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Center for Medicaid, CHIP, and Survey & Certification/Survey & Certification Group

Ref: S&C: 11-19-CLIA

DATE: **April 8, 2011**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Notification of Withdrawal of Centers for Medicare & Medicaid Services (CMS) 2252-P: Cytology Proficiency Testing (PT) Notice of Proposed Rulemaking (NPRM)

Memorandum Summary

- **Purpose:** Notification that CMS has withdrawn the Cytology Proficiency Testing NPRM
- **CMS actions to address NPRM comments:** The majority of recommendations made by the cytopathology and cytotechnology experts and the Clinical Laboratory Improvement Advisory Committee (CLIAC) will be implemented through revised interpretive guidance and administrative policy.
- **Guidance to surveyors:** Cytology laboratories must continue to meet the existing regulations at 42 CFR 493.855 by enrolling and successfully participating in a CMS-approved cytology PT program for the annual testing of the subject individuals.
- **Future steps:** CMS will continue to monitor cytology PT performance and to collaborate with the cytology community on all cytological quality initiatives.

Background

The Clinical Laboratory Improvement Amendments of 1988 (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 proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions." The CLIA regulations that implement this statutory provision require all cytology laboratories and individuals who examine gynecologic cytology specimens to enroll in a CMS-approved cytology PT program and achieve a passing score, annually.

Cytology proficiency testing for pathologists and cytotechnologists has been in place since 2005. Refer to Attachment A for an overview of cytology proficiency testing. The number of individuals who scored less than the passing score of 90% has decreased significantly over time. Following the first test failure, individuals who do not score at least 90% on a PT event are required to obtain focused continuing education, based on the area of testing failure. Observed improvements in participant scores may be due to the post-failure focused continuing education and greater comfort with the testing process.

Because of issues raised about the current cytology PT program, CMS and the Centers for Disease Control and Prevention (CDC) revisited the effectiveness and feasibility of the current cytology PT regulations. A workgroup consisting of nationally recognized cytology experts was assembled under the auspices of the Clinical Laboratory Improvement Advisory Committee (CLIAC), a Secretary's Federal advisory committee. The workgroup developed 16 recommendations to address the concerns of the cytology community and public. CLIAC recommended to the Secretary that CMS and CDC develop an NPRM to include the recommendations made by the group of experts. In 2009, the NPRM which considered all of the CLIAC recommendations was published and public comment and input was requested to additional CMS questions. CMS received a total of 690 submissions by the end of the public comment period which contained 6,503 individual comments from the cytology community and the public.

CMS Analysis / Action

The greater percentage of comments received in response to the NPRM conflicted with the current CLIA statute by requesting replacement of the Cytology PT program with a continuing education program. Cytology continuing education programs do not meet the statutory requirements for the number and frequency of slides to be tested. Additionally, the evaluation of results performed by the continuing education programs is not sufficient to satisfy the statute and regulations, as participation in continuing education programs is voluntary, and the programs have no oversight authority. The educational challenges provided by continuing education programs are initially performed independently by each individual who reads and interprets cytology slides, but a consensus answer is provided to the educational program on behalf of the entire laboratory. Continuing education credits earned for participation are granted to the participants even when there is a failure to successfully identify the challenge which may disguise poor performers. Replacing the current requirements with continuing education would introduce risk to the CLIA program. The current system already includes continuing education tailored to individual areas of failure, and the proposed change would diminish CMS' ability to oversee, monitor and enforce quality testing through cytology PT which has demonstrated proven success.

In response to the public comments requesting a change to cytology PT that is in conflict with the current CLIA statute, CMS has withdrawn the NPRM and will maintain the current robust cytology PT requirements. It is essential to note that CMS will implement 10 of the 16 recommendations where the comments from the public and cytology community demonstrate consensus and CMS sees benefit. These proposed changes will be accomplished through revisions to interpretive guidance and administrative policy and include:

- Encouraging laboratories to participate in educational laboratory programs in addition to individual PT
- Changing current term of "slides" to challenges
- Defining a challenge as case equivalent
- Retaining four response categories and continuing to require at least one challenge from each of the four categories in each test
- Requiring field validation, monitoring challenges continuously, and removing challenges that fail field validation

- Requiring field validation procedures be disclosed by the vendor
- Providing educational feedback for result discrepancies
- Continuing to allow PT providers to determine proctor requirements
- Requiring PT providers to disclose their appeals process in writing
- Changing language to state "individuals who score <90" as opposed to using the word "fail"

