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

INFORMATIONAL SUPPLEMENT (2006)

Medicare, Medicaid, and CLIA Programs: Statutory and Regulatory Requirements Related to Laboratory Participation in Proficiency Testing and the Availability of Proficiency Testing Programs in Cytology

A. Introduction

The Centers for Medicare and Medicaid Services (CMS) or its approved accreditation organizations routinely survey laboratories performing cytology testing biennially. In addition to these surveys, the Clinical Laboratory Improvement Amendment (CLIA) statute requires that individuals performing cytology examinations be tested for their proficiency. Specifically, at Section 353(f)(4)(B)(iv) of the statute, the Secretary is required to perform a "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 current requirements for cytology proficiency testing are found in the CLIA regulations at 42 CFR Part 493, published February 28, 1992 and effective, September 1,1992.

Implementation of cytology proficiency testing has taken an extended period of time due to the absence of qualified national proficiency testing organizations, an insufficient number of referenced cytology testing materials, and significant technical difficulties.

There are three CMS-approved cytology proficiency testing programs. for 2006.

The approval of national cytology PT programs demonstrates CMS' continued dedication and commitment to improve one of the principal issues on women's health; that is, accurate and reliable Pap smear results. With the initiation of cytology proficiency testing on a national basis, CMS has implemented every provision of the CLIA law.

We will continue to add inquiries to this Informational Supplement, as necessary.

B. Background and History

B1. What is "CLIA"?

"CLIA" is the acronym used to refer to the Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578. CLIA regulates facilities that perform tests for health purposes on human specimens. In an effort to establish quality standards for all such laboratories and to ensure the accuracy and reliability of patient test results, the Congress decided that virtually all laboratories would be subject to CLIA. Under that authority laboratories must apply for and maintain an appropriate CLIA certificate in order to operate. Certificates are issued upon submission of an acceptable application and payment of the applicable certificate fee.

B2. Does CLIA require proficiency testing for individuals who screen Pap smears?

Yes. Congress explicitly provided for 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,"

Under this authority, CMS set forth final regulations on, among other things, cytology proficiency testing in the February 28, 1992 *Federal Register.* Following a comment period, these regulations became effective on September 1, 1992. These cytology proficiency testing requirements remain in effect and the affected individuals include cytotechnologists and pathologists.

B3. Why was the Clinical Laboratory improvement Act of 1967 (CLIA'67) revised – especially in regards to cytology?

The impetus behind the promulgation of CLIA was Congress' realization that there were significant problems in, among other things, enforcing compliance with CLIA'67 standards, ineffective proficiency testing, inadequate oversight for cytology testing, and the proliferation of unregulated laboratories.

CLIA'67 did not regulate all laboratories performing testing on gynecologic specimens. It did not provide for a limit on the number of Pap smears that could be examined by an individual in a 24-hour period. Consequently, a number of "Pap Mills" appeared that produced Pap smear results that were erroneous and life threatening. (There is a direct relationship between a cytology test finding and the diagnosis of a specific clinical disease. Gynecologic cytology specimens are frequently the first indication of cervical cancer.) Congress promulgated CLIA to resolve these and other concerns.

The CMS has been delegated the responsibility for administering the CLIA program. Currently, there are 3,500 laboratories certified in the subspecialty area of cytology, which includes gynecologic and non-gynecologic cytology

testing. Only those laboratories that conduct **gynecologic** testing are presently subject to cytology PT and they number approximately 2400.

B4. Are these cytology proficiency testing regulations new?

No. CLIA included statutory requirements for cytology proficiency testing when it was signed into law by President Reagan on October 31, 1988. The regulations implementing these statutory requirements were published in the *Federal Register* on February 28, 1992 and became effective on September 1, 1992. They are still in effect.

B5. Will the current cytology PT regulations ever be changed?

CMS and CDC, based on concerns expressed by the cytology laboratory community, are convening the Secretary of HHS' technical advisory committee, Clinical Laboratory Improvement Advisory Committee (CLIAC) work group, to consider changes to the regulations. The work group will be comprised of pathologists, cytotechnologists and government agency representatives who are subject matter experts and who will provide their expertise, data and experiential information to CMS and CDC. Based on this input, the subsequent recommendations of CLIAC to HHS and the data from the initial year of cytology PT, CDC and CMS will develop a Notice of Proposed Rulemaking (NPRM) to revise the cytology PT regulations.

