and CMS inspections on personnel records is a persistent issue, explains Gerald Hoeltge, MD, checklist commissioner and a member of the CAP Council on Laboratory Accreditation. "Disparities in personnel findings are the big problem area year after year after year," he says.

Dr. Hoeltge

"The drawer for personnel records contains the thickest files in the supervisor's office. The CAP inspectors sample those files to determine whether the lab complies with the CLIA regulations." However, in 100 or so instances

every year, “CMS auditors return to a lab that passed the CAP inspection to check on the efficiency with which our inspection covered all the CLIA regulations, and those auditors take the time to look through every single file. We know from those comparison statistics just how carefully they check for compliance with the personnel regulations. That’s one reason for the disparities.”

GEN.54025, the new checklist requirement on the Personnel Evaluation Roster that labs do an annual audit, is the most important change in this edition, Dr. Hoeltge says. “This requirement is designed to document that labs are doing what most have always been doing: checking through their personnel files every year to be sure they’re up to date and accurate. Supervisors have to look at each person’s file anyway, so they might as well do it systematically, and the checklist should help.”

The annual audit contained in GEN.54025 has technically not been required before, but keeping up to date has always been required, and Dr. Hoeltge believes the audit requirement will make that mandate easier to meet. “If I’m running a lab and all my people are qualified and documented, and tomorrow morning I hire a new person, in order to put them in a CLIA-designated position of either testing or supervisory personnel, you have to ensure they have the proper qualifications before you can let them do any patient testing.” The audit requirement contains the elements that must be met.

Shortening the cycle length was part of the rationale for the annual audits. Formerly, the accreditation program inspectors would have laboratories send in their personnel roster with their reapplications every two years, says Richard M. Scanlan, MD, chair of the Commission on Laboratory Accreditation. “But it’s too hard for the inspectors to cover that many people, especially if it’s a large point-of-care operation, so we wanted to have the labs check changes in the roster on an annual basis.”

Also significant is the inclusion in the roster of a whole section for supervisory personnel, Dr. Hoeltge says. “The roster used to cover only testing personnel. Now the lab has to document that it has checked the supervisors’ files for credentials that are up to date and complete.” The supervisory personnel category also includes every pathologist in the lab. “So that’s a big deal.”

One of the most important steps in completing the form is to have the laboratory director sign it to ensure the integrity of the data. “Not only do you need to do an internal audit, but under GEN.54025, the lab director himself or herself also has to testify to its completeness. That’s because CMS considers systematic deficiencies in personnel records to be a director issue,” Dr. Hoeltge says.

In addition, the personnel workgroup has reformatted the roster to enhance the standardized format in order to make it possible for inspectors to do a quick evaluation. Clearer options are included for noting the records used to confirm the qualifications of testing personnel and the hire dates of new personnel. “The roster is provided as an Excel spreadsheet because that way it’s easy to expand it depending on how large the lab is,” Dr. Hoeltge points out. Field testing has confirmed that the spreadsheet format is easier for inspectors to review.

One of the biggest changes in the 2016 checklists for personnel is the addition, in GEN.54400, of provisions for primary source verification (PSV) reports to be done by third-party agents. A PSV report is based on direct contact with institutions, former employers, or their authorized agents, and it confirms that a job applicant’s degree, certificate, or diploma is authentic, that licenses were granted, and that reported work history (company names, locations, dates, positions) is accurate.

These reports can replace the diplomas and transcripts for each employee that were required in prior checklist editions. Following the CMS’ April 2016 approval of the use of PSV reports to meet accreditation requirements, the Checklists Committee has added a definition of PSV because the term is new to the checklist. Until now, the requirement to maintain diplomas and other credentials in laboratory files has been a big chore for laboratories. Primary source verification allows the outsourcing of this requirement to experts, Dr. Hoeltge says.

