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

AUG 16 2005

Mr. John Scott
College of American Pathologists
1350 I Street, N.W.
Suite 590
Washington, D.C. 20005

Dear Mr. Scott:

I wish to thank your members, and all cosigners of your June 3rd letter, for taking the time to convey your concerns regarding cytology proficiency testing, both in your letter and in recent meetings with both the Centers for Medicare and Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC).

I also wish to thank all affected laboratories for working to fulfill the proficiency testing expectations delineated in law by Congress. Such expectations are important and it is vital that we fulfill them, even as we simultaneously work to ascertain improvements that have merit. To that end CMS has committed itself to working with you, and with all other organizations with interest and expertise to contribute, in order to review current requirements to determine where and how improvements may be made. CMS will extend an invitation to you and others to participate in a process for doing so.

In the meantime, we look forward to completion of the first full year of proficiency testing and full participation among laboratories that perform gynecologic cytology examinations. We do not regard the issues you raise as reason to slow the excellent progress that laboratories are making in ensuring and demonstrating the proficiency of their workers, nor as reason to avoid full conformance with the proficiency requirements specified in law and promised to the American people.

Fulfillment of the statutory requirement on the part of all relevant laboratories will provide data from actual experience to further assess improvements that might be made. This is particularly important since many of the issues raised in your letter were also raised in the public comment period of the administrative rule promulgated in 1992. Many adjustments were made in the regulation in response to those public comments. Although other comments were not accepted, they were carefully considered in the rule-making process at that time and explained in the preamble to the final rule. For a newer and further review, data from the current national testing experience and from the CMS-approved proficiency testing programs will be invaluable. Other issues regarding advances that have been made in the field since enactment of the law will also be informed by what is learned from the current testing. In 2006 we also look forward to the potential for additional, national, proficiency testing programs the will expand the choice, convenience and on-site scheduling opportunities for the testing events.

In preparation for further discussion with CMS, I would like to share with you our perspective on some of the particular issues you raised, and also suggest areas in which further information may be particularly important. While we agree on certain points in your letter, we also disagree with a number of your statements. We offer the responses in the attachment to this letter as a way of advancing our dialogue and preparing for deeper analysis of the issues.

I am confident that continued frank exchange of views will result in the most effective system for testing the proficiency of individuals while protecting the public health and safety of the public. I therefore look forward to your further discussions with CMS and CDC, and appreciate the daily work of all affected laboratories to ensure the highest quality of health care possible.

Sincerely,

Dennis G. Smith
Director

Attachment: Responses to the Specific Issues Raised in the Letter

Annual Testing

The comment is that the statute requires periodic testing; it is the regulation that converted periodic to annual testing.

The original proposed rule was changed in 1992, in response to comments, so that annual testing would occur instead of testing twice per year as originally proposed. We agree that the requirement in the regulation for annual testing is one that merits continued review based on the first two years of proficiency testing. Such information will permit a comparison of the test results from one year to the next and permit an assessment, based on national experience, as to the added value achieved in annual testing compared with an alternate frequency.

Penalties

The comment is that "the regulation calls for escalating sanctions against participants who fail to achieve the minimum mark of 90 percent for satisfactory performance after two attempts," and that the regulation is overreaching and arbitrary.

There are penalties for a *laboratory* that fails to *enroll* and *participate* in a CMS approved cytology proficiency testing program. Beyond this very basic requirement, however, we would take issue with the characterization of penalties if an individual fails an initial proficiency test.

The regulations, first and foremost, provide that individuals who fail be given a second, a third, and a fourth chance to pass a proficiency test. The regulations provide that individuals be afforded appropriate education. They are not impeded from continuing work. After a second failure (first re-test) individuals must obtain remedial education in areas of failure. Only after a third failure do substantive restrictions take place on their ability to perform gynecologic cytology examinations. We regard these as important public protections that are well warranted after an individual has failed to demonstrate proficiency three times. We cannot agree that these are arbitrary. Further, these requirements were subjected to extensive public comment in the rule-making process, with adjustments made in response to those comments. In summary:

