Re-evaluating the Relevance, Validity and Ultimate Effectiveness of Cytology Proficiency Testing

June 03, 2005

Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

On behalf of our organizations, representing the full spectrum of pathology medical practice, we respectfully request that the Department of Health and Human Services (HHS) give strong consideration to re-evaluating the relevance, validity and ultimate effectiveness of Cytology Proficiency Testing (PT) being implemented for the first time this year under 1992 federal regulations related to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). We additionally ask that if this well-intentioned but outdated program is to go forward, it continue to be conducted on an educational basis and without individual punitive sanctions through the end of 2007, at a minimum. An opportunity for our representatives to discuss with you personally our deep concerns with this program would be greatly appreciated.

As you may be aware, your department's own Clinical Laboratory Improvement Advisory Committee (CLIAC) has recently expressed its concern regarding the Cytology PT regulation. Specifically, CLIAC, a highly respected group of pathologists and laboratory professionals, unanimously passed a recommendation at its February 2005 meeting that the regulation and its grading criteria be revisited to ensure it is based on the latest and most current science and clinical practice guidelines. In making its recommendation, this expert advisory committee acknowledges the need to closely study and confirm that this program should not evaluate and, ultimately, sanction individuals based on outdated standards.

In fact, scientific and technological advances, such as computer-assisted screening, location-guided screening, digital imaging and others, have made a significant and positive impact on the practice of gynecologic cytology since CLIA and the 1992 regulations were established. Additionally, thanks to CLIA, the necessary guidelines providing quality assurance for our nation's cytology laboratories have been put in place and working over that same period of time, making the days of "Pap mills" and their inexcusable practice a distant memory. Before CLIA, there were no restrictions whatsoever on the number of Pap test slides a pathologist or cytotechnologist could screen in a 24-hour period. Today, however, there are appropriate and necessary limits in effect. Yet, in the time these critically important developments have taken place within our profession, the regulation that would require federal proficiency testing for pathologists and cytotechnologists has stood still, resulting in a program rooted in outdated science and, even, obsolete procedures.

Given these facts and the knowledge that no other group of physicians or physician specialists are subjected to similar federal qualifying examinations that supercede existing state medical licensing boards and medical specialty certification boards, our strong concerns regarding this new federal program are numerous. As such, it is also worth noting our specific concerns about the regulatory interpretation of this CLIA provision.

Essentially, the underlying CLIA provision is straightforward and brief. In short, it calls for the proficiency testing of parties engaged in the interpretation of Pap tests. On the issues of testing frequency and potential penalties, the regulation establishes requirements that go far beyond those expressed in the law. For instance, the regulatory interpretation of "periodic" testing, as contained in the law, resulted in a final rule calling for annual examinations.

In our view, annual testing is a large leap from "periodic" when the statute is not clear on this point. This is especially true, given the fact that CLIA already provides regulatory safeguards with respect to Pap tests that call into question the need for yearly examinations. For example, CLIA regulations require all laboratories engaging in cytopathology to be federally accredited and inspected every two years. Pathologists are additionally required under the 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 be re-screened. These important measures already in place now guarantee countless hours devoted to quality assurance associated with Pap tests. Given the preponderance of regulatory oversight in this area, a proficiency test administered to pathologists and cytotechnologists every year would be an excessive endeavor.

Regarding penalties for participants who fail this examination, the over-reaching nature of the regulation is especially evident. While the CLIA provision does not include penalties, the regulation calls for escalating sanctions against participants who fail to achieve the minimum mark of 90 percent for satisfactory performance after two attempts. Not only is the regulatory imposition of these penalties arbitrary, the grading criterion used to distinguish between an examination result that is satisfactory and one that is not is vastly outdated. Furthermore, a study conducted by the Centers for Disease Control and Prevention published in peer-reviewed medical literature showed a relatively poor correlation between proficiency testing and actual work performance. 1

Specifically, as has been widely accounted and published in numerous medical journals, 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. In fact, it is the difficulty to reliably distinguish between these two categories that forms a significant portion of the reason for this practice management change. Despite this acute evolution in treatment, the regulation's grading scheme used to make proficiency judgments simply does not take this into account and mandates severe penalties for the inability to distinguish between the two. As a result, this flawed scheme

could cause licensed pathologists with excellent records to have their ability to interpret Pap tests federally revoked for no logical or medically sound reason. Some pathologists have already indicated that they intend to discontinue providing the service altogether due to the invalidated grading scheme and sanctions.