The remaining six recommendations will not be implemented by CMS at this time (See Attachment B for detail). CMS ***will not***:

- Require oversight organizations/agencies to determine if laboratories participate in educational programs and provide laboratories with identification of available resources
- Add a requirement for a transition phase for new technology such as virtual slides when the individual can request retesting with the previous platform/format (e.g., glass slides)
- Reduce the frequency of testing to a 3-year cycle
- Use 20 challenges for every test (initial test and retest)
- Change the grading scheme to a new model that is the same for both technical supervisors and cytotechnologists
- Require biopsy confirmation of category D (HSIL/cancer) challenges, but not category C (LSIL) challenges

Future Steps and Surveyor Guidance

Surveyors are to continue reviewing and enforcing the current Cytology PT requirements for annual enrollment and successful participation during on-site surveys or at the request of CMS per previous policy and guidance. CMS will continue to monitor performance as currently mandated and report these performance indicators to CLIAC who continues to endorse monitoring of individual performance. Additionally, CMS will continue to work closely with the cytology community and monitor current and future quality initiatives and issue guidance, when necessary. A list of frequently asked questions (FAQs) is also being included to assist States and laboratories in addressing questions and concerns from concerned parties.

If you have any questions regarding this memo, please contact Cheryl Wiseman at 410-786-3340 or Cheryl.wiseman@cms.hhs.gov.

Effective Date: This information is effective immediately. Please ensure that all appropriate staff members are fully informed with 30 days of the date of this memorandum.

/s/
Thomas E. Hamilton

Attachments

cc: Survey and Certification Regional Office Management

Attachment A: Overview of Cytology Proficiency Testing

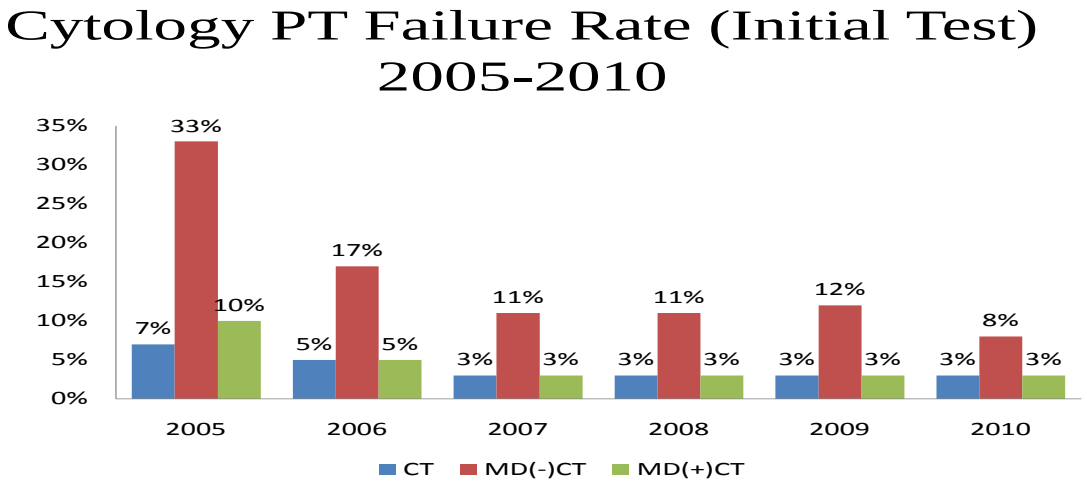
Testing Process

- Pathologists and cytotechnologists are tested individually with test sets composed of slides exhibiting a progression of abnormality from unsatisfactory to cervical cancer.
- There are four test opportunities annually. If an individual fails the first test, he/she can test a second, third or fourth time:

    - Initial Test - ten slides reviewed in two hours (If individual does not obtain a score of 90% they must be retested within 45 days);
    - Second Test - ten slides reviewed in two hours (If individual does not obtain a score of 90% they may continue to screen but results must be checked, obtain continuing education, and re-test);
    - Third Test – 20 slides reviewed in 4 hours (if individual does not obtain a score of 90% they must cease testing and obtain 35 hours of continuing education, and re-test); and
    - Fourth Test – 20 slides reviewed in 4 hours (if individual does not obtain a score of 90% they must cease testing and obtain 35 hours of continuing education, and re-test).

