

# CLIA Corner

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*In This Issue of the CLIA Corner we address:*

- **Part 1: Verification of Laboratory Personnel Qualifications and the Required CLIA Documentation: Primary Source Verification (PSV)**

## **BACKGROUND**

The Centers for Medicare & Medicaid Services (CMS) issued a Survey & Certification memorandum titled “Personnel Policies for Individuals Directing or Performing Non-waived Tests” (Ref: S&C: 16-18-CLIA) dated April 1, 2016 (revised on May 3, 2016). **This memorandum allows CMS CLIA surveyors to accept primary source verification (PSV) documentation as evidence of laboratory compliance with the personnel requirements.**

The CMS CLIA surveyors must determine the laboratory’s compliance regarding whether individuals in prescribed positions meet the personnel qualification and responsibility requirements stated in 42 CFR, Part 493, Subpart M. This includes the positions of laboratory director, clinical consultant, technical supervisor and consultant, general supervisor, testing personnel, cytology general supervisor, and cytotechnologist. The process of verification of personnel qualifications requires surveyors to observe direct evidence of academic achievement.

A laboratory is considered to be non-compliant if: a required position is not filled; an individual does not meet the required qualifications based upon education, training and experience for that position; or an individual does not fulfill the responsibilities of the position.

## **PRIMARY SOURCE VERIFICATION (PSV)**

PSV is the process of confirming an individual’s credentials by verifying that a degree, certificate, or diploma was received; that licenses were granted; and, by confirming reported work history, such as company names and locations, dates, and positions held. Verifications are obtained either directly from an institution, former employers, or their authorized agents. Primary source verification can be achieved through several methods, including, but not limited to, directly contacting the organization from which the credential was issued. This may be done through methods such as documenting a telephone conversation with the issuing source or by facsimile, email, or letter. A secure online database may also be used to determine the validity of the credentials.

In the past, CMS has required surveyors to verify educational qualifications by reviewing direct evidence of academic achievement, e.g. a diploma or transcript. This required the laboratory to collect and maintain paper

documentation on its personnel in addition to maintaining paper records on large numbers of point-of-care testing personnel that perform testing throughout a medical facility.

Due to the many requests CMS received from laboratories, accreditation organizations, and other health care facilities to accept PSV of education, training, experience, and licensure, CMS reviewed the processes from several PSV companies and the documentation that results from a primary source verification. Based on that review, CMS is now allowing CLIA surveyors to accept PSV documentation to determine a laboratory's compliance with the personnel requirements.

It should be noted that the PSV company is **NOT** responsible for determining whether a given individual meets the personnel requirements under CLIA; PSV companies merely confirm that the asserted training, degrees, and credentialing have been achieved or conferred.

**It is also important to note that not all personnel qualifications will be verifiable by a PSV company.** PSV companies do not verify transcripts. Laboratories need to be aware that even if they choose to use PSV, personnel may still need to produce documentation that cannot be verified by PSV companies for those positions in which a transcript is necessary to qualify the individual.

It is always the responsibility of the laboratory to ensure that its personnel meet the CLIA requirements, and CMS, its agents, and accreditation organizations retain full authority to determine compliance with those requirements. The PSV report is one tool that can be used by the surveyor and laboratory to determine if the applicant meets the personnel requirements.

## **GENERAL GUIDANCE**

- **CLIA personnel regulations and the policy on mandatory citations are not changing.** By allowing the use of PSV companies, CMS is giving laboratories another means of verifying and documenting the qualifications of its laboratory personnel.
- PSV organizations may include, but are not limited to, organizations that confirm an individual's credentials by verifying that a degree, certificate, or diploma was received; or that a license was granted; or by confirming reported work history, such as company names and locations, dates, and positions held. **CMS is not issuing standards to be applied to PSV organizations.** Laboratories will need to judge the services offered by PSV companies for themselves. CMS is merely permitting surveyors to use PSV reports when they compare employees' qualifications against the regulatory personnel requirements. As needed, surveyors will continue to ask Laboratory Directors to provide additional documentation on their employees' qualifications when they find the PSV reports inadequate to confirm compliance.
- Organizations that merely collect documentation directly from the qualifying individual are not considered to be performing PSV. However, if those organizations confirm an individual's credentials by verifying, directly from an institution or the institution's authorized agents, that a degree, certificate, diploma, or other credential was received, then they are considered to be performing PSV.
- A Credentials Verification Organization (CVO) Certification Program evaluates credentials verification operations and the processes that a PSV organization uses to provide its services to its clients. CVO certification is generally available to organizations that conduct credentials verification, report the credentialing information to clients and have systems in place to protect the confidentiality and integrity of the information. CMS has not issued standards or specific requirements for either a PSV or a CVO. It is the responsibility of the Laboratory Director to ensure that personnel qualifications are met for each position and that there is sufficient evidence of the qualifications.
- The use of a PSV report as evidence of meeting the Clinical Laboratory Improvement Amendments of 1988 (CLIA) personnel qualifications is **optional** for laboratories. Laboratories have two ways to

demonstrate compliance with personnel regulations. (A combination of the two methods may be used.)

1. Utilize a PSV report
2. Continue to accept direct observation of source documents.

- Laboratories electing to use the PSV option must maintain either paper or electronic reports from the PSV organization.
- Ultimately the Laboratory Director is responsible for choosing a PSV company for their laboratory, based on their own criteria.
- When surveyors find a PSV report that is inadequate to confirm compliance with the personnel requirements, they will ask the Laboratory Director to provide additional documentation on their employees' qualifications. If there are required elements in the personnel regulations that the PSV organization does not verify, it is the Laboratory Director's responsibility to ensure that these personnel qualifications are met by other means. Each Laboratory Director should collect and maintain documentation and records as may be necessary to provide any information that is not included in the PSV report.
- For high school degrees, if there is documentation on a report from a PSV company that they have verified that a high school diploma was awarded, the laboratory need only keep the PSV report showing that the requirement has been met. If there isn't verification on the PSV report of the diploma being awarded, then the laboratory would need to keep a copy of the diploma to demonstrate compliance. CLIA does not dictate what documentation the PSV organization needs to keep. It is ultimately the Laboratory Director's responsibility to choose a PSV company for their laboratory, based on their own criteria.
- If the surveyor identifies potentially serious isolated or pervasive test quality problems that may be attributed to unqualified or untrained individuals performing or directing the laboratory's testing, the surveyor may request such documentation as may be necessary for the surveyor to confirm compliance with the personnel requirements.

## CONCLUSION

PSV is one tool that can be used by the surveyor and laboratory to determine if the applicant meets the CLIA personnel requirements. It is always the responsibility of the laboratory to ensure that its personnel meet the CLIA requirements.

For the complete Survey and Certification Letter (Ref: S&C: 16-18-CLIA) go to:

<https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-18.pdf>