AAPA
American Association of Pathologists' Assistants

AAPA e-News Today

April 7, 2010 *Keeping You Connected to Your Association*

In This Issue

Contact Us

American Association of Pathologists' Assistants
2345 Rice Street, Suite 220
St. Paul, MN 55113
800.532.AAPA or 651.697.9264
Fax: 651.317.8048
info@pathologistsassistants.org
www.pathologistsassistants.org

Executive Director

John E. Mitchell, BS, MSBA, PA(ASCP)CM
252.814.5291
executivedirector@pathologistsassistants.org

Board of Trustees Chair

Michael L. Sovocool, MHS, PA(ASCP)CM
botchair@pathologistsassistants.org

CAP Announces Revised Standard for Grossing Personnel Qualification

Dear AAPA Member,

On March 31st, 2010 the College of American Pathologists (CAP) announced a revision to their Checklist requirement regarding the qualifications of personnel who examine tissues. The text of the CAP announcement is reproduced at the end of this message. This revision should not directly affect members of the AAPA, however it may affect our workflow and it may directly impact some of the people with whom we work in Anatomic Pathology labs.

First, a clarification regarding Certification versus legal requirements for grossing personnel standards. Certification of grossing personnel in Anatomic Pathology is entirely voluntary. There is not, nor has there ever been, a legal requirement that Anatomic Pathology laboratories utilize Certified personnel to examine tissues. The minimum standard for grossing personnel was set decades ago by federal law, in the Clinical Laboratory Improvement Act (CLIA) and subsequent governmental rulings. The branch of the federal government that is responsible for administering CLIA regulations is the Centers for Medicare and Medicaid Services (CMS). According to CMS, the examination of tissues must take place under the supervision of a Pathologist and may be performed by a Pathologist, a Pathology Resident, or a person qualified under CLIA to perform high complexity testing. In order to qualify to perform high complexity testing under CLIA a person must "have earned a minimum of an associate degree in a laboratory science, or medical laboratory technology, from an accredited institution, or…" the person must have education and training equivalent to the above. The details of what CMS considers equivalent to the above degree takes up several pages and can be found in Section 493.1489 of the Code of Federal Regulations. It is important to note that in formulating federal regulations regarding grossing personnel standards, CMS did not make any distinction between different types of tissue. No separate categories for "small" or "simple versus complex" tissue specimens exist to this day, as far as CMS is concerned.

In recent years the CAP developed its own unique interpretation of the federal standard for grossing personnel. The CAP Checklist divided the personnel requirements into different levels depending on how large or complicated the tissue specimen was. The CAP stated that if a tissue specimen was small and uncomplicated and could be totally embedded, the person examining the specimen did NOT need to be qualified under CLIA to perform high complexity testing. In other words, CAP standards indicated that people did not necessarily have to have an associate degree in a laboratory or medical technology field or the equivalent to examine some tissues.

The March 31 announcement from the CAP indicates that the CAP has revised their standard for grossing personnel. The CAP no longer recognizes different categories or complexity levels for tissue specimens. The CAP standard is now in complete agreement with the CLIA/CMS interpretation of the rule. Personnel who examine any and all tissue specimens, no matter how simple or complicated, must have at least an associate degree in the appropriate field(s) in order to perform the work. Neither the CAP nor CMS has ever required anything more than the associate degree to examine tissues, no matter how complex. That has not changed.

This change in personnel standards is expected to affect only those laboratories that employ people who do not have a minimum of an associate degree in a laboratory science or medical laboratory technology or the equivalent to examine tissues. Such laboratories typically utilize these personnel to "process" biopsies and other small, uncomplicated tissue specimens. This announcement from CAP means that henceforth any laboratory employing such personnel to examine tissue specimens will be out of compliance with federal (CLIA) regulations and will also be out of compliance with CAP Checklist standards.

The best resource for determining whether or not your laboratory is in compliance with the above standards will most likely be your clinical laboratory administrators and/or HR personnel. Clinical laboratory tests performed on blood, urine, etc. have for decades been stratified into levels based on complexity. Clinical laboratory tests are categorized as waived tests (simple), moderate complexity tests, and high complexity tests. CLIA gives specific requirements for the qualifications of people who perform lab tests at each level. Hence, laboratory managers have been hiring staff for their laboratories and deciding who can do which tests in their labs based on these CLIA-defined levels of complexity for decades. They should be very familiar with the personnel standards for qualifications of people who may perform high complexity testing. Laboratory managers and the CAP itself should also be able to advise you regarding what documentation is sufficient to show that your staff meets the requirements for performing high complexity testing.