C. CMS Approved Proficiency Testing Program Contacts for 2006

C1. What are the names of the approved cytology proficiency testing programs for 2006, how can I contact them, and where can I find information about them?

The names and contact information of the 3 CMS-approved cytology proficiency testing programs in 2006 are listed below:

1) State of Maryland Cytology Proficiency Testing Program
Maryland Department of Health and Mental Hygiene
Office of Health Care Quality – Laboratory Care
Spring Grove Hospital – Bland Bryant Building
55 Wade Avenue
Catonsville, Maryland 21228
Phone Number: (410)402-8028

2). Midwest Institute for Medical Education, Inc.
9550 Zionsville Road
Suite 110
Indianapolis, Indiana 46268
Phone Numbers: (317)876-4169, (800)575-2342
www.mimeonline.com, www.cytoquest.com, or **www.mimeinc.org/**

3). College of American Pathologists
325 Waukegan Road
Northfield, Illinois 60093-2750
Phone number: 1-800-323-4040
www.cap.org

D. Regulatory Requirements

D1. Who must take this proficiency test?

All individuals (physicians and cytotechnologists) who examine or interpret gynecologic cytology specimens (Pap smears) must enroll and participate in one testing event annually.

D2. If I only screen non-gynecologic cytology specimens, must I participate in this cytology proficiency test?

At the present time, only those individuals who examine gynecologic specimens must enroll and participate.

D3. What is considered a passing score on a proficiency test?

A passing score on all cytology proficiency tests is 90%. Once you have achieved a passing score for a calendar year, you have met your cytology PT obligation for that year.

D4. Will my proficiency test be unannounced or will I know in advance when to anticipate my proficiency test?

Under most circumstances, your Cytology proficiency test will be an announced event. Proficiency testing programs are required to notify laboratories at least 30 days prior to testing for announced proficiency testing. Approved programs must also have the capability of providing unannounced proficiency testing when requested by CMS.

D5. What happens if I miss the testing event in my laboratory?

If a test is missed due to an unexcused absence, the individual receives a test score of “0”.

If the test is missed for an excused absence, laboratories must contact the proficiency testing program to determine when and where the make-up examination will take place. Examples of “excused” absences include prior scheduled, approved leave, natural disasters, hospitalization, death in the family, etc.

D6. If I fail a proficiency test, will I have to stop screening Pap smears?

Individuals have multiple opportunities to take the proficiency test and any retest, if necessary. Initially, individuals are required to take a 10–slide, test within 2 hours, provided in sets.

- If an individual passes the first 10-slide test, he/she has successfully participated for the year and need not be tested again until the following year.

- If the individual fails the first 10-slide test, he/she must take a 10-slide retest within 45 days after notification of test failure.
- When an individual passes the second 10-slide test, he/she has successfully participated for the year and need not be tested again until the following year.
    - If the individual fails the second 10-slide retest:
        - The individual must obtain documented, remedial training in the area of test failure, which will be noted on the test results letter.
        - All Pap smears screened by the individual subsequent to the notification of failure must be reexamined, and
        - The individual must successfully participate in a 20-slide proficiency test within 4 hours.
- If the individual fails the third 20-slide test:
    - He/she must cease examining Pap smears immediately upon notification of failure;
    - The individual must obtain at least 35 hours of documented, formally structured, continuing education in diagnostic Cytopathology which focuses upon the examination of gynecologic cytology; and
    - The individual must successfully participate in another 20-slide proficiency test.
    - This final cycle would continue until the individual successfully participates in another 20-slide proficiency test.

Please see Attachment A at the end of this document for an overview of the testing process.

D7. How much time will I have to take a 10-slide test? A 20-slide test?

Each individual (physician or cytotechnologist) will be allowed a total of 2 hours to complete a 10-slide test and 4 hours to complete a 20-slide test.

D8. How will cytotechnologists and physicians be tested?

Every individual will be tested independently. Each cytotechnologist will receive a test set of referenced slides, examine each slide, identify the diagnostic areas in the same manner as they do patient specimens (by dot or circle), and write their diagnosis on their score sheet. Physicians who perform any primary screening (screen slides which have not been pre-screened by a cytotechnologists) must be tested in the same manner as a cytotechnologist. Physicians who examine slides after they are pre-screened by a cytotechnologist may choose to screen a set of test slides that have been previously screened and dotted by cytotechnologists or they may examine a set of slides that have not been previously screened and dotted. If the physician chooses to examine a pre-screened set, the cytotechnologist's diagnosis will accompany the test set.

