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Charlene Frizzera
Acting Administrator and Chief Operating Officer
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2252-P
P.O. Box 8016
Baltimore, MD 21244-1850

Dear Acting Administrator Frizzera:

On behalf of the American Society for Clinical Pathology, I write to provide comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule amending the Clinical Laboratory Improvement Amendments (CLIA) Cytology Proficiency Testing (PT) Program [74 FR 3264]. ASCP, like our colleagues in the Cytology Proficiency Testing Improvement Coalition, cannot support this proposed rule in its current form as it is a costly, unreasonable, and unjustifiable burden on cytology laboratories and professionals.

The ASCP is a nonprofit medical specialty society representing 130,000 members. Our members are board certified pathologists, other physicians, clinical scientists, certified medical technologists and technicians, cytotechnologists, and educators. ASCP is one of our nation's largest medical specialty societies and is the world's largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

I. OVERVIEW

ASCP appreciates the efforts of the Centers for Medicare and Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC) to revise the current cytology proficiency testing regulations. As a non-profit organization dedicated to public health, ASCP supports the implementation of a modernized cytology PT regulation that is both beneficial to the public health and fair to the cytotechnologists and pathologists who screen and/or interpret cytological preparations. That said, ASCP and many of our colleagues in pathology believe that the proposed cytology PT program suffers from the same fundamental scientific and technical flaws that render the current Cytology PT program an unsound measure of competency. The result is that the proposed rule does not change the fact that the current CLIA cytology PT program forces cytology laboratories, pathologists, and cytotechnologists to engage in a costly, onerous endeavor with no clear or tangible benefits to patients.

Additionally, ASCP and our colleagues in the Cytology Proficiency Testing Improvement Coalition are calling for wholesale changes to this rule that would convert the current CLIA PT program into an education-based assessment PT program tasking the laboratory director with the responsibility to ensure that individuals involved in screening and/or interpreting cytology specimens are competent. It is our view that marrying professional credentialing or board examinations with an annual continuing (medical) education program that holds the laboratory director responsible for ensuring competency would be far better than the Department's proposed (and current) cytology PT program.

Moreover, such a program is better aligned with the Secretary's higher statutory responsibility to "establish national standards...[that] assure consistent performance by laboratories of valid and reliable cytological services" than is the current or proposed rule [See Section 353(f)(4)(A) of the Public Health Act]. From our perspective, the CLIA statute creates a moral obligation for the Department of Health and Human Services to pursue a program that better ensures quality.

The exact form of the PT program is of lesser concern from a statutory perspective. The statutory mandates on CMS specific to cytology PT are amorphous, granting CMS *significant* flexibility to create a cytology PT program. The statutory requirements for cytology PT, identified in Section 353(f)(4)(B)(iv), are simple, requiring CMS to include (as part of the PT program):

"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."

This language says little about the shape or structure of Cytology PT. Notably, it is flexible enough to allow CMS to authorize an education-based assessment program. Moreover, it does not preclude the use of certification or board examinations as a component part of an assessment program. Allowing for an innovative education/assessment program fits squarely within the rubric of the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

Given the scientific and technical challenges of the Department's pure PT program, e.g. to achieve validity the Cytology PT program may need approximately 100 or more test items (which would take at least 10 hours to administer), CMS must rethink the structure of the current and proposed cytology PT program.

Because the proposed rule falls far short of providing stakeholders the regulatory flexibility necessary to establish a rational, worthwhile, and less burdensome cytology PT program, ASCP urges CMS to reexamine the CLIA statute, working with the HHS Office of General Counsel, to identify ways in which CMS can revise its plans for cytology PT with enhanced

flexibility for those involved in screening and/or interpreting cytological preparations. We believe this will help clear the way for CMS to devise a more appropriate cytology PT program, such as the one we, and our colleagues in the Cytology Proficiency Testing Improvement Coalition, are re-proposing via the comment process on this rule today.

II. PRIMARY SUGGESTIONS AND CONCERNS

With regard to the specific proposals outlined in the January 16th proposed rule, ASCP has a number of suggestions and concerns. Chief among these are the proposed grading scheme, the need for an education-based assessment program, and the implementation of the two-year testing schedule. The following comments outline specific concerns about particular aspects of the proposed rule. ASCP has not specifically responded to each of the issues or questions posed in the rule by CMS. CMS should not assume that the lack of a direct response to these queries indicates our approval or lack of concerns thereof.

A. PROPOSED GRADING SCHEME

First and foremost, ASCP strongly urges CMS to utilize a unified grading scheme, such as the grading scheme proposed by ASCP representative Thomas Bonfiglio, MD, FASCP (See below) at the March 28, 2006 meeting of the CLIAC Cytology Work Group Meeting. This grading scheme was later adopted by CLIAC during its June 20-21, 2006 meeting. According to the proposed rule, the American Society for Cytotechnology also supports a unified grading scheme.

