Advancing Excellence

College of American Pathologists

Statement to the

Clinical Laboratory Improvement Advisory Committee (CLIAC)

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Presented by

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Dr. Turner, members of the Committee, my name is Barbara Ducatman, MD and I am Chair of the Department of Pathology at West Virginia University and Director of the National Center of Excellence in Women's Health, at West Virginia University. Today I represent the College of American Pathologists (CAP), where I serve as a member of the Cytopathology Committee.

The College of American Pathologists is a national medical specialty society representing more than 16,000 pathologists who practice anatomic pathology and laboratory medicine in laboratories worldwide. The College's Commission on Laboratory Accreditation is responsible for accrediting more than 6,000 laboratories here and abroad. College members have extensive expertise in providing and directing laboratory services and serve as inspectors in the accreditation program. In addition, the CAP provides laboratories with a wide variety of proficiency testing programs and educational solutions to assist in the improvement of the laboratory's performance and its positive impact on patient care. Specifically, the College has been a leader in developing quality improvement programs for laboratories, including programs in anatomic pathology and cytopathology.

At its February 2005 meeting, this Committee expressed its profound concern regarding the start of cytology proficiency testing regulations last fall, more than a dozen years after their publication in the 1992 Clinical Laboratory Improvement Amendments of 1988 (CLIA) final rule. Specifically, the Committee unanimously passed a recommendation that the regulation—particularly its grading criteria—should be revisited to ensure it is based on the most current science and clinical practice guidelines. In making the recommendation, the Committee acknowledged the need to closely study and confirm that this program should not evaluate and, ultimately, sanction individuals based on outdated standards.

Consistent with the CLIAC recommendations, the College, as part of a coalition of 10 national and 48 state pathology societies representing the full spectrum of pathology practice, asked Health and Human Services (HHS) Secretary Michael Leavitt in a June 3 letter that he strongly consider re-evaluating the relevance, validity and ultimate effectiveness of the cytology PT regulations. (See letter attached) The letter noted that the regulation overreaches the CLIA statute and has fallen far behind current gynecologic cytology practice.

The College is deeply disappointed that, in its response to the coalition's letter to Secretary Leavitt, the Centers for Medicare and Medicaid Services' (CMS) is resolute on moving forward with the cytology PT regulations, despite an overwhelming consensus within the laboratory and pathology profession—including the action taken by this body—that the program requires a prompt and thorough review. CMS continues down the very path we believe will lead to diminished patient access to gynecologic cytology services and a costly and ineffective regulatory burden on providers. The College and its coalition partners are preparing comments to formally respond to the agency's letter.

Grading Criteria/Penalties

We believe CMS is implementing a testing program based on a flawed grading system that ignores a significant evolution in the practice of gynecologic cytology in the many years since the regulation was first issued. The advent of new technologies, including computer-assisted and location-guided screening, has changed the typical process for evaluating slides. In addition, clinical practice guidelines relative to the management of the patient have been modified, resulting in less emphasis on the determination of low-grade vs. high-grade lesions. For example, current management guidelines are evidence-based as a result of our better understanding of the biology of the Human Papilloma Virus (HPV) and the ASCUS Low-Grade Triage Study (ALTS). CMS has indicated that this is an area of the regulation that may warrant further analysis. Meanwhile, this flawed grading criterion could cause licensed pathologists with excellent records to have their ability to interpret Pap tests revoked for no logical or medically sound reason. This is due to the fact 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, despite the fact that the CLIA statute does not provide for such penalties. Some pathologists have already indicated that they intend to discontinue providing the service altogether due to the invalidated grading scheme and sanctions.

Annual Testing

In the area of frequency of testing, the CMS has conceded that its decision to implement annual testing is another area that merits continued review. The agency, however, has indicated that it will utilize data based on the first two years of proficiency testing as the basis of this review. CMS envisions that this information will permit a comparison of the test results and an assessment of the value achieved by annual testing compared with that of an alternate testing frequency. We see no reason for CMS to review comparative data based on the first two years of proficiency testing, particularly when additional policies are already in place to define specific training, skill and competency requirements of individuals subject to the regulation. As well, CMS does not account for the significance of existing regulatory requirements for cytology laboratories under CLIA'88. For example, CLIA regulations require all laboratories engaged in cytopathology to be certified/accredited and inspected every two years. Additionally, pathologists are required by law to maintain full state licensure and medical board certifications, meet current CME requirements and ensure that 10 percent of all gynecologic cases interpreted to be negative are re-screened. CLIA also imposes a limit on the number of slides an individual may review within a 24-hour period. These important measures guarantee countless hours devoted to quality assurance associated with Pap tests. Given the preponderance of regulatory oversight in this area, we believe a proficiency test administered to pathologists and cytotechnologists every year is excessive.

Individual Testing

In the area of the regulation of individual testing, we have argued that while all other general proficiency testing under CLIA is directed toward 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.

For this reason, CLIA's primary focus on laboratory proficiency testing is well placed. While we certainly recognize CMS' position that the statutory language governing PT for gynecologic cytology mentions testing of individuals, it is equally important to note that language also specifies that the Secretary of Health and Human Services should establish quality assurance standards that "assure consistent performance by laboratories of valid and reliable cytological services...with such testing to take place, to the extent practicable, under normal working conditions." In our estimation, "normal working conditions" can be reflected in this examination only by including the collaborative team approach that is a fundamental aspect of pathology practice and the laboratory environment. The regulation's premise that individuals conducting laboratory work are doing so in isolation and making determinations alone is false. As a matter of general practice, clinical laboratories often function through collective conference and decision-making. Any PT program seeking to adequately assess true-to-life results must reflect this workplace reality in its testing approach.

CMS has taken a position that utilizing a team-based approach to testing rather than individual testing should demonstrate equivalent value. We believe that laboratory-level testing is both permitted under the law and is a better approach to ensuring quality laboratory results, and is more reflective of how Pap tests are performed in laboratories. In fact, although the CLIA statute requires "periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparation," it does not specify the manner in which this task is to be accomplished. This suggests that the proficiency of individuals need only be periodically confirmed and evaluated and that formal enrollment of the individuals in a proficiency testing program, in lieu of laboratory enrollment in such a program, would be unnecessary.

The College remains committed to ensuring the highest quality laboratory testing for our patients. However, we believe that this federally imposed annual proficiency examination is not necessary, will not improve quality and could result in the unintended consequence

of discouraging well qualified pathologists from providing these type of services altogether.

We respectfully request, once again, that HHS strongly consider re-evaluating the relevance, validity and ultimate effectiveness of cytology PT requirements carried out for the first time this year under the 1992 CLIA regulations. The College looks forward to participating with the CLIAC, along with staff from CMS and the Centers for Disease Control and Prevention (CDC), to review current requirements and recommend revisions to this regulation.

On behalf of the College of American Pathologists, I would like to thank the committee for this opportunity to provide comments on this most important issue.