Allowing PSV is a change for which the CAP has long been advocating. “This request was pending for years

because it's not easy for CMS to make changes," Dr. Hoeltge explains. "But this is something that labs have found very helpful and now it's official from CMS that you can do this. The CAP was able to put it in the checklist in a helpful way." The CMS has approved the checklist revisions that were made to incorporate its approved PSV alternative.

The primary source verification that the 2016 checklist provides for will be of particular use to large institutions that have, say, 3,000 nurses doing point-of-care testing, Dr. Scanlan says. "The third-party agents can say, 'This person claims to have an RN degree, and, yes, she does.' The same thing can be done for medical technologists." In this way, the PSV third-party agents are extensions of what some hospitals do for hiring purposes, he adds.

"The responsibility is still yours," Dr. Hoeltge warns laboratory directors. "Just because you're asking a third party to do that legwork for you doesn't mean you're not still responsible for its accuracy."

Dr. West, too, cautions: "PSV is just a bit of a shortcut. You still have to practice due diligence in verifying credentials but it's a simpler way of doing it."

Dr. Scanlan describes the PSV report as taking "a first pass over people."

"What the reports frequently don't do is give you necessary detail. For example, if somebody needs to have certain experience or a bachelor of science degree with 60 hours of a certain kind of study, PSVs don't verify that. So if you are using PSVs, they're good up to a point. But when you get into special circumstances, you still have to end up with a transcript."

Personnel standards are a difficult area, and part of the difficulty is language related, Dr. West notes. "There is high and moderate complexity, there is waived and nonwaived testing, and the government uses somewhat different, more legalistic language for some of the related personnel compared with common terms that may be used in the lab."

A person referred to as a bench supervisor in the lab, for example, might need to be called a general supervisor under CLIA. Or a laboratory might have section directors who in CLIA lingo would often be technical supervisors. "So people get confused. You really have to look at each lab and make sure what the positions mean and how they translate into CLIA-driven language," Dr. West says.

The personnel roster's new format should help laboratories make sure they name the CLIA-required positions. "The form basically forces you, in the first section, to take supervisory personnel and specifically spell out which CLIA positions they occupy," Dr. West explains. "Then later, it has added or clarified the particular qualifications of the CLIA-designated position and makes you spell out how your lab decided that this employee met those qualifications."

As part of the package of 2016 changes, requirements for the roles of technical supervisor (GEN.53400), general supervisor (GEN.53600), clinical consultant (GEN.53650), and technical consultant (GEN.53625) have been clarified in the appropriate parts of the checklist. "That's in response to calls of participants," Dr. Hoeltge says. The new language in GEN.53400 for technical supervisor, for example, is the CLIA regulatory language.

One change Dr. Hoeltge highlights is the requirement that the technical supervisor's training and experience must be in the designated specialty or subspecialty for which he or she has responsibility. "That's intuitively obvious, but it hasn't been in there before," he says. Other updates: The general supervisor list of responsibilities is now complete to reflect everything listed in the CLIA regulations, and a reminder has been added that the lab has to follow any local or state regulations that are more stringent than anything already in the checklist.

To clarify the background needed to conduct high- and moderate-complexity testing, the GEN.54750 changes relating to additional testing personnel qualifications will also add more meat to the detail of that checklist requirement, Dr. West says. "Previously there was a bare-bones description of what was needed to qualify for high-complexity testing. Now it's spelled out in more detail."

Work on the checklist's supervisory language changes began last year. "There were some special requirements that were not clearly defined in the checklists that we wanted in the regular checklist upgrade," Dr. Scanlan says. "But the change was more complicated, so we held off until this year." In the 2016 edition, changes to the personnel roster were made to call out the special requirements for technical supervisors, he says. "For some high-complexity areas, there are supervisory personnel who have to be MDs or DOs with special training. Their training can't be anything less than that."

In considering new checklist language, the personnel workgroup found that people weren't specifically designated to do the supervisory tasks required under CLIA in some situations. "We were getting citations by the CMS inspectors because people weren't qualified to fill those positions, or because nobody was officially designated." This was one significant source of the discrepancies with the CMS inspection findings on personnel, Dr. Scanlan says. "What the new Personnel Evaluation Roster form does is force people to think about that, write it down, and check the boxes. If somebody has to be an MD or have a BS, the roster and checklist requirement were set up to state who's doing it and whether they are qualified."

