



February 14-15, 2005

Statement of the

American Society for Clinical Pathology

before the

Clinical Laboratory Improvement Advisory Committee

on the

Status of the Revision of the CLIA Cytology Proficiency Testing Regulations

My name is Matthew Schulze and I am the Senior Manager for Federal and State Affairs for the American Society for Clinical Pathology. ASCP appreciates the opportunity to address this distinguished committee. My purpose here today is to raise concern about progress on revising the cytology proficiency testing regulations.

Over the past few years, CLIAC has held several discussions on the CLIA cytology proficiency testing regulations and the urgent need for their revision. ASCP is pleased that last June CLIAC held a consensus meeting to discuss and provide a comprehensive set of recommendations for the revision of these rules. ASCP appreciates the willingness of CLIAC and CMS to address the concerns of the cytopathology community in revising these regulations.

Concern about the burden involved with CLIA's current cytology proficiency testing rules led ASCP and many in the pathology and laboratory community to urge CMS to expedite its revision of these rules. Unfortunately, despite initial assurances that this rules revision would be handled in an expedited manner, they have not yet been released for public comment nor have they been submitted for regulatory approval by the Office of Management and Budget, a process itself that can take months.

ASCP is disappointed CMS has not made greater progress on this rules revision. ASCP believes this delay is unacceptable. It's unclear to us the breadth of the necessary regulatory revisions, but the regulations concerning cytology proficiency testing are only a few pages long. I would like to point out that when CMS had the unenviable task of drafting regulations to implement the Medicare Part D prescription drug benefit, the agency had to draft over one thousand pages of regulations. It took the agency approximately one year to complete this assignment.

To help accelerate CMS' progress on this rule revision, ASCP is asking CLIAC to urge CMS to *fast track* its revision of this rule and to urge CMS to publish it *as soon as possible*. ASCP looks forward to working with CLIAC and CMS to secure the speedy publication of a revised cytology proficiency testing regulation incorporating the consensus recommendations provided by CLIAC last year. The American Society for Clinical Pathology (ASCP) appreciates the opportunity to provide this statement to the Clinical Laboratory Improvement Advisory Committee.