D9. Who will receive a copy of my test results and will they be kept confidential?

CMS will receive all testing results from each CMS-approved Proficiency Testing Program. The laboratory director of your laboratory will receive a summary of the test results for all the participants in the laboratory within fifteen days after the proficiency testing event. The notification will include whether each individual passed or failed the test, their score, and, if appropriate, the area of failure. In addition, each participant will receive a letter with his/her individual test results, including whether he/she passed or failed the test, the score, and, if appropriate, the area of failure. If an individual works at more than one laboratory, a copy of the individual's test results will be sent to each laboratory director where the individual is employed.

CMS will make every attempt to maintain the confidentiality of the test scores. See Section H, Confidentiality, of this document for further details on the recordkeeping system.

D10. How are the slides referenced by the proficiency testing program?

All slide preparations must have 100% consensus agreement among a minimum of three physicians certified in anatomic pathology. Additionally, non-negative slide preparations must be confirmed by tissue biopsy, either by comparison of the reported biopsy results or reevaluation of biopsy slide material by a physician certified in anatomic pathology.

D11. Will the test sets be comparable?

Yes, each of the test sets, whether 10-slide or 20-slide, will be comparable. Each test set must include at least one slide representative of each of the diagnostic categories listed in the CLIA regulations. Test sets must also be equivalent to each other. Several times a year, each slide must be evaluated for staining, breakage, and diagnostic agreement by the CMS-approved Proficiency Testing Program.

D12. What diagnostic categories are used in the test sets?

The diagnostic categories for Pap smears in the test sets include at least one slide from each of the following categories:

- Unsatisfactory samples (i.e., scant cellularity, air drying, and obscuring material (blood, inflammatory cells or lubricant));
- Normal or Benign Changes (i.e., 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 – includes: Cellular changes associated with HPV, Mild Dysplasia/CIN-1,
- High Grade Squamous Intraepithelial Lesion and Carcinoma – includes moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in-situ/CIN-3, Squamous Cell Carcinoma, Adenocarcinoma and other malignant neoplasms.

NOTE: These diagnostic categories are consistent with those listed in the 2001 Bethesda Conference report.

D13. Are cytotechnologists and physicians scored the same way?

No. Cytotechnologists and physicians are not scored the same way. Physicians are scored more stringently because they are ultimately responsible for all diagnoses made in the laboratory.

For the 10-Slide Test, the scoring grids are listed below:

Cytotechnologists:

	Participant Diagnosis			
	A	B	C	D
Correct Diagnosis				
A	10	0	**5**	**5**
B	5	10	**5**	**5**
C	5	0	10	**10**
D	0	-5	**10**	10

Technical Supervisors:

	Participant Diagnosis			
	A	B	C	D
Correct Diagnosis				
A	10	0	**0**	**0**
B	5	10	**0**	**0**
C	5	0	10	**5**
D	0	-5	**5**	10

The highlighted areas on the grids demonstrate those diagnostic categories where the cytotechnologist's and technical supervisor's score would differ.

To determine the final score of a testing event, each slide is given a numerical value, as specified on the scoring grids. Cytotechnologists receive a score based on the "Cytotechnologist Grid" and the Technical Supervisor's score is based on the "Technical Supervisor Grid". The Cytotechnologist's and Technical Supervisor's diagnosis can be found along the X-axis. The Proficiency Testing Program diagnosis, based upon 100% consensus of at least 3 physicians board certified in anatomic pathology and tissue biopsy confirmation of cases in the premalignant and malignant categories can be found along the Y-axis. Both Cytotechnologists and Technical Supervisors begin with a score of zero. Points

are accumulated based on the accuracy of their diagnosis to the diagnosis specified by the Proficiency Testing Program.

D14. If I miss a high-grade lesion or a cancer, will I pass the test?

No. Individuals (cytotechnologists or physicians) will not obtain a passing score if a slide determined by the proficiency testing program to exhibit a high-grade lesion or cancer is identified as "Normal or Benign Changes" during the testing event.

D15. What would happen in a laboratory if the cytotechnologist passes the test and the technical supervisor fails the test?

