The following represents a position statement by the American Association of Pathologists' Assistants regarding New York Pathologists' Assistant Licensure

The American Association of Pathologists' Assistants (AAPA) is very concerned about the large number of individuals who appear, based on their credentials, to be unqualified but are being granted a New York Pathologists' Assistant license during the grandfathering period which extends to November 28, 2019.

The AAPA understands that in order to prevent disruption of the medical laboratory workforce, laboratory personnel licensure bills often include "grandfathering provisions" to allow individuals who have established careers as laboratory personnel to continue working at their current professional levels. At a minimum, any Pathologists' Assistant working under a "grandfathering provision" must meet CLIA requirements for high complexity testing.

The AAPA has been informed that individuals functioning as biopsy technicians have been incorrectly granted a Pathologists' Assistant license. The AAPA does not wish these individuals to be prohibited from performing their duties as before and believes these biopsy technicians could still work within their scope of duties under a more appropriate license, such as MLS or histological technician.

Applicants Applying Under the New York Grandfathering Pathway:

Applicants for licensure under the grandparenting [sic] licensure pathway must satisfy the requirements contained in section 8853 of the Education Law Article 169. After November 27, 2019, the grandparenting [sic] pathway expires. However, the licenses issued under it will not.

Licenses may be revoked for professional misconduct or for licenses obtained fraudulently.

From Article 169 Section 8853:

***§8853. Special provisions; eligibility**

An individual who meets the requirements for a license as a licensed pathologists' assistant except for examination and education and who has been performing the duties of a pathologists' assistant for two of the five years prior to the effective date of this article may be licensed without meeting additional requirements, provided that such individual submits an application to the department within two years of the effective date of this article and prior to November 28, 2019. For this purpose, the applicant's supervising physicians, who must practice anatomic pathology, must attest to the applicant's experience and competence.

Only supervised experience gained between November 28, 2012 and November 28, 2017 may be used to meet the grandparenting [sic] requirements.

*NB Effective November 28, 2017

After this Grandfathering Licensure Pathway has closed, the following qualifications are required:

***§8852. Requirements for licensure as a pathologists' assistant:**

To qualify for licensure as a "licensed pathologists' assistant," an applicant shall fulfill the following requirements:

- Education: to meet the education requirements for licensure as a pathologists' assistant, you must either have successfully completed a bachelor's or higher degree in a pathologists' assistant program registered by the Department, or the substantial equivalent thereof, in accordance with the commissioner's regulations; or have a bachelor's or higher degree from a National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) accredited pathologists' assistant program.
- Examination: obtain a passing score on an examination acceptable to the department; the pathologists' assistant certification exam offered by the American Society for Clinical Pathology Board of Certification (ASCP-BOC) is an exam acceptable for licensure.
- Age: at the time of application be at least twenty-one years of age.
- Character: be of good moral character as determined by the department.
- Fee: pay a fee determined by the department for an initial license and for each triennial registration period.

*NB Effective November 28, 2018

Brief New York Licensure History:

As of 2006, Pathologists' Assistants working in the state of New York have been required to be licensed. Initially, there was no specific category for licensure for Pathologists' Assistants in New York state, and Pathologists' Assistants were instead licensed in other categories. These routes to licensure were unacceptable to the employers of Pathologists' Assistants, the New York Pathologists' Assistants, and the AAPA. These groups, with the aid of the Greater New York Hospital Association, lobbied New York legislators to clarify the status of Pathologists' Assistants in New York and called for reasonable and practical regulations and licensure specifically for Pathologists' Assistants.

In late 2016, New York governor, Andrew Cuomo signed a bill creating a licensure category for Pathologists' Assistants. This move ensured that only qualified individuals worked as Pathologists' Assistants in New York. Enacting this licensing law was to take 1-2 years to become fully effective. During this waiting period, Pathologists' Assistants were still required to obtain a limited license as a histological technician until the new Pathologists' Assistant licenses were available.