We believe that a unified scoring scheme is imperative for reasons of fairness and scientific validity. Cytopathologists and cytotechnologists are both expected to have the same understanding of morphologic criteria. Moreover, though the pathologist is ultimately responsible for reporting results, the cytotechnologist is accountable for the initial location, interpretation, and marking of representative cells.

ASCP Proposed Unified Grading Scheme for Pathologists and Cytotechnologists - 20 Slide Test				
Correct Response	Examinee Response			
	A – UNSAT	B – NEGATIVE	C – LSIL	D – HSIL
A – UNSAT	5	0	0	0
B - NEGATIVE	2.5	5	0	0
C – LSIL	0	0	5	5
D – HSIL	0	-5	5	5

ASCP believes that whatever scoring scheme CMS adopts in its final rule, it must be reflective of clinical practice. If in clinical practice there is no differentiation with regard to the treatment or follow-up between two possible interpretations of a patient specimen then the scoring scheme must reflect this reality. For example, ASCP believes that if a pathologist responds that an HSIL cytology challenge is LSIL, or vice versa, such a response should not

count negatively against their score, since under the Bethesda System for Reporting Cervical Cytology patient cases of LSILs and HSILs are treated with the same follow up: colposcopy.

We note that the recent ASCCP clinical guidelines for managing patients with LSIL vary for differing age groups. Under the current guidelines for adolescents (women under 20), an adolescent who receives an interpretation of LSIL is simply followed up with a repeat Pap on an annual basis due to the high probability of regression or immunologic clearance of this non-progressive/non-oncogenic diagnostic entity. Therefore, should the clinical history for a PT test indicate the patient is under 20 and the target diagnosis is LSIL, then the PT test should not penalize the individual for rendering a diagnosis of NEGATIVE or LSIL for the adolescent patient population.

The proposed ASCP grading scheme is congruent with the “real world” clinical management paradigm, with the exception of adolescent women. Therefore, CMS should either: 1) not test the individual on a target diagnosis of LSIL provided the clinical history indicates the individual is under the age of 20, or 2) if CMS chooses to test under the parameters illustrated above, it should make an exception to the ASCP proposed grading system and not penalize the individual for rendering an interpretation of NEGATIVE or LSIL when calculating the final score of the PT participant. We cannot emphasize enough that we believe a unified grading scheme is the only grading scheme that comes close to replicating current clinical practice. To do otherwise is unfair and would not be based on sound public policy rationale.

ASCP supports elimination of the automatic failure penalty, the highly punitive deduction for identifying an HSIL or cancer as a normal or benign change. Clearly a penalty is appropriate for misidentification, but the current penalty for such a response is excessive.

B. ESTABLISHING AN EDUCATIONAL REQUIREMENT

In its current and proposed forms, CMS’ cytology PT program suffers from serious scientific and technical deficiencies. While many of the changes in this proposed rule attempt to address these deficiencies, they remain significant concerns that prevent this rule from truly providing patients with the assurances they deserve that cytology professionals are competent. The number of challenges necessary for a valid assessment of competence is far higher than the number currently required or proposed. At the same time, requiring program participants to review significantly more challenges than proposed in this rule is unfeasible for laboratories and cytology professionals, exceptionally costly, and not guaranteed to provide an accurate assessment of competency.

The most cost effective way for CMS to address these problems and to meet its statutory directive “to assure consistent performance of valid and reliable cytological services” [See Public Health Law Sec. 353(f)(4)(A)] would be to require individuals engaged in the screening and/or interpreting of gynecologic cytology specimens to enroll in a program that incorporates continuing (medical) education and competency assessment. Program participants should be able to utilize competency examinations, like those provided by nationally recognized medical specialty boards and allied health credentialing agencies, and

continuing competency programs. The American Board of Pathology, it should be noted, recommends pathology proficiency recertification at 10 year increments. Hence, we believe testing intervals could be once every 10 years.

These education and assessment products, including the ASCP Cytotechnologist national certification examination, undergo regular and extensive psychometrics and other reviews to ensure these tools are reliable, accurate measures of competency. Moreover, since CLIA 88 has been enacted, certification is now time-limited to three years and mandates the Cytotechnologist accrue 36 hours of continuing education under each of the specific areas of the discipline in order to re-certify.

Consistent with ASCP's long held views that the cytology PT programs should task the laboratory director to ensure compliance, ASCP believes responsibility for ensuring compliance for individual participation in an educational program should fall to the laboratory director. This approach would also allow laboratories and the laboratory director to tailor educational programs to the individual needs of cytology professionals. Oversight of participation in this program could be provided as part of the laboratory accreditation/inspection process.