In this instance, the cytotechnologist would have completed their testing for that year under CLIA, and the technical supervisor will need to be retested as described in Question C6.

D16. May I enroll in another cytology proficiency testing program when one becomes available?

Individuals must remain in the CMS-approved cytology proficiency testing program for one calendar year. Participants will be provided with their own unique Proficiency Testing Registration Number. This number will be used to identify each individual's enrollment. After that time, individuals are welcome to participate in any CMS-approved program.

D17. Must I remain with the same PT program for re-testing if I fail my test(s)?

Individuals who fail a test must remain with their originally selected PT program for that calendar year to complete any necessary re-testing.

D20 Are the PT slides field validated?

For 2006 initial and subsequent testing sets for cytology PT are field-validated.

E. Enrollment and Testing

E1. What are the initial cytology proficiency testing enrollment requirements?

Beginning in 2005, every cytotechnologist and pathologist examining gynecologic cytology specimens must be enrolled in a CMS-approved Cytology Proficiency Testing Program and take a proficiency test annually. CMS strongly recommends that all cytology laboratory testing sites enroll in a CMS-approved Cytology Proficiency Testing Program as soon as possible each year to assure they receive their preferred PT provider and are assigned their requested testing date(s).

E2. What are the dates by which laboratories and individuals must be enrolled and tested?

Laboratories must enroll and individuals tested in a CMS-approved cytology proficiency testing program for each calendar year. Laboratories must meet the regulatory deadline for enrollment and participation in an annual testing event, which may include retesting where necessary. Initial testing must be completed by December 31 of the testing year in order to comply with regulatory provisions.

Subsequent re-testing or testing for special circumstances must be completed by April 2 of the following year and must follow the regulatory protocol, timeframes and remedial actions. CMS strongly encourages laboratories to enroll in one of the CMS-approved Cytology Proficiency Testing programs as soon as possible each year.

E3. Where do I take the Cytology proficiency test?

Proficiency testing may occur on-site in your laboratory or at an alternate site designated by your PT program.

Contact the Proficiency Testing Program in which you have enrolled for specific requirements, testing locations and procedures.

CMS will work with the PT programs to determine cost-effective and timely means to accomplish certain re-testing that is currently conducted off-site.

E4. I screen slides on the night shift (4:00 PM - 12:00am). When will I be tested?

To the extent practicable, testing should take place under your normal working conditions. Laboratories should contact their Proficiency Testing Program for specific information on this issue.

E5. If I examine only liquid based specimens at my laboratory, will I be required to take my proficiency testing with conventional Pap smear?

A CMS-approved Proficiency Testing Program will offer testing materials that are prepared in a similar manner to the patient specimens routinely examined.

Contact the CMS-approved Proficiency Testing Program in which you have enrolled for specific requirements.

E6. What happens if I work at more than one laboratory? Must I take the test at each laboratory where I am employed?

No. If you work at more than one laboratory, you will be required to select one laboratory, in conjunction with the respective laboratory directors, prior to the first testing event, as the primary site where you will be tested. All laboratory directors, however, must ensure that you participate in the required annual testing in order to meet their regulatory duties and these directors will also receive copies of your test results.

E7. Will locum tenens and Temporary Employees in laboratories also need to be tested?

Yes. Any individual, including a locum tenens or temporary employee, who examines gynecologic cytology specimens must participate in annual testing and score at least 90%.

E8. Who will proctor the proficiency test?

The CMS-approved Proficiency Testing Program will provide specific guidance and requirements for individuals who will proctor the proficiency test.

Contact the CMS-approved Proficiency Testing Program in which you have enrolled for specific information on proctors.

E9. What should I do if I get a test set with a broken slide?

The test proctor should be notified immediately upon discovery of a broken slide. Proctors have specific protocols to follow when this occurs. The laboratory will be held financially responsible for any slides broken during testing.

E10. If the laboratory hires a new employee just prior to the scheduled proficiency test, can this individual also take the scheduled proficiency test?

Please call the Proficiency Testing Program for specific procedures.

E11. If I fail a test or retest, can I take the retest in my laboratory?

The Proficiency Testing program will have options for retesting. Please contact the program in which you are enrolled for additional information. See # E3.

E12. How many individuals can be tested with one test set?

