

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Office of Media Affairs

CMS FACT SHEET

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**PROPOSALS TO IMPROVE CYTOLOGY PROFICIENCY TESTING
REQUIRED BY THE CLINICAL LABORATORY IMPROVEMENT
AMENDMENTS OF 1988**

OVERVIEW:

On January 15, 2009, the Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would improve the requirements for proficiency testing (PT) for individuals who screen and interpret Papanicolaou (Pap) tests to identify cervical cancers at an earlier, more treatable stage. The proposals would affect approximately 12,500 pathologists and cytotechnologists who review 60 million Pap tests in the United States annually. In developing the proposed rule, CMS worked closely with the Centers for Disease Control and Prevention (CDC), which along with the Food and Drug Administration (FDA), share responsibility for improving clinical diagnostic laboratory testing in the United States.

Prior to the widespread adoption of Pap testing, cervical cancer was the leading cause of death for women in the United States. With early detection and treatment, the number of deaths has dropped dramatically, and today, the five-year relative survival rate for the earliest stage of invasive cancer is 92 percent. More information about the history and current status of cervical cancer diagnosis and treatment is attached as Appendix A.

The proposed changes to the regulatory requirements under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for cytology proficiency testing would improve the efficiency and effectiveness of cytology PT and reduce the regulatory burden on laboratories that perform this screening by decreasing the test frequency from annually to biennially.

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BACKGROUND:

Deaths from incorrectly read Pap tests were a major impetus for the passage of CLIA just over 20 years ago. CLIA regulates nearly all clinical laboratories that conduct testing for medical purposes in the United States. Concerns about the quality of Pap testing and the potentially deadly impact of an incorrect Pap test result led Congress to establish certain unique regulatory requirements for those conducting Pap testing. Recognizing that it takes highly skilled and trained pathologists and cytotechnologists to screen cellular specimens from the female reproductive tract for early signs of cancer, Congress specified that each individual involved in screening or interpreting Pap tests was to be required to demonstrate proficiency through participation in an approved proficiency testing (PT) program. This PT is designed to test the individual's ability to locate and identify what may be only a few abnormal cells out of thousands of cells on a slide.

CURRENT CYTOLOGY PT PROGRAM:

Cytology PT was implemented nationwide in 2005. There are currently two CMS-approved cytology PT programs that operate nationwide from which laboratories may choose: one offered by the American Society for Clinical Pathology (ASCP) (which is a continuation of the PT program originally approved to be run by the Midwest Institute for Medical Education, Inc. (MIME) in 2005) and another offered by the College of American Pathology (CAP), which was approved to begin testing in 2006. A third program run by the State of Maryland was approved by CMS to begin testing in 1995 but is limited to laboratories screening Pap tests from residents of Maryland.

While CLIA provides for PT of laboratories in other specialties, the PT for cytology (Pap) testing requires the periodic testing of the individual pathologist or cytotechnologist (a laboratory technologist with special training in cytology) who screens or interprets gynecologic samples in Pap tests). This requirement recognizes that intense concentration is needed to examine the cells in a Pap test and that most Pap tests are screened by a single individual, without a second level review. Under the CLIA regulations, the individual taking the test is given at least four chances in a testing cycle (currently annual, but proposed to be biennial) to achieve a passing score of 90 percent.

Currently, for both the initial test and the first retest, the individual is required to screen 10 slides within two hours. For the second and third retests (where necessary), the number of slides is increased to 20 and the time for completing the screening is increased to four hours. An individual who does not score at least 90 percent on the initial test may continue to screen slides, but must retake the test. If the individual does not score at least 90 percent on a second test, he or she may continue screening slides but the results must be confirmed by a colleague who has passed the test during the current calendar year. The individual must also undergo additional

training and take a third test and obtain a score of at least 90 percent. Only after failing to obtain a score of 90 percent on the third test is the individual precluded from performing further screening of patient samples until he or she has obtained 35 hours of continuing education and achieved a score of at least 90 percent on a 20 slide retest.

Under current rules, missing even one high grade lesion or cancer case will result in automatic failure.

EXPERIENCE DURING FIRST THREE YEARS OF PT PROGRAM:

Over the three years that the nationwide cytology PT programs have been in effect, the percentage of personnel who pass the test on the first attempt has steadily increased. This is true without regard to whether the individual taking the test is a pathologist screening slides without the assistance of a cytotechnologist, a pathologist screening with the assistance of a cytotechnologist, or a cytotechnologist screening alone under the supervision of a pathologist. The improvements seen in the results for pathologists who screen slides without the assistance of a cytotechnologist have been the most striking. In 2005, 33 percent of pathologists screening slides without the assistance of a cytotechnologist failed their initial test; by 2007, the failure rate for this group on the initial test dropped to 11 percent.

