



Advancing Excellence

Statement to the
Clinical Laboratory Improvement Advisory Committee

Statement Presented by
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Introduction

Good morning. My name is Dr. Thomas M. Wheeler I am Professor and Interim Chair with the Department of Pathology at Baylor College of Medicine in Houston, Texas. I am appearing today on behalf of the College of American Pathologists as their Chairman of the Council on Scientific Affairs. The College appreciates the opportunity to appear before you today and provide our perspectives on cytology proficiency testing and our recommendations for modifications of the cytology proficiency testing (PT) program.

The College was approved by CMS in August 2005 as a PAP PT provider for the testing year 2006. However, despite being an approved PT provider, the College has advocated to CMS and to the Congress that significant changes to the current federal requirements are necessary.

Fundamentally, the College believes that the regulations exceed the scope of the Act as mandated by Congress. We concur with our professional colleagues on the Cytology Educational and Technical Consortium that the regulations are seriously outdated due to the scientific and technological advances that have occurred in the last 14 years. As currently written, the regulations do not reflect “normal working conditions” which is a collaborative, team approach fundamental to the laboratory environment and most pathology practices.

Finally, the CAP has never agreed with the agency's interpretation that the statute prohibits the evaluation of the performance of the laboratory, rather than individuals.

The College also believes that the Agency has a large degree of discretion to revise the Cytology PT standards based on the legislative intent behind CLIA. Significantly, CLIA does not specify whether these individuals must be enrolled as individuals in an approved PT program or whether the laboratory can be enrolled on behalf of the individuals.

Since the current regulation is being re-examined, now there is an opportunity and indeed an obligation for the Agency to perform a regulatory analysis that evaluates the costs and

benefits of the planned regulation as well as any alternative approaches.

The College believes the cost benefit analysis conducted by CMS for the 1992 rule was seriously flawed. This earlier analysis was not evidence-based and relied on unsupported assumptions, including that PT reduces false negatives and positives. In fairness, in its analysis CMS acknowledged PT benefits were difficult to measure.

The College urges CMS to re-calculate the potential benefits including: 1) the effect on false negatives and/or positives, 2) potential savings in treatment costs and 3) reductions in mortality. In fact, this same methodology was used by the FDA to evaluate the costs and benefits of the Mammography Quality Standards Act (MQSA). The College believes that if a similar cost benefit analysis is conducted on the

cytology PT program it will show that the costs significantly outweigh the potential benefits, indicating the regulation in its current form is not cost-effective.

The College believes that a proposal similar to MQSA offers a more-desirable alternative regulatory approach. Its impetus was a similar quality-of-care concern---diagnostic screening services. And, the objective was the same—to reduce false negatives.

In summary, the FDA's approach under the MQSA regulations:

- 1) uses annual medical outcomes data audits which allow for voluntary training and/or testing as appropriate

- 2) relies on internal corrective action vs. external enforcement
- 3) rejects proficiency testing of the individual

The FDA rejected individual PT because of the lack of consensus on testing standards and measurements. The FDA noted that the general consensus was that “PT would be excessive, unnecessary, costly, impractical, and duplicative of examinations already in place.” The College believes that the same lack of consensus and measurements exists for cytology today.

Instead of proficiency testing, the FDA established a comprehensive mammography medical outcomes audit program, noting its potential to act as the basis for performance outcome standards. The College believes that the medical outcomes audit provided for in the MQSA is similar to the re-screening

protocols provided for under CLIA. If anything, the re-screening protocols provide the basis for evaluating laboratory performance based upon actual outcomes.

Under the College's alternative approach, which is similar to MQSA, laboratories would have to participate in a laboratory PT program, in which all individuals who screen or interpret gynecologic slides would have to participate as part a continuing medical education requirement. Proficiency testing results would be reportable to the laboratory director, who would be required to document testing results. The laboratory director would utilize the proficiency testing results as another tool to assess laboratory performance. Accrediting organizations would review and examine laboratory proficiency testing results based upon laboratory director's documentation.

In conclusion, the College firmly believes that if CMS parallels the MQSA approach and conducts a similar regulatory analysis, it will reach the inescapable conclusion that the existing re-screening protocols under CLIA are the most direct, accurate, and cost-effective method of assessing laboratory performance.

Given these facts, as well as the knowledge that no other group of physicians is subject to similar federal qualifying examinations, the College recommends the regulatory approach taken by the FDA for the MQSA.

We believe the MQSA approach is more preferable because it would better reflect “normal working conditions” and would

focus on a laboratory's team based practice. The regulations as currently implemented do not measure present day practice nor provide for an overall evaluation of laboratory performance in this area of laboratory testing.

The College of American Pathologists respectfully urges CLIAC to recommend to HHS that they adopt a regulatory approach more consistent with MQSA.

I will be happy to answer any questions that you may have. Thank you.