The Proficiency Testing Program will determine how many test sets are needed to test all individuals in the laboratory.

E13. Who in the laboratory can reexamine the Pap smears that were read by someone who has failed the first retest?

A qualified individual who has obtained a passing score in the current year is eligible to reexamine gynecologic cytology specimens after someone has failed.

E14. What should I do if I see someone sharing test results during the test?

Discussion during and after the course of testing is prohibited. Every individual who participates in a proficiency test must sign an attestation statement that he/she has examined the test set slides independently and did not share his/her results either during or after testing. If a participant observes results sharing, the proctor must be notified of the situation. The proctor will contact the proficiency testing program immediately. The program will notify CMS. CMS may initiate further investigation of these laboratories.

E15. Will instructors, researchers, and individuals who perform internal quality control or quality assessment functions be required to participate in cytology proficiency testing?

Those individuals (instructors and researchers) who do not examine gynecologic patient specimens for the purpose of making a diagnosis or providing any information to be used toward a diagnosis are not required to participate in gynecologic cytology proficiency testing. However, those individuals who review patient specimens during the course of their jobs (internal quality control/quality assessment) where a diagnosis might be changed because of their review must participate in cytology proficiency testing.

E16. Are newly certified ASCP cytotechnologists and board certified pathologists subject to cytology PT?

New graduates of schools of cytotechnology, who have taken the certification examination administered by the American Society for Clinical Pathology (ASCP) Board of Registry (BOR) and obtained a passing score, have demonstrated an initial competency level in the examination of cervical cytology and therefore, will not be monitored for cytology PT in the calendar year in which they passed their examination.

New graduates of schools of cytotechnology who are employed and who have not obtained a passing score on the BOR examination must participate in cytology PT each calendar year.

Anatomic pathologists who are newly certified by the American Board of Pathology or the American Osteopathic Board of Pathology have demonstrated an initial level of competency by passing this examination and therefore, will not

be monitored for cytology PT by CMS for the calendar year in which they became certified in anatomic pathology.

Cytopathologists who receive the added qualification in cytopathology from the American Board of Pathology or the American Osteopathic Board of Pathology have demonstrated competency interpreting cervical cytology by passing this examination and therefore, will not be subject to cytology PT for the calendar year in which they became board certified in cytopathology.

E17. Are residents and fellows subject to cytology PT?

Anatomic pathology residents are not required to participate in a CMS approved cytology PT program because they are under constant supervision of fully licensed physicians and are not responsible for the final diagnosis of cervical cytology specimens.

Anatomic pathology fellows whose responsibilities in the cytology laboratory include the examination and final diagnosis of gynecologic specimens must enroll and participate in cytology PT each calendar year.

F. Appeals

F1. Is there a procedure to be followed when an individual disagrees or questions their test results?

The proficiency testing program should be contacted directly to discuss all disagreements or questions regarding the testing process. All approved programs must have a scientifically defensible process for determining the correct result for each challenge offered. That is, each PT program must have a process to resolve technical, administrative, and scientific problems about program operations.

G. Enforcement

G1. Will CMS monitor the participation of individuals in a CMS-approved Cytology Proficiency Testing Program?

Yes. CMS will closely monitor the enrollment and participation of cytotechnologists and pathologists in CMS-Approved Cytology Proficiency Testing Programs.

G2. What happens if I fail my proficiency test and my laboratory does not take the appropriate corrective actions to help me pass the retest?

If the laboratory where you are tested does not ensure that you participate in an annual testing event, are retested timely or the laboratory fails to take the appropriate remedial actions as described in the regulatory protocol and in Question D6, CMS will initiate sanctions against the laboratory including Civil Money Penalty (CMP), limit the laboratory's CLIA certificate for cytology, and if applicable, suspend the laboratory's Medicare approval for cytology. CMS suggests that laboratory management be made aware of the consequences of the laboratory's failure to be enrolled and tested in a CMS-Approved Cytology Proficiency Testing Program, and take appropriate corrective actions in the event of test failure.

H. Confidentiality

H1 Will CMS protect the confidentiality of an individual's test results?

Yes.

