



AMERICAN ASSOCIATION OF PATHOLOGISTS' ASSISTANTS

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February 15, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Memorandum (S&C -16-18-CLIA)

Attention: CMS-3326-NC,

The American Association of Pathologists' Assistants (AAPA) is writing to address serious issues pertaining to the Memorandum (S&C -16-18- CLIA) from the Centers for Medicare and Medicaid (CMS) to State CLIA Survey Agency Directors. In the Memorandum Summary, CMS states that an associate or bachelor's degree in nursing is the equivalent to an associate or bachelor's degree, respectively, in biological sciences for purposes of performing moderate and/or high complexity testing. The AAPA strongly disagrees with the CMS Memorandum.

The coursework requirements for a nursing degree and a biological science degree are vastly different. A typical degree in a biological science includes at least 63 hours of natural science courses compared to a nursing degree, which requires approximately 16 hours of natural science courses. Scope of Practices must also be compared. The Scope of Practice for pathologists' assistants includes the macroscopic examination of surgical specimens and the performance of postmortem examinations. According to the American Nurses Association, their responsibilities include:

- Performance of physical examinations and take health histories
- Provision of health promotion, counseling and education
- Administration of medication, wound care, and many other personalized preventions
- Interpretation of patient information and make critical decisions about needed actions
- Coordination of care, in collaboration with a wide array of healthcare professionals
- Direction and supervision of care delivered by other healthcare personnel such as LPNs and nurse's aides
- Conduction of research in support of improved practice and patient outcomes

Pathology is the science of the causes and effects of disease, especially the branch of medicine that deals with the laboratory examination of samples of human tissue for diagnostic or forensic purposes. The AAPA considers the current CLIA minimum education requirements to be inadequate for those performing macroscopic examination of human tissue specimens and samples. A degree in nursing is

also seen as inadequate. This type of testing should only be performed by a board-certified pathologist or an ASCP certified pathologists' assistant.

A pathologists' assistant is qualified by academic and practical training to provide, under the direction and supervision of a licensed, board-certified, or board-eligible anatomic pathologist, the following services:

Surgical Pathology:

- Preparation, macroscopic description and dissection of human tissue surgical specimens including:
 - Assuring appropriate specimen accessioning.
 - Obtaining pertinent clinical information and history, including imaging results and laboratory data.
 - Describing macroscopic anatomic features of surgical specimens, preparing tissues for histological processing, obtaining biological samples such as blood, tissue and toxicological material for studies such as flow cytometry, cytogenetics, microarray, image analysis, immunohistochemistry, etc., and performing special procedures including specimen imaging and tumor triage.
 - Preparing and submitting appropriate tissue sections for light microscopy (routine processing) as well as special procedures such as frozen section, electron microscopy and immunofluorescence microscopy.
 - Photography of all appropriate gross specimens and microscopic slides.
 - Performing duties relating to the administrative maintenance of surgical pathology protocols, reports and data, including the filing of reports, protocols, photographic data, microscopic slides, and assisting in the completion of specimen coding and billing.
 - Assuring proper maintenance of equipment, provision of adequate supplies and cleanliness of the surgical pathology suite.
 - Assisting in the organization and coordination of anatomic pathology conferences.

Autopsy Pathology:

- Preparation of human postmortem examination, including:
 - Ascertaining proper legal authorization for autopsy.
 - Obtaining/accessing the patient's medical record and other pertinent data for review with the attending pathologist.
 - Conferring with the attending pathologist(s) to identify any special techniques and procedures to be utilized in the completion of the examination (e.g., cultures, touch preparations, cytogenetics, histochemical, immunofluorescence, toxicological, viral or electron microscopic studies, etc.), and notifying all personnel directly involved.