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. For this reason, CLIA's primary focus on laboratory proficiency testing is well placed. While we certainly recognize 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 Cytology PT provision's premise that individuals conducting laboratory work are doing so in isolation and making determinations alone is a false one. 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.

To this end, the pathology community has long held that the testing result produced by a laboratory is the most critical measure for ensuring public safety and has embraced proficiency testing at the laboratory level. It is worth noting that the College of American Pathologists has conducted an Interlaboratory Comparison Program in Cervicovaginal Cytology (PAP) for more than 15 years. This is a highly respected and scientifically proven field-validated gynecologic testing system that has consistently utilized interpretive categories and statistically validated grading to gauge proficiency of laboratories. Currently, the vast majority of affected laboratories, pathologists, and cytotechnologists are enrolled in this very effective program.

Lastly, the outdated nature of this Cytology PT provision is further crystallized by the actions of Congress just two years ago. With the 2003 passage of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), Congress included legislative language that set a maximum of three years that could elapse between when HHS could issue a proposed rule on a topic and when it issues a corresponding final rule. While this law is not directly applicable to the Cytology PT regulation, the premise behind it speaks to the core problem: the more than a decade gap that exists between when the program's regulations were promulgated and when they were implemented. As the108th Congress rightly recognized, the conditions and climate that lead to legislation and regulations change greatly over time. Nowhere is this more evident than in gynecologic cytology and this PT regulation in question.

We collectively remain committed to ensuring the highest quality laboratory testing for our patients. However, 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 the service altogether.

Thank you again for your full consideration of this important issue and our meeting request. We look forward to your response, which can be directed to John Scott, Vice President of Membership and Advocacy at the College of American Pathologists, at jscott@cap.org or (202) 354-7109.

Sincerely,

National Pathology Organizations:

College of American Pathologists
American Board of Pathology
American Pathology Foundation
American Society for Clinical Pathology
American Society of Cytopathology
Association of Directors of Anatomic and Surgical Pathology
Association of Pathology Chairs
Association for Molecular Pathology
National Association of Medical Examiners
United States and Canadian Academy of Pathology

State Pathology Societies:

Alabama Association of Pathologists
Arizona Society of Pathologists
Arkansas Society of Pathologists
California Society of Pathologists
Colorado Society of Clinical Pathologists
Connecticut Society of Pathologists
Delaware Pathology Society
Florida Society of Pathologists
Georgia Association of Pathologists
Hawaii Society of Pathologists
Idaho Society of Pathologists
Illinois Society of Pathologists
Indiana Association of Pathologists
Iowa Association of Pathologists
Kansas Society of Pathologists
Kentucky Society of Pathologists
Louisiana Pathology Society
Maine Pathology Society
Maryland Society of Pathologists
Massachusetts Society of Pathologists
Michigan Society of Pathologists
Minnesota Society of Pathologists
Mississippi Association of Pathologists
Missouri Society of Pathology
Montana State Pathology Society
Nebraska Association of Pathologists
Nevada Society of Pathologists
New Hampshire Society of Pathologists
New Jersey Society of Pathologists
New Mexico Society of Pathologists
New York State Society of Pathologists
North Carolina Society of Pathologists
North Dakota Society of Pathologists
Ohio Society of Pathologists
Oregon Pathologists Association

Pennsylvania Association of Pathologists
Rhode Island Society of Pathologists
South Carolina Society of Pathologists
South Dakota Society of Pathologists
Tennessee Society of Pathologists
Texas Society of Pathologists, Inc.
Utah Society of Pathologists
Vermont Society of Pathologists
Virginia Society of Pathologists
Washington State Society of Pathologists
West Virginia Association of Pathologists
Wisconsin Society of Pathologists, Inc.
Wyoming Society of Pathologists

Cc: Honorable Mark B. McClellan;
Administrator, Centers for Medicare and Medicaid Services

1 Keenlyside RA, Collins CL, Hancock JS et al. Do proficiency test results correlate with the work performance of screeners who screen Papanicolaou smears? *Am J Clin Pathol.* 1999;112:769-76.