DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/ Quality, Safety & Oversight Group

Ref: S&C-09-28 EXPIRED

DATE: December 04, 2025

TO: State Survey Agency Directors

FROM: Director, Quality, Safety & Oversight Group (QSOG)

SUBJECT: **EXPIRED:** Publication of Proposed Regulations for Gynecologic Cytology Proficiency Testing (PT) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

Memo Information:
Memo expiration date: **2025-12-04**
Original release date: **2009-03-13**

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) announced the publication of proposed regulations aimed at assuring the competency of those conducting the most common screening test for cervical cancer, the Papanicolaou (Pap) test.
- The proposed rule would update the current regulations implementing a statutory mandate that physicians (pathologists) and cytotechnologists (laboratory technologists with special training in cytology) who screen Pap tests to periodically demonstrate their proficiency in examining and interpreting proficiency testing samples.
- The proposed rule (74 FR 3263) was published on January 16, 2009.
- Public comments will be accepted until March 17, 2009.
- We encourage comments from the State Survey Agencies, CMS Regional Offices, and the general public.

Background

Concerns about erroneous Pap smears results were one of the major impetuses behind the enactment of CLIA which established minimum quality standards for nearly all clinical laboratories testing in the United States. The law contains specific requirements for cytology testing including the "…periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytologic preparations…"

Cytology PT was not implemented on a nationwide basis until 2005 because of the difficulty obtaining a sufficient number of referenced gynecologic cytology slides to evaluate the proficiency of individuals on a national basis. Now, however, there are two national CMS-

approved cytology PT programs from which laboratories may choose: the American Society for Clinical Pathology (ASCP) (formerly the Midwest Institute for Medical Education), first approved in 2005, and the College of American Pathologists (CAP), approved in 2006. A third program in Maryland was first approved in 1995, but is limited to those laboratories that examine Pap tests from residents of the State of Maryland only.

Test Results

In the first three years of nationwide testing, the percentage of personnel who pass on the first attempt has steadily increased. Improvements have been most striking for pathologists who screen slides without the assistance of a cytotechnologist. In 2005, 33 percent of such pathologists failed their initial test. By 2007, 11 percent did not pass. This level of failure is still of concern and reflects the necessity of continuing cytology PT on an ongoing basis.

Comparison of Current Regulation and the Proposed Regulation

The following chart gives an overview of the current requirements vs. the proposed requirements that would directly impact pathologists and cytotechnologists participating in cytology PT:

Current Regulation	
10 Slides/Test	20 Slides/Test
2 Hours/Test	4 Hours/Test
Annual Test	Biennial Testing
Test Composition: 1 Unsatisfactory Challenge 1 Normal Challenge 1 Low Grade (LSIL) Challenge 1 High Grade (HSIL) or Cancer (CA) Challenge	Test Composition: 1 Unsatisfactory Challenge 1 Normal Challenge 1 Low Grade (LSIL) Challenge 2 High Grade (HSIL) or Cancer (CA) Challenge
1 Missed HSIL/CA=Automatic Failure	2 Missed HSIL/CA=Automatic Failure
Glass Slide Test	Glass Slide Test and Opens Door for New Technologies
Field Validation of Slides Not Required	Field Validation of Slides Required
Appeals Process Not Required	Appeals Process Required
Different Scoring Grids for Pathologists and Cytotechnologists	Different Scoring Grids for Pathologists and Cytotechnologists

(This proposed rule was developed at the request of the cytology community and the Secretary's Clinical Laboratory Improvement Advisory Committee (CLIAC))

We request you read the proposed regulation and its preamble. You will see specific questions after each explanatory section of the preamble. Your responses to these questions will be of great assistance to us as we, with the Centers for Disease Control and Prevention, develop a final rule for cytology GYN proficiency testing. Please do not limit your comments to only those questions. We solicit your input as well as that of the general public on all aspects of the proposed regulation.

The proposed rule (74 FR 3263) was published on January 16, 2009. Public comments will be accepted until March 17, 2009. After carefully considering the comments, CMS, in collaboration with CDC, will issue a final rule.

We strongly encourage the submission of comments.

CMS-Approved PT Programs for 2009

- The State of Maryland Cytology Proficiency Testing Program is approved and tests only pathologists and cytotechnologists who examine Pap tests from Maryland residents;
- The American Society for Clinical Pathology - ASCP; and
- The College of American Pathologists - CAP.

Oversight Approach until Proposed Rule is Final

For 2009, we will continue the same approach for cytology PT that we previously adopted for 2005, 2006, 2007, and 2008. Laboratories will not fail cytology PT, have deficiencies cited, or have sanctions imposed against their CLIA certificate provided each:

1. Enrolls all individuals who interpret GYN smears (i.e., cytotechnologists and pathologists) in a CMS-approved PT program for the CY 2009 testing cycle, and
2. Ensures that all such individuals are tested in a timely manner within 2009, in accordance with the regulatory protocol. The regulatory protocol under 42 CFR 493.855 identifies the extent to which additional testing, education or limitations must be put in place with regard to individuals who do not pass the test.

