



Center for Medicaid and State Operations/Survey and Certification Group

Notification of Cytology Proficiency Testing (PT) Policy Regarding PT Referral

CMS has become aware of a few pathologists who, at a certified remote location, examine gynecologic cytology specimens for a main laboratory facility. Their cytology PT is being performed in a similar manner. Specifically, a previously screened and marked PT slide set is sent to the pathologist at a remote location to be evaluated as part of the pathologist's annual cytology PT. Because this meets the definition of PT referral, CMS has determined that this practice must cease.

Pathologists who examine gynecologic cytology specimens at a remote location must make arrangements to participate in the annual cytology PT at the main location. In the event this is not feasible, laboratories may make arrangements for a cytotechnologist from the main location to travel to the remote location of the pathologist so he or she may participate in the testing event. Failure to implement this policy will result in enforcement actions. Section 493.801(b)(4) states, "... Any laboratory that CMS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples." In addition, Section 493.1840(a)(8) states " CMS may initiate adverse action to suspend, limit, or revoke any CLIA certificate if CMS finds that a laboratory's owner or operator or one of its employees has ... within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)"

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