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(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.855 Standard; Cytology: gynecologic examinations

(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS by January 1, 1995, if available in the State in which he or she is employed.

Interpretive Guidelines §493.855(a)

Confirm by review of the attestation of enrollment documentation that all the individuals examining gynecologic cytology slides are enrolled in a CMS-approved cytology PT program.

If an individual works at more than one laboratory, the individual will be required to indicate, prior to the first testing event, one laboratory as the primary laboratory where the individual will be tested. Each laboratory is responsible for ensuring that all individuals examining gynecologic preparations in their laboratory indicate a location of testing.

Pathologists who routinely examine gynecologic cytology slide preparations, only after

they have been examined and marked by a cytotechnologist, may be tested by one of two methods:

a. Using a test that has been previously examined or marked by a cytotechnologist in their laboratory accompanied by the cytotechnologist's PT answers or b. Using a test set that has not been previously examined.

A pathologist, who examine and interprets slide preparations without pre-screening by a cytotechnologist, must be tested using a test set that has not been previously examined.

Each individual participating in a CMS-approved Cytology PT Program will be assigned a unique national PT registration number (PRT#) that will remain, regardless of the CMS-approved PT program utilized or future places of employment. Identifying information for individuals will be placed in a Privacy Act protected System of Records at CMS, and its confidentiality will be maintained in accordance with applicable law.

Personnel Requirement for Cytology Proficiency Testing (PT)

Cytotechnologist—Newly Certified by ASCP

New graduates of schools of cytotechnology who have taken the Certification Examination in Cytotechnology administered by the American Society for Clinical Pathology (ASCP) Board of Registry (BOR) and obtained a passing score have demonstrated an initial competency level in the examination of cervical cytology. These newly certified individuals will **not** be monitored for PT by CMS throughout the calendar year in which they passed their ASCP BOR Examination.

 New graduates of schools of cytotechnology who are employed, have taken the Certification Examination in Cytotechnology administered by the ASCP BOR, but have **not** obtained a passing score are required to participate in a CMSapproved Cytology Proficiency Testing Program.

Pathologists—Newly Board Certified

- Anatomic pathologists who are newly certified by the American Board of
 Pathology or the American Osteopathic Board of Pathology have demonstrated an
 initial level of competency interpreting cervical cytology specimens by passing
 the examination. These newly board certified individuals will **not** be monitored
 for PT by CMS throughout the calendar year in which they became board
 certified in Anatomic Pathology.
- Cytopathologists who receive added qualifications in Cytopathology from the
 American Board of Pathology or the American Osteopathic Board of Pathology
 have demonstrated competency interpreting cervical cytology specimens by
 passing this examination. These newly board certified individuals will **not** be
 monitored for PT by CMS throughout the calendar year in which they became
 board certified in Cytopathology.

Residents and Fellows

- Anatomic pathology residents are not required to participate in a CMS-approved Cytology PT Program. Pathology residents are under the constant supervision of fully licensed physicians and are not responsible for the final diagnosis of cervical cytology specimens.
- cytology specimens.
 Anatomic pathology fellows whose responsibilities in the cytology laboratory include the examination and interpretation of gynecologic specimens must enroll and achieve a passing score in a CMS-approved Cytology PT Program each
- All Other Cytotechnologists and Pathologists

 All other individuals subject to Cytology PT must enroll and be tested during each

calendar year.

calendar year.