COLLEGE of AMERICAN PATHOLOGISTS

CLIAC November 2024

CAP Statement on the Utilization of Remote Technology for Competency Assessments

The College of American Pathologists (CAP) appreciates the opportunity to provide written comments to the Clinical Laboratory Improvement Advisory Committee (CLIAC). As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide. The CAP supports CLIAC's interest in reducing the burden of Competency Assessment (CA).

Competency Assessment is a critical piece of ensuring laboratory quality, requiring pathologists in the role as laboratory director to manage and track the qualifications, continuing education, and assessments for the laboratory staff they oversee. In the case of large laboratories or when one individual serves as laboratory director for multiple laboratories, satisfying the current CA requirements can take up a significant portion of their time, taking their attention away from patient testing and diagnosis. CAP Accreditation has not detected quality issues originating from the current CLIA CA requirements. Thus, the CAP supports the current scope of Competency Assessment under CLIA, believing that expansion could have negative consequences in terms of staff burden and burnout without an upside of quality improvement.

The six required elements of competency assessment for nonwaived testing include:

1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing, and testing.
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results.
3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
4. Direct observation of performance of instrument maintenance and function checks.
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
6. Evaluation of problem-solving skills.

All but the two elements requiring direct observation may already be done remotely. Direct observation can also be done remotely, as was demonstrated during the Public Health Emergency (PHE) remote assessments proved to be practical and adequate. The requirements outlined in CMS's remote survey process during the Public Health Emergency (PHE)could inform the development of permanent policy for remote competency assessment.

College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100

From a technical perspective, conducting direct observation remotely is entirely feasible. The CAP and other accreditors conducted some inspections remotely using off-the-shelf technology. The CAP found that conducting remote assessment via video calls on a mobile device, for example a laptop on top of a wheeled cart, or a smartphone mounted on a tripod, provided enough sight of the laboratory work being done to satisfactorily assess competency.

Enabling assessments to be done remotely, without a supervisor traveling, and without laboratory personnel modifying their workday and workflow to accommodate an additional person in the laboratory will same time and resources while still upholding quality standard. Small rural hospitals or clinics where there is a single technologist working may benefit the most from this possible option. To maximize the benefits of moving to remote observation, the technology involved must be readily available, affordable, and easy to implement in the laboratory.

Requirements for remote observation of competency assessment should be developed using a consensus-based approach to gain a solid understanding of CLIA's goals and the capabilities and challenges specific to current laboratory practice. One of the challenges might be ensuring that the competence records are maintained and available at the location with that CLIA number so that all records are available for inspections. To identify suitable technology tools for conducting remote assessments, CMS should clarify what is needed to be viewed on screen, if it needs to be from a 1st-person vantage point, and when CA is done using real patient samples, considerations would need to be made around how protected health information is viewed and stored.

Once again thank you the time to discuss the CAP's concerns and recommendations and we welcome the opportunity for further dialogue. Please contact Andrew Northup at anorthu@cap.org or 202.297.3726.

Closing,

The College of American Pathologists

College of American Pathologists
1001 G Street, NW, Suite 425W
Washington, DC 20001
202-354-7100