Here is the text of the CAP announcement:

"March 31, 2010
Attention Anatomic Pathology Laboratories:
In preparation for the release of the 2010 CAP Checklist Edition in June of this year, CAP is notifying all accredited anatomic pathology laboratories of a revised checklist requirement that may have an impact on your laboratory's staffing.
The revisions will require that all non-pathologist individuals who perform macroscopic tissue examinations meet the personnel requirements for high complexity testing in accordance with CLIA. This interpretation of the CLIA requirement was recently provided to CAP from CMS. As a service to CAP Accredited laboratories, the CAP offers compliance alerts to help your laboratory maintain continuous compliance.
Previously, the Anatomic Pathology checklist differentiated two levels of macroscopic examination, "processing" and "grossing." In this context, "processing" means macroscopic examination of small specimens not requiring knowledge of anatomy, which are entirely submitted for microscopic examination, while "grossing" means macroscopic examination of more complex specimens. Unlike individuals who performed grossing, individuals who performed "processing" were not required to be qualified as high complexity testing personnel. *In the 2010 checklist edition, the concept of macroscopic tissue "processing" will no longer be recognized. All macroscopic tissue examinations will be considered to be "grossing."*
Therefore, any individual who performs macroscopic tissue examinations must be a pathologist, pathology resident, or an individual qualified to perform high complexity testing under the supervision of a pathologist (refer to ANP.11610).

Please contact the Laboratory Accreditation Program at (800) 323-4040, option 1, then 4, or 1-847-832-7000, or accred@cap.org if you have any questions.

ANP.11610 Phase II

If individuals other than a pathologist or pathology resident assist in gross examinations, do such individuals qualify as high complexity testing personnel under CLIA regulations?

NOTE: The laboratory director may delegate the dissection of specimens to non-pathologist individuals; these individuals must be qualified as high complexity testing personnel under CLIA regulations. The minimum training/experience required of such personnel is:

1. An earned associate degree in a laboratory science or medical laboratory technology, obtained from an accredited institution, OR
2. Education/training equivalent to the above that includes at least 60 semester hours or equivalent from an accredited institution. This education must include 24 semester hours of medical laboratory technology courses, OR 24 semester hours of science courses that includes 6 semester hours of chemistry, 6 semester hours of biology, and 12 semester hours of chemistry, biology or medical laboratory technology in any combination. In addition, the individual must have laboratory training including either completion of a clinical laboratory training program approved or accredited by the ABHES, NAACLA, or other organization approved by HHS (note that this training may be included in the 60 semester hours listed above), OR at least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing.

The CLIA regulations on high complexity testing personnel may be found at HC Testing Personnel.

In addition, the CLIA regulations include exceptions for grandfathered individuals; these regulations (42CFR493.1489 and 1491) may be found at the above Web address and at Grandfathered Exceptions.

It is the responsibility of the laboratory director to determine whether an individual's education, training and experience satisfies the requirements of this checklist question.

This checklist question applies only to laboratories subject to U.S. regulations.

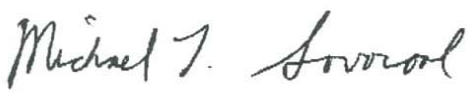
References

1. Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*. 2003(Oct 1):1070-1071 [42CFR493.1489], 1071-1072 [42CFR493.1491]

2. http://www.naacls.org/news/naacls-news/archives.asp?article_id=599 "

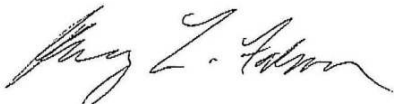
Again, this announcement by the CAP does NOT represent a change in what the requirements are for grossing surgical pathology specimens. This announcement represents a clarification of standards that have been out for a long time. The strength of the pathologists' assistant profession has never been founded on legislation or standards, but on the proven quality of its members and the value that we add to the anatomic pathology community. What steps can or should be taken by the AAPA, as an association, into such legislative matters obviously need to be carefully evaluated.

Sincerely,



Michael L. Sovocool, MHS, PA (ASCP)[CM]
Chair, Board of Trustees

Sincerely,



Rosie Falcon, MS, PA (ASCP)[CM]
Legislative Committee Chair