Should CMS decline to adopt ASCP's proposal to convert the current cytology PT program into an educational/assessment program, we strongly urge the Institute of Medicine of the National Academy of Sciences to be tasked with conducting a comprehensive review of the CLIA Cytology PT program. This study should consider its validity and necessity as well as policy options, such as the education/assessment program proposed here by ASCP and by members of the Cytology Proficiency Testing Improvement Coalition, that can better assess quality and in a manner that is fair and feasible for the cytology community.

C. TESTING INTERVALS

As previously mentioned, ASCP believes that an education-based assessment program could help reduce the need for the competency assessment component of the PT program to as little as once every ten years.

With regard to CMS' proposal to move to a two-year testing cycle, it is unclear how CMS plans to execute this two year cycle once the proposal is implemented. Assuming this proposal goes into effect, if all laboratories are required to complete the PT requirement in the first year after implementation of the rule, then it appears that PT providers would not be providing any significant testing services in the second year. It creates certain administrative issues trying to satisfy demand in the "on" years. Moreover, this on/off revenue stream is not conducive to sustaining viable PT programs as PT providers would see little if any revenue in off years.

ASCP encourages CMS to adopt some system, perhaps a lottery program, to determine which cytology laboratories should be tested in the first or second year assuming CMS continues toward implementation of this proposal. Staggering the years in which laboratories

participate in a pure PT program should improve the ability of PT providers to meet the need of their client base.

III. ADDITIONAL ISSUES PER REGULATORY OUTLINE

A. CYTOLOGY CHALLENGES AND NEW TECHNOLOGY

ASCP approves of CMS' substitution of the term "challenges" for the term "slide." ASCP has long advocated changing the regulation to allow for advancements in testing media, and this terminology appears sufficiently flexible to accommodate new technologies. With regard to image-based testing media, ASCP does not believe that, at this point, there are new media available that rival the quality and reliability of glass slides but we have little doubt that advances in technology will soon allow for alternatives.

That said, ASCP strongly believes that CMS should put in place an internal process to rigorously review alternative testing media, such as adaptive computer-based certification examinations, to ensure that they can serve as reliable, quality alternatives to glass slides for assuring competency. ASCP believes that another element necessary for approving new testing media is that it should be, and in accordance with CLIA, reflective of the media regularly used in actual clinical practice (to replicate normal working conditions). Moreover, alternative media should be able to demonstrate its statistical validity. ASCP does not believe that CMS should specify the criteria for approving new technologies in the regulations so as to provide the agency with greater flexibility to consider new technologies.

Another item CMS should reconsider is how the four-hour test event time frame should relate to alternative testing media. As new testing media are approved, the four-hour timeframe may not be appropriate. Consequently, specifying a four hour time frame in the regulations could adversely affect the development or availability of alternative test media, such as certification or board examinations.

Further, ASCP concurs with CMS that once alternatives to glass slides are available that PT providers should offer program participants the option of glass slides as their testing medium.

B. TESTING INDIVIDUALS

As previously mentioned, ASCP encourages CMS to require enrollment and participation in an educational program as part of its Cytology PT program. ASCP believes that in implementing such a program, the responsibility for ensuring participation should fall to the laboratory director.

C. FREQUENCY OF TESTING

Theoretically, a higher number of challenges per test event improves the ability of that test to assess performance. Moreover, given the costs and burdens of cytology proficiency testing and the lack of data suggesting cytology screening or interpretative skills decline over time, decreasing the frequency of testing intervals is appropriate. As previously noted, ASCP

believes establishing an education/assessment model to replace the current PT program could allow for test events to occur as little as once every 10 years.

Additionally, there are a host of other safeguards imposed by CLIA and laboratory accrediting organizations to ensure quality cytology screening and interpretation. Among these safeguards are the biennial inspection requirement for laboratories, 10 percent random re-screening of all negative specimens, correlation histology and cytology reports, and retrospective review of a patient's negative specimens within 5 years of the initial identification of HSIL or cancer. Additionally, at least one laboratory accrediting organization, the College of American Pathologists, requires laboratories performing gynecologic cytology to participate in an annual educational program. Further justification for extending the frequency of testing could be provided were CMS to require participation in the aforementioned educational assessment model proposed by ASCP.

The current annual testing interval presents many administrative challenges to laboratories and program participants. Moving to a less frequent testing interval may reduce the overall burden of compliance.

D. NUMBER OF CYTOLOGY CHALLENGES

Despite its good intentions, the Cytology PT program in its current form does too poor of a job at correctly identifying competent individuals to justify its onerous demands on cytology laboratories, pathologists and cytotechnologists. As discussed by Dr. George K. Nagy of the New York State Department of Health during the June 2006 CLIAC meeting, the "current 10 slide test lacks the discriminatory power to differentiate between competent and incompetent test takers." Increasing the number of slides that program participants should help improve validity of the CMS cytology PT program to better identify poor performers. That said, the number of slides that would be necessary to ensure competence is impractical as the costs and burdens on laboratories, program participants and cytology PT providers would be unacceptable.