- Notifying the attending physician, the funeral home, and all other appropriate authorities prior to the beginning of the autopsy; and coordinating any requests for special specimen sampling (e.g., organ transplantation, tumor protocols, molecular studies, research, etc.).
- Performing postmortem examinations which may include: external examination; in situ organ inspection; evisceration; dissection and dictation or recording of data such as organ weights, presence of body fluids, and gross anatomic findings.
- Selecting, preparing and submitting appropriate gross tissue sections for frozen section analysis as well as for light, electron, and immunofluorescent microscopy.
- Obtaining biological specimens such as blood, tissue, and toxicological material for studies including flow cytometry, cytogenetics, image analysis, immunohistochemistry, etc.; and performing special procedures such as coronary artery perfusion, central nervous system perfusion, enucleation, inner ear bone dissection, and spinal cord removal.
- Photographing the body, organs, microscopic slides and other pertinent materials.
- Gathering and organizing clinical information and data pertinent to the preparation of the preliminary summarization of the clinical history.
- Preparing the body for release, (including indicating the presence of biohazards such as contagious diseases, radioactive implants, etc.) and releasing the body to the appropriate mortuary or mortuary services representative.
- Performing duties related to administrative maintenance of anatomic pathology protocols, photographic images, and microscopic slide imaging, and assuring the completion of coding.
- Assisting in the organization and coordination of anatomic pathology conferences.
- Assuring the proper maintenance of equipment and the provision of adequate supplies.

The AAPA is the premier professional association for pathologists' assistants, supporting the individual practitioners as they serve patients, pathologists, and the profession. The AAPA advocates, promotes and sustains the highest education and professional standards for the profession, for all associated educational training programs, and for individual pathologists' assistants. Additionally, the AAPA strives to promote and support high quality standards within the scope of practice for pathologists' assistants in anatomic pathology, ensuring the provision of high quality patient care. Rigorous educational and training requirements are necessary to understand and perform this type of complex laboratory testing. Pathologists' assistants must also participate in the American Society for Clinical Pathology (ASCP) Credential Maintenance Program to maintain their certification.

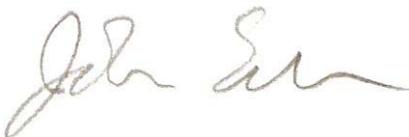
The CMS regulations do not require specific training requirements from an accredited medical laboratory program for personnel performing and managing moderate and high complexity laboratory testing. Nor does CMS require certification as a benchmark for competency. CMS excuses individuals with a nursing degree from the requirement to complete clinical training prior to engaging in patient

testing. Per the CLIA regulatory requirements for high complexity testing, individuals who possess a bachelor's degree or higher in a chemical, physical, or biological science are exempt from the requirement to complete specific clinical training in laboratory sciences before performing diagnostic testing [See 42 CFR 493.1489(b)(1)]. However, only those individuals with an earned associate degree in a laboratory science or medical laboratory technology are required to complete an accredited training program or other documented laboratory training prior to performing patient testing [See 42 CFR 493.1489(b)(ii)(B)]. The AAPA has grave concerns regarding individuals performing laboratory testing including the macroscopic examination of human tissues without adequate and appropriate training. This would most certainly and negatively affect the quality and reliability of complex laboratory testing in our healthcare facilities and will put patient's health in danger.

The stark differences in the pathologists' assistant profession and the nursing profession are clear. No patient would want a nurse to perform their high complexity testing or examine their surgical specimen. Conversely, no patient would want a pathologists' assistant or medical technologist to be their nurse. The level of compulsory experience to be capable at either of these professions is too great to be able to perform both jobs well. You must have the right person for the right job. Laboratory personnel, including pathologists' assistants would never advocate to perform the work of a nurse. Laboratory and nursing careers require very different backgrounds, knowledge, and skill sets to be performed optimally. Safety of our patients is of utmost importance, and consequently, patients will be put at risk if nurses with no clinical training are permitted to perform laboratory procedures.

The AAPA appreciates the opportunity to raise these concerns and fervently urges CMS to rescind this memorandum. The AAPA Board of Trustees welcomes the opportunity to discuss our concerns in person. The AAPA may be reached at (800) 532-2272.

Sincerely,

A handwritten signature in black ink, appearing to read "John Eckman". The signature is fluid and cursive, with a long horizontal stroke at the end.

John Eckman, MHS, PA(ASCP)^{CM}
Board of Trustees Chair