Office of Advocacy

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Advocacy Suggests that the Centers for Medicare and Medicaid Services Analyze of the Impacts of Cytology Proficiency Testing on Small Health Care Businesses

On March 17, 2009, the Office of Advocacy (Advocacy) filed comments with the Centers for Medicare and Medicaid Services (CMS) asking that the agency analyze the economic impacts of new cytology proficiency testing requirements on small health care businesses. A copy of Advocacy's letter may be accessed at **http://www.sba.gov/advo/laws/comments**.

On January 16, 2009, CMS published Medicare, Medicaid and Clinical Laboratory Improvement Amendments of 1988 (CLIA) Program; Cytology Proficiency Testing (PT) in the *Federal Register* (74 Fed. Reg. 3264). The CLIA required CMS to develop standards for personnel qualifications, quality control and proficiency testing of laboratory cytology technicians. CMS was not required to perform an Initial Regulatory Flexibility Act (IRFA) analysis in the proposed rule, because it certified that PT requirements would not have a significant impact on a substantial number of small businesses. CMS stated that any impacts imposed by the rule would be offset, because the increased slide testing requirements (from 10 slides to 20) would be negated by decreased testing frequency (from annual testing to every other year).

Advocacy was contacted by concerned small health care businesses and their representatives who thought that CMS had underestimated the impacts of the rule and had failed to appreciate alternative approaches that would be less onerous to the industries affected by the proposed rule while still achieving the regulatory objective. For example, they suggested that PT of laboratory technicians should be part of the overall education of cytotechnologists and that current cytology testing programs developed in the 15 years since the passage of CLIA already comply with the statute's mandates.

Advocacy suggested to CMS that had it performed an Initial Regulatory Flexibility Analysis pursuant to the Regulatory Flexibility Act, the agency would have been in a better position to determine whether the new PT measures were beneficial to public health or whether the measures were unnecessary because of the development of education-based training programs put into place by the industry after the passage of the CLIA. Also, CMS would have been better able to determine whether the new testing requirements resulted in increased costs to the affected industries.

For more information, visit Advocacy's web page at www.sba.gov/advo or contact Linwood Rayford at (202) 205-6533.