Cytology PT Results

CMS monitors the cytology PT results continuously and conducts appropriate follow up on enrollment and performance failures. The following chart depicts the performance of individuals (i.e., cytotechnologists, pathologists who work with cytotechnologists and solo pathologists who do not receive assistance from cytotechnologists) that examine gynecologic cytology and are therefore required to participate in cytology PT. Individual performance is measured in percentages and represent cytology PT results from 2005 (implementation of testing) through 2010.



Key: CT = Cytotechnologists

MD(-)CT= Solo Pathologists who examine gynecologic cytology without assistance from cytotechnologists
MD(+)CT = Pathologists that examine gynecologic cytology with the assistance of cytotechnologists.

Value to Women's Health

The value of cytology PT is best demonstrated by its results:

- Annual results from cytotechnologists, pathologists who examine their own slides and pathologists who examine slides with the assistance of a cytotechnologist have improved.
- During the 1st year of testing, pathologists who examined slides on their own failed the first test 33% of the time. The failure rate for these pathologists has improved significantly since 2005, but is still significant enough to cause CMS concern.
- The test is geared to identify individuals who require focused continuing education and ensures those individuals obtain the continuing education, as part of the testing process.

Attachment B – CLIAC Recommendations that will not be implemented by CMS

In-depth analysis of the comments to these six CLIAC recommendations demonstrated a lack of consensus and agreement among commenters.

CLIAC Recommendation	CMS Response
Oversight organizations, agencies and surveyors should determine if laboratories participate in educational programs and provide the laboratories with identification of available resources	Seven of seventeen commenting Organizations requested that cytology PT be withdrawn and replaced with an education program. CMS does not have the statutory authority to require laboratories or individuals to participate in educational programs. However, CMS does encourage laboratories to participate in continuing education. Professional organizations and their meetings and seminars provide education and /or resources, along with publications, subject matter experts, the Internet, etc.
Add requirements for a transition phase for new technology (e.g. virtual slides), when the individual can request retesting with previous platform/format (e.g. glass slides)	Commenter responses ranged from no new technology to having no requirements in the regulations for a transition phase. This recommendation was not accepted due to the lack of consensus and agreement by all commenters. Just as routine PT was phased in over time for previously unregulated laboratories, so then would CMS phase-in any new technologies utilized to conduct cytology PT.
Reduce the frequency of testing to a 3-year cycle	Four of seventeen organizations could not specify a testing timeframe. Other suggested testing frequencies ranged from yearly to every 10 years (comments from 7 of 17 organizations). Five organizations did not address this recommendation. Due to the lack of consensus, no discernable, appropriate frequency could be ascertained. No data exists to demonstrate a better interval for testing.
Use 20 challenges for every initial and retest	Seven of the seventeen organization commenters stated that the use of 20 challenges would result in increased costs to PT programs and individuals. Other comments indicated that there are not sufficient numbers of slides available to provide 20 challenge test sets for a national program. No data exists to demonstrate the optimum number of slides for the test. One article's suggestion is infeasible.
Change the grading scheme to a new model that is the same for both technical supervisors and cytotechnologists	Three organizations that commented favored separate schemes for pathologists and cytotechnologists with seven organizations not addressing the recommendation. Three organizations favored a unified scheme. The CLIAC work group experts did not reach consensus on this issue. CMS determination to score pathologists more stringently reflects their

	role in the final clinical diagnosis in abnormal cases.
Require a biopsy confirmation of category D (HSIL/cancer) challenges, but not category C (LSIL) challenges	Four of seventeen organizations favored retaining the biopsy confirmation on LSIL while four other organizations did not support this. Nine organizations did not comment on this recommendation. This decision constitutes the practice of medicine and therefore, it is the patient's physician who should make the final determination based on patient-specific clinical knowledge and history.

Frequently Asked Questions
(Withdrawal of CMS 2252P – Cytology Proficiency Testing Notice of Proposed Rule Making)

1. Why was the Cytology Proficiency Testing (PT) Notice of Proposed Rule Making (NPRM) withdrawn from the Unified Agenda?

A cytology workgroup was formed under the auspices of the Secretary's Clinical Laboratory Improvement Advisory Committee (CLIAC) to review the Cytology PT regulations. This workgroup developed 16 recommendations that were submitted to CLIAC. The CLIAC reviewed these recommendations and requested that the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC) develop a NPRM that would incorporate all of these recommendations. The NPRM was published in 2009 and CMS received a total of 690 letters from the cytology community and public that contained 6,503 individual comments.

