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CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations / Survey and Certification Group

Ref: S&C-07-04

DATE: **December 7, 2006**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: State Survey Agency (SA) Responsibilities for 2007 Regarding Gynecologic Cytology Proficiency Testing (PT) under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and Additional Program Information—**UPDATE**

Letter Summary

- ***Purpose***: This memo provides further guidance for assessing cytology laboratory compliance with CLIA requirements for cytology PT, and updates S&C Memo #05-11 dated 12/16/04 and S&C Memo #06-07 dated 1/23/06.
- ***2007 Approach:*** For CY 2007 we are continuing the approach we previously adopted in 2005 and 2006 for the implementation of national PT. This means that laboratories will not fail cytology PT, have deficiencies cited, or have sanctions imposed against their CLIA certificate provided they:
    1. Enroll all affected individuals in a Centers for Medicare & Medicaid Services (CMS) approved testing program for the CY 2007 testing cycle, and
    2. Ensure that all such individuals are tested in a timely manner within 2007, 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.
- ***Choices for 2007 Testing Cycle:*** The State of Maryland, the American Society for Clinical Pathology (ASCP) and the College of American Pathologists (CAP) have been approved by CMS as cytology PT providers for 2007. *(Note: the ASCP acquired the Midwest Institute for Medical Education (MIME) in February 2006. MIME was the only national cytology PT provider in 2005)*
- ***Current Developments:*** CMS and the Centers for Disease Control and Prevention (CDC) received recommendations from a workgroup under the auspices of the Secretary's Clinical Laboratory Improvement Advisory Committee (CLIAC) to refine the cytology PT standards to address issues of concern and optimize proficiency tests. CMS and CDC are currently in the process of developing a new regulation. We expect to publish the proposed rule in 2007.
- ***The CLIA Web site*** at: www.cms.hhs.gov/clia includes current cytology PT performance data and policies, as well as responses to issues of concern.

Background

The CLIA statute requires the "periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site PT of such individuals, with such testing to take place, to the extent practicable under normal working conditions." See 42 USC sec. 263a(f)(4)(B)(iv) section 353(f)(4)(B)(iv) of the Public Health Service Act.

The CLIA regulations that implement this statutory provision require cytology laboratories and individuals who examine gynecological cytology specimens to enroll in a CMS-approved cytology PT program and achieve a passing score, annually. Specifically:

- 42 CFR 493.801 specifies that, "Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification."

- 42 CFR 493.855 provides that, "To participate successfully in a cytology proficiency testing program for gynecologic examinations . . . ." "(a) The laboratory must ensure that each individual engaged in the examination of gynecologic preparations is enrolled in a proficiency testing program approved by CMS by January 1, 1995, if available in the State in which he or she is employed [applicable to Maryland]. The laboratory must ensure that each individual is tested at least once per year and obtains a passing score [universally applicable]."

CMS-Approved PT Programs for 2007

- The State of Maryland Cytology Proficiency Testing Program is approved to test the proficiency of physicians and cytotechnologists who examine Pap smears from Maryland residents.
- The American Society for Clinical Pathology (ASCP) has met the statutory and regulatory requirements for CMS approval as a national cytology PT program for CY 2005, CY 2006, and CY 2007. The Midwest Institute for Medical Education (MIME), the only national cytology PT provider in 2005, was acquired by the ASCP in 2006.
- The College of American Pathologists (CAP) has been approved for national cytology PT in CY 2006 and CY 2007.

2007 Approach

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

1. Enroll all affected individuals (i.e., cytotechnologists and pathologists) in a CMS-approved testing program for the CY 2007 testing cycle, and
2. Ensure that all such individuals are tested in a timely manner within 2007, 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. See detailed information below and in the regulations.

Continuation of this approach will permit laboratories and individuals to enhance their training and education, as well as make the best decisions for future testing. It also provides CMS the opportunity to compile and evaluate the performance data from 2006.

CLIAC Cytology PT Work Group

In 2006 we supported a workgroup, convened under the auspices of the Secretary's Clinical Laboratory Improvements Advisory Committee (CLIAC), to advise us on standards to optimize gynecological cytology examination PT. Workgroup members with appropriate expertise provided vital input to the full Advisory, which then communicated recommendations to optimize cytology PT standards. We expect to publish a proposed rule in 2007 that will make refinements in the PT system.

Survey Protocols for Compliance with Cytology PT

The attachment to this memorandum contains the special survey protocols for 2007.

Communications

All questions regarding this correspondence should be directed to CMS' Division of Laboratory Services at (410) 786-3531. We will post contacts for CMS-approved PT organizations on the CMS website at www.cms.hhs.gov/clia, as well as other information regarding cytology PT, including updated performance data, policies, and CMS responses to concerns.

Effective Date: The effective date of this memorandum is January 1, 2007. All surveys conducted on or after this date must incorporate the provisions of this memorandum.

Training: The information contained in this memo should be shared immediately with all CLIA survey and certification staff and managers who have responsibility for the oversight of gynecologic cytology laboratories.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachment: Survey Protocols for Compliance with Cytology Proficiency Testing - 2007

In the conduct of surveys beginning January 1, 2007, 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 2007, 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 2007, 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 (CY 2005, CY 2006, if applicable, and CY 2007);
- ***Ensure Testing in 2007***: Fails to ensure that all individuals examining gynecologic cytology slides in 2007 are enrolled in a CMS-approved cytology PT program and are tested in a timely manner within 2007, 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 in 2007:*** 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 2006 Testing***: Fails to ensure that the 2006 testing has occurred by April 2, 2007 (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)[1].

In early 2007 any accredited or non-accredited laboratories that did not fulfill the 2006 testing requirements (see S&C Memo #06-07 dated 1/23/06) will be notified via letter of the problem and the action they can take by April 2, 2007 to prevent potential sanction(s).