Survey Protocols for Compliance with Cytology PT

The attachment to this memorandum contains the special survey protocols for 2009 and ongoing.

Contact:
For questions or concerns relating to this memorandum, please contact LabExcellence@cms.hhs.gov

Effective Date:
Immediately. Please communicate to all appropriate staff within 30 days.

/s/
David R. Wright
Director, Quality, Safety & Oversight Group

Attachment: Survey Protocols for Compliance with Cytology Proficiency Testing – 2009

Resources to Improve Quality of Care:
Check out CMS's new Quality in Focus interactive video series. The series of 10–15 minute videos are tailored to provider types and aim to reduce the deficiencies most commonly cited during the CMS survey process, like infection control and accident prevention. Reducing these common deficiencies increases the quality of care for people with Medicare and Medicaid.
Learn to:

- *Understand surveyor evaluation criteria*
- *Recognize deficiencies*
- *Incorporate solutions into your facility's standards of care*

See the Quality, Safety, & Education Portal Training Catalog, and select Quality in Focus

Receive email notification for memos:
Get guidance memos issued by the Quality, Safety and Oversight Group by going to CMS.gov page and entering your email to sign up. Check the box next to "CCSQ Policy, Administrative, and Safety Special Alert Memorandums" to be notified when we release a memo.

Attachment: Survey Protocols for Compliance with Cytology Proficiency Testing - 2009

In the conduct of surveys beginning January 1, 2009, until further notice, State Survey Agencies (SAs) must accomplish the following:

- ***Enrollment*:** Confirm by review of enrollment documentation that the individuals examining gynecologic cytology slides are enrolled in a CMS-approved cytology PT program for this calendar year and that all laboratory cytology testing sites are enrolled.
- ***Testing***: Inquire of the laboratory director as to the status and outcomes of each individual's testing to ensure that the laboratory is following the regulatory protocol.

  NOTE: For laboratories that will not be surveyed in 2009, the SAs will receive guidance from CMS Central Office (CO), based on monitoring of enrollment and testing performance data from the Survey & Certification Group.

- ***Exempt States & Approved Accrediting Organizations (AOs)***: Exempt and accredited laboratories will be overseen by their respective States or AOs and CO, consistent with these protocols.
- ***System of Re-Testing:*** Confirm that individuals who fail the initial proficiency test are being re-tested timely in conformance with the procedures of 42 CFR 493.855.
- ***Additional Systems of Controls:*** Confirm that the laboratory has in place procedures for and documentation of the review of slides examined by individuals who have failed a second test and their education in the area of failure. There should also be procedures for and documentation of appropriate follow-up of individuals who fail a third test; i.e., prohibition of screening following test failure notification and acquisition of 35 CEUs in a formal pertinent cytology educational program. These situations are extremely rare.
- ***Verification of Compliance***: For laboratories that will not be surveyed in 2009, CO will monitor their performance and provide additional guidance to the CMS regional offices.

Enforcement When the Other Approaches Fail

The CMS regional office, in conjunction with the SA, will initiate intermediate sanctions that may include Civil Money Penalties of up to $10,000, limitation of the laboratory's CLIA certificate for cytology, and, if applicable and serious, suspension of the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with subpart R of the CLIA regulations if the laboratory fails to accomplish any of the following:

- ***Ensure Enrollment***: Fails to enroll all gynecologic cytology testing sites in a CMS-approved cytology PT program for each calendar year (CY2005, CY2006, , CY2007, CY 2008 and CY2009);
- ***Ensure Testing in 2009***: Fails to ensure that all individuals examining gynecologic cytology slides in 2009 are enrolled in a CMS-approved cytology PT program and are tested in a timely manner within 2009, in accordance with the regulatory protocol. The regulatory protocol under 42 CFR 493.855 identifies the extent to which additional testing, education or limitations must be put in place with regard to individuals who do not pass the test initially[1].

[1] **NOTE:** CMS will not take enforcement action for failure to complete a cytology proficiency test with respect to any otherwise-qualified individual who meets the CMS criteria for special circumstances, as described in the "Cytology PT Informational Supplement 2006" posted on the CMS website at www.cms.hhs.gov/clia.

- ***Ensure Re-testing for Any Individual who Fails a Test:*** Fails to ensure that an individual who fails a cytology PT test takes any required additional education or remedial actions, and is retested, as specified in the CLIA requirements, if such individual continues to examine slides for the laboratory.
- ***Complete Previous Year's Testing***: Fails to ensure that the 2008 testing has occurred by April 2, 2009 (as described in S&C memo 05-11, 12/16/04 and S&C memo 06-07). This applies to individuals who were subject to the 2006 testing cycle but who were not tested in CY 2006 (and who are not excused/excepted to examine slides).