Requirements After Failure to Pass a Proficiency Test

Test	Requirements for Individual Who Fails	Requirements for the Lab for an Individual Who Fails
First Test	Take a 10 slide test in 2 hours. If individual does not score at least 90%, take a re-test within 45 days.	1) Enroll each individual in a CMS approved cytology proficiency testing program. 2) Schedule a retest within 45 days after receipt of the notification of failure.
Second Test Failure	Take remedial training if the individual does not score at least 90% on the second 10-slide test.	1) Provide remedial training and education in areas of failure. 2) Assure that all gynecologic slides evaluated subsequent to the notification of failure are reexamined, until the person passes a re-test. 3) Schedule a retest within 45 days after completion of remedial

		training and education.
Third Test Failure	Take 35 hours of continuing education if the individual does not score at least 90% on the third test (a:20 slide retest in 4 hours);	1) Assure that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations. 2) Ensure individual ceases examination of gynecologic slides subsequent to notification of failure until individual is retested and scores at least 90%. 3) Schedule a retest within 45 days after completion of continuing education.
Fourth Test Failure	Cease examining gynecologic cytology specimens if failing to obtain a score of at least 90% on the fourth test.	1) Assure that the individual obtains at least 35 hours of documented, formally structured, continuing education in diagnostic cytopathology that focuses on the examination of gynecologic preparations. 2) Ensure individual ceases examination of gynecologic slides subsequent to notification of failure until individual is retested and scores at least 90%. 3) Schedule a retest within 45 days after completion of continuing education.

Grading Scheme

The comment is that "the grading scheme used in the 1992 regulation is centered in triage and management guidelines that have changed substantially over the past 13 years. For example, when the regulation was written, the resulting diagnostic evaluation for patients with Low Grade Squamous Intraepithelial Lesions (LSIL) was often far different from that of those with High Grade Squamous Intraepithelial Lesions (HSIL)—LSIL patients often received repeat cervical cytology, where HSIL patients were triaged for colposcopy and biopsy. Today, however, colposcopy is the recommended management practice for both LSIL and HSIL."

The argument for not making a distinction between LSIL and HSIL depends heavily on certain recommended practices, such as universal colposcopy, that are not adopted by everyone or in all cases. In promoting optimum accuracy, the regulations require the individual's ability to make distinctions that do not depend on the management practices of others in order to ensure their accuracy and full utility. We cannot assume, nor propose, that the laboratorians take on a clinician's responsibility and determine the treatment of the patient. The laboratory examines the slides and reports the findings.

The diagnostic categories used in the testing event reflect the nomenclature used in the 2001 Bethesda System. Individuals are asked to make a distinction between cases that are: unsatisfactory for diagnosis, normal or demonstrate benign changes, low grade lesions, and high grade lesions. These diagnostic categories are used routinely in cytology laboratories.

While the argument is that changes have occurred since 1992, the arguments themselves have not substantively changed and were raised in the public comments in the 1992 rule-making process, to which the agency responded.

Although we may have a different view on the extent to which LSIL and HSIL distinctions are important, we agree that this is an area that merits further analysis and

mutual deliberation to determine if there are alternatives that are equal to the job without raising the concerns that are expressed. CMS will engage with you, the Clinical Laboratory Improvement Advisory Committee (CLIAC) and others to review these issues.

Individuals v. Lab Testing

The comment is that "It is also greatly troubling that while all other general proficiency testing under CLIA is directed towards measuring results at the laboratory level, this provision departs from that approach and singles out individuals. In reality, much of the work conducted within a laboratory is done so in consultation within a team of pathologists and trained medical staff."

Individual testing is specified in the law. We would simply note that Congress was very clear and specific when it singled out gynecological cytology examination for *individual* rather than *laboratory* proficiency. Insofar as effective team-based practice is built upon the competencies of the individual team members, an argument in favor of abandoning individual proficiency testing ought to be able to demonstrate equivalent value.

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CMS, the agency responsible for oversight of cytology proficiency testing through the Clinical Laboratory Improvement Amendments of 1988, remains committed to protect the health and safety of women and balance that mandate with the concerns of the cytology community.

CMS has committed itself to working with all organizations with interest and expertise to contribute to a process of reviewing current requirements to determine where and how improvements may be made to ensuring proficiency in gynecological cytology. CMS will be extending invitations to national organizations to do so.