As a caveat to this bill, a grandfathering period of 2-years, during which persons who have been practicing in New York for at least two of the five years prior to the effective date of the law would be permitted to become licensed if their supervising physicians attested to their experience and competence. This has the unintended or intended consequence of allowing grossing/biopsy technicians who are not qualified Pathologists' Assistants to apply for licensure as Pathologists' Assistants. After the grandfathering period is over, any new Pathologists' Assistant applicant will be required to meet all educational and examination standards of the law in order to obtain a license.

This provision that allows grossing/biopsy technicians without appropriate training or credentialing to be "grandfather" licensed as Pathologists' Assistants was introduced by New York State Senator LaValle in the legislature. He would not introduce the bill to license Pathologists' Assistants without the loophole that now allows grossing technicians to be licensed as a Pathologists' Assistant without the examination and education requirements (Section 8853 from Article 169).

CLIA Regulations:

The personnel qualifications required by CLIA address only the minimal requirements, and the AAPA believes these are insufficient to fully protect patients. CLIA requires only an associate degree and minimal laboratory training to perform high complexity testing. The AAPA believes state licensure laws should provide higher standards as the adoption of higher standards will ensure that patients are better protected.

The macroscopic examination of pathology specimens is classified as high complexity testing as set forth in CLIA regulations.

Policy 42 CFR 493.1489 personnel qualifications for high complexity testing, equivalent laboratory training, and experience includes the following:

- Possess a current license issued by the State in which the laboratory is located, if such licensing is required; AND
- Meet one of the following requirements:
    - Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution;
    - Have earned an associate degree in a chemical or biological science, or medical laboratory technology from an accredited institution; OR
    - At least 60 semester hours or equivalent from an accredited institution that, at a minimum includes 24 semester hours of medical laboratory technology courses; OR
    - 24 semester hours of science courses that include six semester hours of chemistry, six semester hours of biology, and 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; AND
    - Laboratory training including either completion of a clinical laboratory training program approved or accredited by the ABHES, NAACLS, or other organization approved by HHS (this training may be included in the 60 semester hours listed above); OR
    - At least three months documented laboratory training in each specialty in which the individual performs high complexity testing.

In essence, a legitimate license acquired during the grandfathering period would meet the definition of CLIA high complexity testing; however, it does not meet the definition of "Pathologists' Assistant" in the AAPA's view or the view of our members.

Ultimately, Pathologists' Assistants must conform to CLIA rules for high complexity testing. If grandfathered individuals do not meet at least CLIA requirements for high complexity testing, it would be appropriate to report these individuals to:

The University of the State of New York
The State Education Department Office of the Professions
Division of Professional Licensing Services
(see http://www.op.nysed.gov/opd/complain.htm).

At the center of this issue is patient care. Laboratories must ensure excellent patient care and access to quality anatomic pathology services. Quality results are difficult to ensure without adequately trained "Pathologists' Assistants" and may pose a potential threat to the safety and quality of healthcare.

Human resource professionals, employers, and the New York State Education Department must look to Pathologists' Assistant ASCP-BOC certification as the benchmark for appropriately educated and adequately trained Pathologists' Assistants. Certifying boards enhance the legitimacy of a profession and allow the public to recognize competent staff. If the "Pathologists' Assistant" does not have the appropriate qualifications, these individuals could be appointed as a biopsy technician with a clear job description and a biopsy technician salary but not as a Pathologists' Assistant. A license does not guarantee that someone will be hired as a Pathologists' Assistant, but it does allow a person with inadequate training and without appropriate credentialing with competency-based examination to function as a Pathologists' Assistant, which the AAPA believes is an inappropriate consequence of this New York state law.

The AAPA is supportive of state licensure for Pathologists' Assistants, and state licensure legislation should ensure that Pathologists' Assistants possess appropriate academic and clinical training through NAACLS accredited Pathologists' Assistants programs, pass a competency-based examination conducted by the ASCP-BOC, and participate in continuing education programs. These elements serve as important tools for enhancing quality patient care and patient safety. Without proper training and credentialing, the likelihood of specimen mishandling and erroneous macroscopic tissue examinations will increase, which could have a significant negative impact on patient care.

