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Statement
of
The American Society for Clinical Pathology

House Committee on Small Business
July 25, 2007

Hearing on

**“Competitive Bidding for Clinical Lab Services:
Where’s it Heading and What Small Businesses Can Expect.”**

Chairwoman Velázquez and distinguished members of the Committee, the American Society for Clinical Pathology (ASCP) commends the House Committee on Small Business for this opportunity to comment on the proposed implementation of the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project by the Centers for Medicare and Medicaid Services (CMS).

For reasons of patient safety and public health, ASCP is opposed to the implementation of competitive bidding for clinical diagnostic laboratory services. ASCP understands the congressional mandate on CMS to implement the demonstration project and recognizes the Herculean task of developing a sound competitive bidding demonstration project. Clearly the multiple complexities of implementing this project without harm to patients and the nation’s laboratory infrastructure remain.

ASCP joins with our colleagues in the Clinical Laboratory Coalition in requesting that the Secretary for Health and Human Services stop the demonstration project. We also join with our colleagues in asking Congress to repeal the project.

The specific details of the proposed demonstration project that have been outlined to date by CMS are inadequate. There has been both a lack of clarity in the details as well as lack of focus on patient safety and public health issues. Additionally, the agency has not reported on the potential impact of the proposed demonstration project on local laboratory infrastructure. ASCP firmly believes that, should this project launch, it threatens to rip apart the fragile health care infrastructure in a Metropolitan Statistical Area (MSA). It is clear that to date, the United States Department of

Health and Human Services (HHS) has failed to assure the public and Congress that this demonstration project will “do no harm.”

Now that CMS has reached a critical stage in the development of the project it should, at a minimum, take additional steps to ensure that the nation’s health is protected. In fact, at last week’s Open Door Forum, ASCP asked the agency to provide the laboratory community and the public with additional information and opportunities for input before they proceed with the demonstration project. Here are the steps that ASCP asked the agency to implement before they proceed:

- The confirmation of a new CMS Administrator. Kerry Weems, deputy chief of staff at the (HHS) has been nominated and if confirmed by the Senate, stakeholders and experts should have an opportunity to brief the new CMS leader on the parameters and complexities of the project.
- A “Quality of Care” impact statement should be issued by an independent body for any potential competitive bidding site. This report should focus on both the short and long-term impact of the demonstration project to public health, patient safety and laboratory infrastructure.
- Prior to a “Bidders Conference” the agency should conduct field hearings in proposed sites that involve all stakeholders including Medicare beneficiaries, laboratory personnel and other affected entities.

In closing, ASCP does not believe that CMS will be able to maintain public health and patient safety standards if it implements this project. Allowing this demonstration project to proceed without providing full assurance to the public that there will be no major disruptions to the delivery of quality health care is irresponsible public policy. Therefore, ASCP respectfully requests Congress to repeal the Medicare Clinical Laboratory Services Competitive Bidding Demonstration Project

ASCP is a nonprofit medical specialty society representing 140,000 members, including board certified pathologists, other physicians, clinical scientists, medical technologists and technicians. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive education programs, publications and self-assessment materials

If you have any questions or comments, please contact Jeff Jacobs, Vice President, Public Policy in the ASCP Washington Office by phone at (202) 347-4450, or fax at (202) 347-4453.