For this reason, ASCP firmly believes that CMS should replace its pure Cytology PT model with a regulatory framework that utilizes a education/assessment model. By relying on an educational assessment model, CMS and CDC would more closely match their statutory mandate to assure consistent performance of valid and reliable cytological services. While doubling the time to four hours may be essential at this time for an image-based examination, as alternative testing media are considered, such as certification and board examinations, the four-hour test timeframe may not be appropriate.

E. RESPONSE CATEGORIES

ASCP supports maintaining the current four response categories and CMS's proposal to modify "unsatisfactory" to "unsatisfactory for the evaluation of epithelial abnormality." ASCP does not support establishing a fifth category for "cancer" at this time.

F. CYTOLOGY CHALLENGE REFERENCING

ASCP agrees that there should be 100 percent consensus among at least three physicians certified in anatomic pathology, but we also believe that the challenge referencing process should include cytotechnologists. ASCP's cytology PT program referencing process requires 100% consensus of 3 Pathologists and 2 Senior-level Cytotechnologists. ASCP also agrees that these physicians should examine gynecologic preparations on a routine basis. Moreover, ASCP believes that in addition to challenge referencing, field validation is necessary. By itself, challenge referencing is insufficient to establish the suitability of slides for the testing of cytology PT program participants.

G. BIOPSY CONFIRMATION

ASCP concurs that it is unnecessary to require biopsy confirmation of LSIL cytology challenges used in PT testing. Maintaining the biopsy requirement for HSIL cytology challenges used in PT testing is acceptable.

H. VALIDATION OF CYTOLOGY CHALLENGES

ASCP agrees with the need for field validation of cytology challenges to ensure that cytology challenges are accurate depictions of their intended response category. Likewise, ASCP believes that the disclosure requirements are useful. Further, ASCP believes that requiring PT providers to use continuous field validation is an appropriate safeguard to ensure that each cytology challenge is an accurate and reliable representation of its intended challenge category. CMS should not develop specific regulations outlining how such a requirement must be structured. CMS should allow PT provider's the flexibility to develop their own continuous field validation programs.

I. SCORING SCHEME

As previously mentioned, ASCP believes CMS should adopt the unified scoring scheme for pathologists and cytotechnologists proposed by the ASCP in March 2006 and then later endorsed by the Clinical Laboratory Improvement Advisory Committee and American Society for Cytotechnology. We believe that a unified scoring scheme is imperative for reasons of fairness and scientific validity. The scoring scheme should also reflect actual clinical practice. Given our aforementioned comments concerning differentiation of HSIL/LSIL for pathologists and the differentiation of negative and LSIL for adolescents, we believe a single unified grading scheme is essential.

ASCP supports elimination of the excessive penalty (auto-failure) for identifying a HSIL or cancer as a normal or benign change. A penalty is appropriate but the current penalty is unwarranted.

J. RETESTING AND REMEDIATION

ASCP is not opposed to CMS' proposals regarding the retesting timeframes. The new proposal that a retest following remedial training occur within 45 days of the completion of training may help improve program participant pass rates. ASCP strongly urges that PT programs be given the flexibility to determine the site of the retest as this should help

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programs meet the requirement to retest within 45 days of the completion of remedial training while enhancing the flexibility of the PT program and helping to keep program costs manageable. ASCP believes that PT programs should be required to provide feedback to cytology laboratories and program participants with information regarding incorrect responses.

K. APPEALS PROCESS.

ASCP agrees that PT programs should provide all program participants a written description of the appeals process.

L. TESTING SITE

ASCP believes PT programs should be able to offer testing services at other venues, such as at professional conferences, seminars, etc. Given that such meetings are usually centered around an educational mission, such meetings match up well with the concept of an education-based assessment program. Allowing PT testing events at other venues is also consistent with the goals of both CMS and CLIAC to encourage laboratories and their staff to participate in educational programs. Moreover, this may help lower the cost and facilitate retesting of program participants.

M. PROCTORS

ASCP does not oppose CMS's proposal for the use of proctors, in part because they mesh with ASCP's desire to see the PT rules more directly utilize and empower the laboratory director. ASCP agrees with the proposed prohibition on the use of any resources that may aid program participants with the interpretation of testing media or duplication of testing materials.

In closing, ASCP strongly encourages CMS to replace the proposed cytology PT program with an education-based assessment PT program. ASCP appreciates the opportunity to present these comments. If we can be of further assistance, please do not hesitate to contact me or Matthew Schulze, ASCP's Senior Manager for Federal and State Affairs, at (202) 347-4450.

Sincerely,



Barbara McKenna, MD, FASCP
President, ASCP

cc: Thomas Hamilton, CMS
Judy Yost, CMS
Nancy Anderson, CDC