Licensure provides the mechanism to accept and extend the concept of certification over time so that continued personnel competency is assured through periodic self-assessment, competency evaluation, and continuing anatomic pathology education. Licensure can be a process through which the Pathologists' Assistants' competency is continually maintained.

High Macroscopic Examination Standards Must Be Upheld

The justification for licensure is to protect the public from significant harm caused by incompetent or inadequately trained members of an "occupational group." Since the macroscopic examination of surgical specimens forms the basis for medical diagnoses and therapies, the potential exists for serious harm from macroscopic tissue examination errors by unqualified personnel.

Quality of the macroscopic examination of surgical specimens is influenced by the same requirements that are the foundation of personnel licensure, specifically academic education, clinical training and/or work experience, a competency assessment examination, and continuing education.

AAPA Tenets on State Licensure

The AAPA believes that both NAACLS program-trained and prior to 2010, grandfathered on-the-job trained Pathologists' Assistants who pass the ASCP-BOC Pathologists' Assistant Certification Examination are qualified as competent mid-level practitioners in anatomic pathology.

The AAPA believes that state licensure should provide a mechanism to assure that anatomic pathology services are performed with an adequate level of professional competence by requiring appropriate anatomic pathology entry level qualifications for Pathologists' Assistants that includes training, experience, and certification as qualified and competent to perform the functions of a Pathologists' Assistant.

The AAPA believes that minimum requirements for licensure should include graduation from a NAACLS accredited Pathologists' Assistant program, or prior to 2010, on-the-job training **and** passage of the ASCP-BOC Pathologists' Assistant Certification Examination.

The AAPA believes that through appropriately stringent competency requirements established by licensure for Pathologists' Assistants, the health and safety of our patients is enhanced.

The AAPA believes that state licensure provides a key legal basis to restrict incompetent practitioners from providing anatomic pathology services to the public.

The AAPA believes that it is essential to define in state statutes, the Pathologists' Assistant qualifications, certification, and scope of practice and to exclude those who have not acquired the appropriate requisites for licensure.

The AAPA believes that licensure renewal should require documentation of continuing education as a means of demonstrating continuing competence.

The AAPA appeals to the Department of Education to require the following elements for licensure of Pathologists' Assistants in New York State under §8852 Requirements for licensure as a Pathologists' Assistant:

- Graduate from a NAACLS accredited Pathologists' Assistant training program or prior to 2010 grandfathered on-the-job trained Pathologists' Assistant
- Obtain a passing score on the Pathologists' Assistant ASCP-BOC Certification Examination
- Earn 60 continuing education credits every three years (increased from 45 effective 1/1/2022) as required to maintain certification by the ASCP-BOC Credential Maintenance Program.

As a final point, the AAPA recommends a proposal to create a restricted license for biopsy technicians where they would be limited to handling surgical pathology cases that do not require dissection or selective sampling.

About the AAPA: *The American Association of Pathologists' Assistants (AAPA) was founded in 1972 as a not-for-profit volunteer organization of allied health practitioners dedicated to the advocacy and advancement of the pathologists' assistant 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. It is our mission to provide our members with high quality, targeted continuing education (CE) opportunities, as well as professional development and*

leadership activities to include networking and support. 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. There are approximately 2,500 ASCP certified pathologists' assistants practicing in hospitals and labs throughout the United States. Approximately 50 of these are certified PAs working internationally in Canada, New Zealand, and Australia. The AAPA as a whole represents 2,000 certified or certification exam eligible members. The AAPA is an organizational member of the ASCP, the American Joint Committee on Cancer (AJCC), the Commission on Cancer (CoC), and the National Accrediting Agency for Clinical Laboratory Science (NAACLS).

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