CMS will generally not have individuals' test results during the 2005 and 2006 testing cycles as CMS has adopted an educational approach to national implementation of cytology PT during these years. At this time CMS plans to request only reports on individual test results that use code numbers in lieu of individual names. The relevant laboratories (but not names of individuals) will be identified in these reports to CMS. Individually-identifiable information may be requested by CMS in the event of a survey or complaint investigation if there is a question regarding the laboratory's compliance with the proficiency testing requirements. Otherwise, CMS will not maintain individually identifiable information on cytology PT testing during the 2005-2006 educational phase.

At the end of 2006 CMS will review the national progress in cytology proficiency testing and reassess the extent to which CMS must maintain individually-identifiable information in a data base. To the extent that individually-identifiable information is maintained in the future, the confidentiality protections published in the Federal Register and described below would be applicable.

Any individually identifiable agency records regarding the registration, participation and outcome of annual cytology proficiency testing events for cytotechnologists and physicians who evaluate gynecologic cytology specimens would be maintained in CMS' "Cytology Personnel Record System (CYPERS)," a defined system of records (SOR).

CMS may disclose individually identifiable information from the CYPERS SOR in response to a request from the individual who took the test. To the extent allowed by law, CMS will limit all other disclosures to outside parties in accordance with the routine uses established in the CYPERS SOR notice. See 70 FR 2637.

In response to Freedom of Information Act (FOIA) requests for CLIA proficiency testing results, CMS will, to the extent allowed by Federal law, assert applicable FOIA exemptions to protect any exempt records or individual information from release. The FOIA exemptions are set forth in Department of Health & Human Services Freedom of Information regulations at 45 CFR Part 5 Subpart F.

Our mission is to ensure that all individuals subject to the cytology PT requirements are registered, tested and achieve a passing score; to use the testing process and results to promote education and skills development so as to ensure proficiency; and in other ways to faithfully and effectively implement the proficiency testing requirements of the CLIA statute.

This mission is best served by ensuring confidentiality protections whereby cytology PT participants may take part in a candid evaluation of their clinical

practices and skills. As CMS recognized that public release of individual test results could create a chilling effect that would interfere with the above purpose, CMS established very limited uses for the information in CYPERS (see the Privacy Act "system of records" (SOR) notice that was published in the Federal Register on January 14, 2005. See, 70 FR 2637).

Under this SOR notice, release of any individually-identifiable information is restricted to:

(a) releases for which the individual has granted consent, or
(b) "routine uses" (described in the federal register) "which are compatible with the purposes for which the information was collected." *(Emphasis added).*

Under the limited routine uses, CMS may release the information to a Member of Congress or to a Congressional staff member in response to an inquiry made at the written request of the constituent about whom the record is maintained (i.e. only at the written request of the tested individual). Alternatively, CMS may release the information without consent of the tested individual to the Department of Justice, court or adjudicatory body when:

- The US Government, the Agency, or the employees or agents (i.e., contractors) of the US Government or the agency are a party to litigation or has an interest in such litigation, and by careful review, CMS determines that the records are both relevant and necessary to the litigation;

In terms of test results themselves, CMS regards the results as final only after the annual testing cycle is complete. Individuals have up to four opportunities to achieve a passing score in a testing cycle.

H2 What is an example of litigation in which CMS might release information about an individual's test results?

Example: if a laboratory contested in court an enforcement action undertaken by CMS for a laboratory's failure to ensure that affected individuals took the proficiency test(s) (and/or failed to follow the regulatory protocols in the event a passing score was not achieved), and if CMS determined that withholding the individual's test result would be detrimental to the agency's position in the case, then CMS might release the confidential information to the court.

H3 What has been the State of Maryland's experience regard to release of personally-identifiable information from cytology proficiency testing?

The State of Maryland reports that, in ten years of individual proficiency testing, no individually-identifiable test result information has been released in a malpractice suit, or in any other situation, other than to the tested individual and the laboratory (or laboratories) in which the tested individual was employed. **Each state has different laws governing state programs, of course, and we**

advise any reader interested in the Maryland proficiency testing program to contact the appropriate Maryland officials for more information.

I. Fees

I1. What is the enrollment fee to participate in this proficiency testing program?

The proficiency testing program determines all relevant charges for laboratory participation based on their operational costs as a private non-profit organization or a Federal or State agency or entity acting as a designated agent for the State.

I2. If I fail the test in my laboratory and have to travel to be retested, who will pay the expenses?

Financial obligations for enrollment and testing are the responsibility of the laboratory. Retesting is subject to individual policies of the PT program.