PROPOSALS IN THIS NOTICE OF PROPOSED RULEMAKING:

In response to concerns expressed by the cytology testing community, CMS is proposing to refine the cytology PT program in a number of ways, based on recommendations provided by cytology experts. For example, the proposed regulation would increase the number of slides or other approved media (challenges) in the first test and first retest to 20, and the time for completing the screening to four hours. The score required to pass would remain at 90 percent, but by doubling the number of challenges, each error would have only half as much impact on the total score. Missing two high-grade lesions or cancers would result in automatic failure. The proposed rule would also require PT testing biennially rather than annually as in the current rules. The proposed rule also provides for the approval of media other than glass slides for cytology PT to accommodate the use of future PT technologies.

The proposed rule would also affect the providers of cytology PT, by requiring them to explain their appeals process prior to the administration of a test and imposing more stringent obligations on PT programs to maintain high quality testing sets. The proposed rule requests additional information from cytology PT providers and others to analyze trends in PT failures over time.

A chart comparing the key differences between the current regulation and the proposed regulation is attached as Appendix B.

Comments on the proposed rule will be accepted until March 17, 2009. After carefully considering the comments it receives, CMS, in collaboration with the Centers for Disease Control and Prevention (CDC), plans to issue a final rule.

More information on CLIA and a copy of the proposed rule are available on the CMS website at: www.cms.hhs.gov/center/clinical.asp.

CERVICAL CANCER – AN OVERVIEW

- Cervical cancer was once the leading cause of death for women in the United States. In 2008, the estimated number of new cases of cervical cancer was 11, 070 and deaths from cervical cancer were 3,870.
- Cervical cancer may not cause any symptoms at first, but later, symptoms may include pelvic pain or vaginal bleeding.
- Cervical cancer is the easiest female cancer to detect with regular screening tests and follow-up, and is highly curable when found and treated early.
- During the past 50 years, the number of deaths from cervical cancer has declined by nearly 75 percent, largely because of the widespread use of the highly successful screening test, the Pap test, to detect the presence of abnormal cells in the cervix and vagina.
- Despite the availability of early detection and treatment, 6 out of 10 new diagnoses occur in women who have never received a Pap test or have not been tested in the preceding 5 years.
- All women are at risk of cervical cancer, although it occurs most often in women over 30.
- The United States Preventive Services Task Force strongly recommends that women get their first Pap test within three years after first having sex, or at age 21, whichever occurs first, and undergo periodic screening thereafter.
- Women at increased risk or who are of child-bearing age and have had an abnormal test result within the preceding three years should be screened annually.
- Infection from the Human Papillomavirus (HPV) is the most important cause of and risk factor for cervical cancer. HPV is a sexually transmitted virus. There are many strains of HPV but not every strain causes cervical cancer. There are simple tests physicians can request to determine whether a woman is infected with the HPV virus and if she is infected, the strain of virus with which she has been infected.

**COMPARISON OF KEY PROVISIONS IN THE PROPOSED
REGULATION AND CURRENT RULE**

Current Regulation	Proposed Regulation
10 Slides/Test	20 Slides/Test
2 Hours/Test	4 Hours/Test
Annual Test	Biennial Testing
<u>Test Composition:</u> 1 Unsatisfactory Challenge 1 Normal Challenge 1 Low Grade (LSIL) Challenge 1 High Grade (HSIL) or Cancer (CA) Challenge	<u>Test Composition:</u> 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 Glass Slide Test	2 Missed HSIL/CA=Automatic Failure Glass Slide Test and Opportunity for New Technologies
Field Validation of Slides Not Required	Continuous 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

NOTE: The diagnostic categories used to develop the Pap Testing challenges (consistent with those listed in the 2001 Bethesda Conference report) are:

- **Unsatisfactory samples** - i.e., scant cellularity, air drying, and obscuring material (blood, inflammatory cells or lubricant));
- **Normal or Benign Changes** - normal, negative, or otherwise within normal limits, infections other than Human Papilloma virus (HPV) (e.g., *Trichomonas vaginalis*, changes or morphology consistent with *Candida* spp., *Actinomyces* spp., or *Herpes simplex* virus);
- **Low Grade Squamous Intraepithelial Lesions (LSIL)** - includes: Cellular changes associated with HPV, Mild Dysplasia/CIN-1;
- **High Grade Squamous Intraepithelial Lesion and Carcinoma (HSIL)** - includes moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in-situ/CIN-3, Squamous Cell Carcinoma, Adenocarcinoma and other malignant neoplasms.

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