Dr. Scanlan, who is acting chairman and a professor of pathology at Oregon Health and Science University, has been reporting on parts of the requirements in presentations targeted at supervisors and directors as part of the CAP's Clinical Pathology Improvement Program, or CPIP. "We are trying to explain to pathologists, who are most of the CPIP subscribers, that this is supposed to be happening under you and to keep an eye on it and make sure it's happening and to warn them about particularly problematic areas." (A self-assessment module, or SAM, on CLIA requirements for supervisors and directors will be available Nov. 21 at the CPIP page, https://learn.cap.org/casebased.aspx, or the Learning Search page, https://learn.cap.org/LearningSearch.aspx.)

At a presentation in Arizona, Dr. Scanlan found that the audience was especially interested in the transfusion requirements. "They instantly latched onto those. Those requirements caught them by surprise." One reason: A potential pitfall in the transfusion area is that a lot of pathologists are board certified in anatomic pathology only. "It turns out that to cover transfusion services, which most laboratories have, you have to be a clinical-pathology–eligible or board-certified CP pathologist. What they may have been doing is having a medical technologist do all the documentation, and then the AP pathologist was cosigning that work, but CMS does not consider them qualified to cosign."

Dr. Scanlan

"This is the sort of thing we were trying to get out there, that there are special areas of the lab, highly complex areas, that have extraordinarily restrictive requirements as to who can do the work of technical supervisor," Dr. Scanlan says. "People may have casually been doing this work in some areas, and then during a CMS inspection, they find out that they're not doing the right thing. That's what we're trying to avoid."
One example of a change that may need to be made is if a pathology group is led by an AP-only pathologist who is signing off on blood bank work, he or she will need to designate a colleague who is CP-certified to sign off.

Another example might be in delegation of competency assessment. The minimal requirement for this is a bachelor-level person, but this person would have to have at least one year on the job before the responsibility could be assumed. "So in some cases, you need to look at how much experience in the lab a person has," Dr. Scanlan says.

The CLIA regulations in these areas aren't new. "CMS recently started emphasizing supervisor qualifications and this has resulted in some disparities in the audit findings," he says. In helping laboratories stay in compliance with

the regulations, “we realized our checklists weren’t as helpful as they could be. We’d like the checklist to be a roadmap for compliance, so in these revisions we tried to clarify what the correct way to do things was.” That’s something the Checklists Committee does often in these revision projects, he adds.

Overall, the revisions should make the checklist not radically different but more usable. “What we want somebody to be able to do is read each checklist requirement and know exactly whether they are doing the right thing or not,” says Dr. Scanlan, who believes the checklist should be like an open-book exam. “If they open it up and do everything it says, they’re not going to get in trouble.”

The important message about the 2016 checklist changes, Dr. Scanlan says, is that they will help let laboratories know whether what they are doing is right. “It may seem like a nuisance to have to dust off the personnel roster once a year, but it really is important because personnel changes happen, and going back once a year to ask, are these the only people doing a supervisory role, and have there been personnel changes, and is that information up to date, is the main thing. People may see it as our putting another burden on the lab, but a lot of labs do have trouble with this.”

The checklist is more prescriptive this time around than it has been in the past, says Dr. Hoeltge. “Everyone gets a little concerned when that happens, but there are not too many requirements that are new.”

Dr. West promises further improvements in the personnel checklist requirements as the Checklists Committee continues its work. In the 2017 checklist, “we’re tackling director responsibilities to make them more uniform, to clarify that whether the director is on site or off site, the same general principles apply.”

In the meantime, with the new personnel provisions of the 2016 checklist, “With the way we’ve designed it and set it up, we hope it will help labs be more effective at keeping these complex records up to date and in line with the inspections, whether they are by the CMS or by the CAP.”
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