DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

March 30, 2005

IMPORTANT INFORMATION PLEASE READ

Dear Laboratory Director:

On January 31, 2005, your laboratory was sent an official notification from the Centers for Medicare & Medicaid Services (CMS) containing information on the availability of cytology proficiency testing programs and a brief overview of the cytology proficiency testing requirements under CLIA. The purpose of this letter is to remind laboratories examining gynecologic specimens of the necessity to enroll and participate in one of the two CMS-approved cytology proficiency testing (PT) programs for calendar year 2005.

The two CMS-approved cytology PT programs for calendar year 2005 are the State of Maryland Cytology PT Program and the Midwest Institute for Medical Education (MIME) program. Both programs have received CMS approval for testing in 2005 under the requirements for cytology PT under Subparts H and I of the CLIA regulations. *See* 42 CFR Part 493. While we expect to receive application materials from additional programs that could then be approved for cytology PT testing for 2006, the application window has closed for approving additional programs for testing in 2005. Therefore, every laboratory performing the examination of gynecologic specimens must enroll in one of the two programs listed above.

In our previous letter, CMS reminded you that all CLIA certified laboratories (accredited and non-accredited) and CLIA-exempt laboratories that perform gynecologic cytology testing must ensure that each individual (cytotechnologists and pathologists) is enrolled in a CMS-approved cytology PT program for 2005. To avoid potential enforcement actions, such individuals should enroll as soon as possible in order to complete their initial testing by December 31, 2005 and annually thereafter. Following enrollment, you will be notified of the scheduled PT test date at least 30 days prior to the administration of the test. Every individual subject to Cytology PT is required to have completed their initial test no later than December 31, 2005.

The CMS is closely monitoring the enrollment and testing process during calendar year 2005. We recognize the fact that individuals need time to enroll in a Cytology PT program and the programs and laboratories need time to make the logistical arrangements necessary for testing. Numerous laboratories have enrolled and participated in Cytology PT, thereby ensuring compliance with this statutory and regulatory requirement. However, CMS is also aware of a number of laboratories that have thus far failed to enroll in an approved cytology PT program. This letter serves as a strong reminder to laboratories that have not yet enrolled and participated in a CMS-approved PT program that they should do so. Enforcement provisions will have to be applied against laboratories that disregard the cytology PT requirements. The CMS regional office will initiate alternative sanctions or limit the laboratory's CLIA certificate for cytology, and if applicable, suspend 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 enroll in a CMS-approved cytology PT program;
- Fails to ensure that all individuals examining gynecologic cytology slides are enrolled in and successfully completed a CMS-approved cytology PT program;

- Fails to ensure that an individual who fails a cytology PT test is retested in accordance with the regulatory requirements for retesting, if such individual continues to examine gynecologic slides for the laboratory; or
- Fails to take the required remedial actions (including retesting, documented remedial training in the area of failure, reexamination of gynecologic slides, cessation of the examination of gynecologic slides, and 35 hours of documented formally structured continuing education in diagnostic cytopathology) specified in the CLIA requirements.

Newly hired individuals who are entering the profession from college or a school of cytotechnology will be granted a 6 month grace period in which they must be enrolled with a CMS-approved program and tested.

If you have additional questions, please refer to the Cytology PT information on the CLIA website at www.cms.hhs.gov/clia/ or you may call the State Agency (SA) in the State where your laboratory is located as listed below.

Sincerely,

Judith A. Yost
Director,
Division of Laboratory Services
Center for Medicare & Medicaid Services