DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and State Operations

January 23, 2006

Dear Cytology Laboratory Director:

I am writing to provide an update with regard to Clinical Laboratory Improvement Amendments of 1988 (CLIA) gynecologic cytology proficiency testing (PT), a national effort in *improving the healthcare of women*, for calendar year (CY) 2006.

We in the Centers for Medicare & Medicaid Services (CMS) wish to thank you and all laboratories that conduct gynecologic cytology screening for your efforts to ensure and demonstrate proficiency through such examinations. We appreciate that fulfillment of the legal requirements for PT was not an easy undertaking in 2005, though nearly all affected laboratories enrolled, and were able to accomplish the proficiency testing in 2005. Such achievement exemplifies the professionalism of the nation's cytotechnologists and pathologists.

We are pleased to convey the following information.

2006 Cytology Proficiency Testing Cycle

In 2006 we are continuing the educational approach to national testing. In the educational approach, laboratories will not have deficiencies cited or have sanctions imposed against their CLIA certificate, provided they:

- Enroll all affected individuals (i.e., cytotechnologists and pathologists) in a CMS approved testing program for the CY 2006 testing cycle, and

- Ensure that all such individuals are tested in a timely manner within 2006, 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.

Instructions to continue the educational approach have already been issued to the nation's surveyors and may be accessed at our website at:
http://www.cms.hhs.gov/CLIA/02_CytologyProficiencyTesting.asp#TopOfPage

In CY 2006 laboratories will also have additional choice for cytology PT providers in 2006. The CMS-approved PT programs are:

- State of Maryland Cytology PT Program (Only for laboratories testing specimens from MD residents)
- Midwest Institute for Medical Education (MIME)
- College of American Pathologists (CAP)

We are reviewing an additional application which, if it meets regulatory requirements, would add a fourth testing option.

Another improvement for 2006 concerns the very small number of individuals (0.8%) who might need a third test in order to achieve a passing score. In the past, such individuals have been required to travel a considerable distance in order to take the PT a third time. We are working with the approved testing programs to promote additional options that would be more convenient. MIME, for example, has already requested and received approval for a third-test option and will provide the appropriate information on their website. CAP also is considering additional options.

2005 Testing Follow-Up

In the educational approach adopted for 2005, we made a commitment that we would not undertake sanctions provided laboratories and individuals undertook the 2005 testing by April 2, 2006. If you are among the very small number of laboratories that have needed the extra time, we urge you to make the necessary arrangements forthwith. If you have not undertaken testing in 2005 with a program approved to conduct the 2005 testing, you will need to do so by April 2, 2006. The laboratory will then also need to enroll for the CY 2006 testing cycle.

If the educational approach fails, and you have not enrolled or undertaken PT testing by April 2, 2006 for the 2005 testing cycle, the laboratory will be subject to sanctions that may include: Civil Money Penalties of up to $10,000; limitation on the laboratory's CLIA certificate, and/or suspension of Medicare payment for cytology testing. These are outcomes we would all like to avoid.

Consideration of Program Improvements for the Future

In August 2005 we made a commitment to (a) evaluate testing results at the end of the calendar year and (b) consider specific ideas for program improvement. We will soon have the final data for 2005 and will expeditiously fulfill the commitments we made. To that end, we are undertaking the following:

- ***CLIAC Workgroup***: CMS is collaborating with the Centers for Disease Control and Prevention , and with the cytology community, to explore any concerns with the CLIA cytology PT requirements. A Clinical Laboratory Improvement Advisory Committee (CLIAC) work group, composed of individuals with cytology expertise, will review those ideas and provide recommendations to the Advisory Committee, which in turn will advise us. Among the agenda topics will be:

    - ***Frequency of Testing***: What are the merits and implications (for proficiency and for women's health care) if the PT occurred every two years rather than every year?
    - ***Scoring***: Are there merits, and if so what are the implications, of adjusting the scoring system?
    - ***Diagnostic Categories:*** Is it advisable to adjust any of the diagnostic categories used in the testing?

- ***Cytology PT Informational Supplement***: By the end of January we will update the Cytology PT Informational Supplement that contains frequently-asked questions and provides other cytology PT information. In the update we will elaborate on the manner in which CMS maintains confidentiality of testing so as to promote an environment that is optimally conducive to both testing and education. Please visit www.cms.hhs.gov/clia. Finally, we will establish a CMS e-mail box to which any questions or comments pertaining to CMS policy or workgroup efforts may be addressed.

We look forward to further work with laboratory professionals and key professional organizations to promote and protect the health and safety of women in this country.

Judy Yost, Director
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Survey & Certification Group