Analysis of the comments revealed a lack of consensus and agreement among the responses to the 16 CLIAC recommendations. The majority of the comments were in conflict with the current Clinical Laboratory Improvement Amendments of 1988 (CLIA) statute because they recommended the replacement of the Cytology PT program with a continuing education program.

2. How many of the workgroup recommendations were accepted and how will they be implemented by CMS?

CMS has identified 10 of the original recommendations that will be implemented through guidance. The remaining 6 recommendations will not be implemented.

3. Why are continuing education programs excluded from fulfilling the requirement for PT in cytology?

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

Current continuing education programs in cytology do not meet the statutory requirements for the number and frequency of slides to be tested, and participation in these programs is entirely voluntary. Evaluation of the results performed by these continuing education programs is not sufficient to satisfy the CLIA Statute and regulations. Continuing Educational (CE) challenges are initially performed independently by each individual but a consensus result is provided on behalf of the entire laboratory. CE credit is given to all participants even when the challenge has not been successfully identified. As a result, poor performers are not identified.

Replacing the current requirements with a continuing education program would introduce redundancy and risk to the CLIA program. The current system already includes continuing education tailored to individual areas of failure. This proposed change would remove CMS'ability to oversee, monitor and enforce quality testing.

The table below compares the three cytology continuing education programs that are currently available.

Organization	Educational Component	Annual Laboratory Comparison	Individual Score
College of American Pathologists (CAP)	5 slides sent 2 times a year 2 online cases 2 times a year	Yes Yes	CME credit earned just for participation. Correct answer not necessary
American Society of Clinical Pathologists (ASCP)	4 slides sent three times a year	Yes	CME credit earned just for participation. Correct answer not necessary
American Society of Cytopathology (ASC)	Case studies, educational CD-ROM, monthly cyto-teleconferences, annual scientific meetings, journal club	No	Yes Estimated 800 attendees

4. Some cytology professional organizations have expressed their concern with the CMS decision to withdraw the cytology PT NPRM. They have concerns about the psychometric validity of the test. There have been published articles claiming to bolster these concerns. How does CMS address these concerns?

Psychometric Validity of the Test

CMS is concerned that some organizations are confused about proficiency testing. PT is not a competency test – it is used to verify the accuracy and reliability of testing. Reviews of proficiency test reports by the laboratory staff and director alert them to areas of testing that are not performing as expected, as well as indicating subtle shifts and trends that would, over time, affect patient results.

Psychometrics is the measurement of psychological variables such as intelligence, aptitude, and emotional disturbance and it is used for the statistical design of psychological tests and measures.

5. **Some cytology organizations have concerns about the lack of demonstrated robust clinical validation of the test slides**.

   There is a 6 year history of clinical validation of the test slides. In the 6 years that Pathologists and cytotechnologists have participated in the PT process, the rates of individuals who scored less than 90% have decreased significantly. Individuals who do not score at least 90% on a PT event are required to obtain continuing education. This continuing education may be the reason for improvement in the scores of all test participants.

6. **Will there be changes to the current appeals process?**

   Individuals will still be allowed to appeal test findings. Each of the 3 cytology PT programs have appeals processes in place that allow individuals who score less than 90% to have slides reviewed with the potential of a decision change from a score of less than 90% to one at 90% or higher.

   Furthermore, CMS feels that the appeals processes in place add to the robustness of the test slide validations as demonstrated by these statistics for 2010:

2010 Statistics:

Cytology Program (*10 slide test)	**# individuals tested**	**# individuals not scoring at least 90% or higher**	**Number of appeals**
State of Maryland	333	18	No appeals
American Society for Clinical Pathology	3178	105	3 Appeals and 3 Denials
College of American Pathologists	8559	254	21 Appeals and 14 Denials
Totals	12,070	377 (3%)	

*NOTE: Each test is comprised of 10 slides. 12,070 Individuals X 10 Slides per set = 120,700 slides examined as part of the initial test.

7. What type of guidance can CMS offer cytology laboratories and State Survey Agencies?

Cytology laboratories should continue to enroll in and successfully participate in the current cytology PT programs.

CMS will continue to work with the cytology organizations and monitor current quality initiatives such as the recent cooperative agreement awarded to the College of American Pathologists and the University of Michigan by the CDC. Under this agreement, CAP and the University of Michigan will examine all aspects of quality assurance practices in gynecologic cytopathology, including PT. CMS will attend this meeting and any others that address cytology issues on an ongoing basis and, when necessary, issue appropriate guidance or policies.