CMS will continue to work with the PT providers to develop timely and cost-effective means to accomplish re-testing that is currently conducted off-site.

J. Overview of Cytology Proficiency Testing (PT)

J1. In summary, what must laboratories and individuals do each year in order to comply with the cytology proficiency testing regulations?

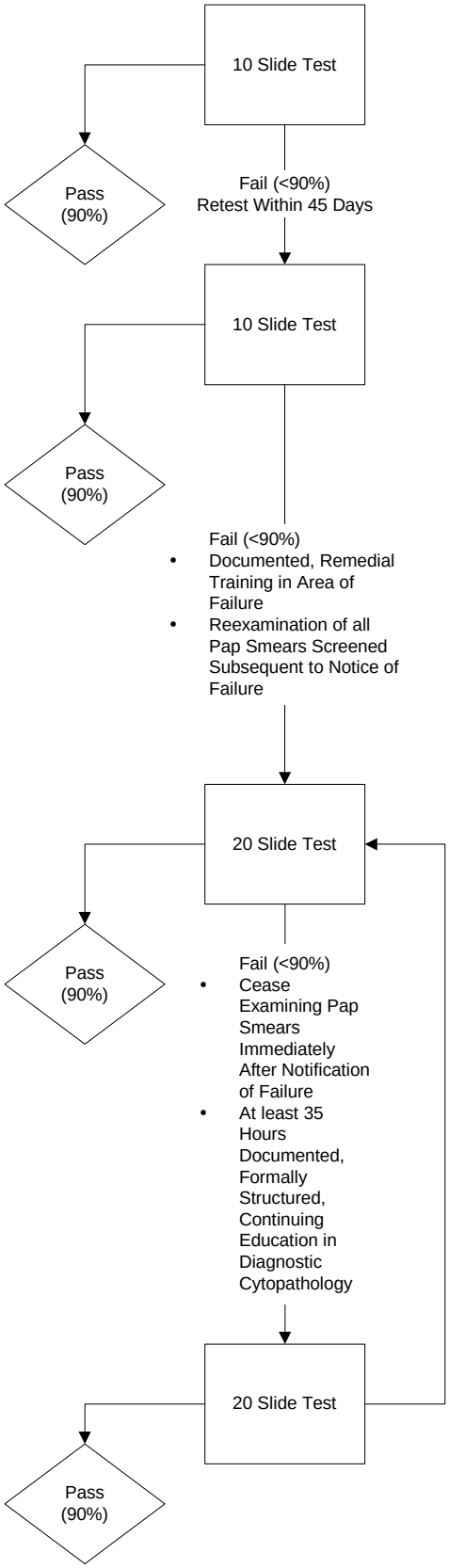
- Laboratories must enroll each site that is performing gynecologic cytology testing and must ensure that each cytotechnologist and pathologist examining or interpreting gynecologic cytology preparations is enrolled and tested according to the regulatory protocol within the specified timeframes by a CMS-approved Cytology PT program each calendar year.
- Cytotechnologists and pathologists who are not routinely employed in a laboratory must contact a CMS-approved Cytology PT Program directly to enroll or CMS for further information..
- Cytotechnologists and pathologists must score at least 90% to pass cytology PT for the calendar year..
- Laboratories must ensure that individuals who fail a test are retested within the regulatory timeframes.
- Laboratories must take the appropriate remedial actions, following the regulatory protocol, for any individuals who fail a cytology PT event.
- For further information, visit the CMS/CLIA web site at: **www.cms.hhs.gov/clia**.

NOTE: See Attachment A on Page 21 for a flow chart of the cytology PT regulatory process.

K. Attachment A – Overview Testing Process

ATTACHMENT A

Overview of Testing Process for Individuals Examining Pap Smears



L. National Testing Results for 2005

L1. What are the national testing results for 2005?

Preliminary results are as follows:

% Passing	1st test	2nd test	3rd test
Cytotechnologists	93%	96%	100%
*Primary MD	66%	66%	71%
Secondary MD	90%	90%	86%

* Reads slides unaided by a cytotechnologist.

L2. Do the 2005 national cytology PT results compare to Maryland's, a state that has conducted cytology PT for a number of years, and to other cytology educational programs?

Maryland's results from their initial year of testing are comparable to those of CMS. CAP published data from their educational cytology PT program reflecting similar findings as well.