March 17, 2009

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2252-P
P.O. Box 8016
Baltimore, MD 21244-8050

Re: Medicare, Medicaid, and Clinical Laboratory Improvement Amendments of 1988 (CLIA) Program; Cytology Proficiency Testing (PT) (74 Fed. Reg. 3264, January 16, 2009)

Dear Acting Administrator Weems:

As Acting Chief Counsel for Advocacy, I am submitting comments on this matter because I am concerned about the Centers for Medicare and Medicaid Services' (CMS) compliance with the requirements of the Regulatory Flexibility Act (RFA) in this rulemaking. Section 612 of the RFA requires Advocacy to monitor agency compliance with the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act.[1] Congress established the Office of Advocacy (Advocacy) under Pub. L. 94-305 to represent the views of small business before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA); as such the views expressed by Advocacy do not necessarily reflect the views of the SBA or of the Administration.

I. Background

According to the proposed rule's preamble, the Clinical Laboratory Improvement Amendments of 1988 (CLIA) established minimum standards for all clinical laboratories

[1] Pub. L. No. 96-354, 94 Stat. 1164 (1981) (codified at 5 U.S.C. §§ 601-612) amended by Subtitle II of the Contract with America Advancement Act, Pub. L. No. 104-121, 110 Stat.857 (1996). 5 U.S.C. § 612(a).

in the United States performing testing on human specimens for health purposes. The CLIA required the Secretary of the Department of Health and Human Services to develop standards that included: 1) personnel qualifications and quality control, 2) and quality assurance procedures, 3) and required proficiency testing (PT) as one measure of ensuring quality laboratory testing. According to CMS, the proposed rule amends the CLIA regulations for cytology PT to reflect changes in cytology laboratory operations and practices. The rule amends certain definitions, lengthens the testing interval, requires validation of cytology challenges before use in testing, increases the minimum number of cytology challenges per testing event, changes the grading scheme, and allows flexibility to accommodate new technologies.[2]

CMS states in this proposed rulemaking that the majority of cytology laboratories and cytology PT programs are considered to be small entities for RFA purposes.[3] My office has received several verbal and written communications from small laboratory health care providers and their representatives who are concerned with the proposed rule's provisions regarding cytology PT. Industry stakeholders argue that CMS' attempt to regulate under the CLIA resulted in a program that fails to measure competency adequately, is not supported by science, and does not support improved health outcomes. Further, they believe that CMS failed to analyze whether the PT provisions result in a measurable benefit to the Medicare and Medicaid programs, and that the provisions are economically burdensome to the small businesses regulated by the rule. Advocacy presents CMS with the following comments based on our review of the proposed rule and the concerns brought to our attention by stakeholders.

II. Industry representatives argue that CMS' certification of no impact lacks a factual basis and that CMS should analyze the impacts of the proposed rule on the industry.

Section 605(b) of the RFA provides that if the head of the agency makes a certification that the regulation will not have a significant economic impact on a substantial number of small entities, the agency is not required to perform an Initial Regulatory Flexibility Analysis (IRFA). The certification must be accompanied by a statement providing the factual basis for the certification. In the proposed rule, CMS certifies that the rule will not have a significant impact on a substantial number of small entities.[4] CMS supports the certification by asserting that, "because only two of the proposed changes to the current PT requirements are anticipated to have non-negligible impacts, and these two changes are largely offsetting (that is, the rule requires an increase in the number of cytology challenges per test from 10 to 20, and a decrease in the frequency of testing from annually to every other year)."[5]

Industry representatives suggest that CMS' certification is misplaced because the true impact of the regulation is not measured by the increased number of cytology challenges

[2] 74 Fed. Reg. 3264.
[3] 74 Fed. Reg. 3282.
[4] Id.
[5] 74 Fed. Reg. 3283.

per test nor in the decreased testing frequency. Rather, the true impact should be measured by the savings achieved by increased technician proficiency and the increased costs to affected industries. The representatives believe that the proposed regulatory scheme lacks statistical validity and the utility necessary to assess individual proficiency (i.e., increasing the number of slides and decreasing the frequency of testing will not statistically improve cytology PT).

Stakeholders note that they are already subject to twenty-one federal quality standards to ensure quality Pap testing and individual proficiency, as overseen by the laboratory director and as part of a federal CLIA-required laboratory inspection and accreditation program. While the proposed regulatory scheme was under development during the last fifteen years, industry has adopted an educational approach to improving cytology PT that has resulted in a reduction in cervical cancer rates in the U.S. Therefore, the stakeholders believe that CMS should adopt an alternative regulatory scheme which provides for proficiency testing and documented assessment of skills in the context of the existing laboratory educational framework, as overseen by the pre-existing 21 federally mandated laboratory quality measures.[6] This scheme would incorporate complex, difficult Pap tests; utilize contemporary best practice and technology; and would take into account existing performance requirements. The industry believes that CMS should study the impacts of the proposed rule on the industry, which is predominately comprised of small businesses. It is their belief that such a study would illustrate that the proposed regulatory scheme lacks societal benefit, and that alternative approaches exist that reduce burden on the industry and prove more effective in protecting public health.

Under the RFA, if the agency cannot certify "no impact" in the proposed rule, it is required to prepare an IRFA.[7] The law states that the IRFA shall address the reasons that an agency is considering the action; the objectives and legal basis of the rule; the type and number of small entities to which the rule will apply; the projected reporting, record keeping, and other compliance requirements of the proposed rule; and all Federal rules that may duplicate, overlap, or conflict with the proposed rule.[8] The agency must also provide a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant economic impact on small entities.[9]

Industry representatives suggest that the rule will increase costs for industry despite the CMS certification of no impact. While those representatives acknowledge that some costs will remain the same because of pre-existing testing requirements, there will be increased administrative costs associated with transitioning from the 10-slide test to the 20-slide test.

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[6] This recommendation seems to be consistent with the congressional legislative attempts to improve cytology PT testing – see H.R. 1237 the Cytology Proficiency Improvement Act of the 110 Congress and the companion Senate Bill, S.2510. Neither Bill was passed into law.
[7] 5 U.S.C. § 603(a)(5).
[8] 5 U.S.C. § 604(b)(1-4).
[9] 5 U.S.C. § 604(b)(5).

Advocacy encourages CMS to perform the analysis required by the RFA and requested by the stakeholders. The analysis would increase transparency and provide the public with important information that will either serve to support the need for the proposed regulatory scheme, or it will result in data and a discussion of reasonable alternatives designed to reduce the overall burden of the rule. This request is supported by the legislative intent underlying the RFA and other federal rulemaking requirements (e.g. the Paperwork Reduction Act of 1995 and Executive Order 12866) designed to ensure sound regulation. Also, the analysis would comport with the legislative intent of the CLIA, which sought to assure protection for the public by putting into place PT of laboratories and technicians.

III. Industry representatives agree that the current cytology PT program needs to be revised but argue that CMS' attempt to modify the current oversight model is not consistent with the CLIA's legislative intent.

The CLIA provides for "periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions." Industry representatives told Advocacy that CMS interprets the statute as meaning that laboratories must ensure that each individual participates in an annual testing event that involves the examination of a 10-slide test. Individuals who score less than 90 percent on the initial slide set are retested with another 10-slide test set. Individuals who score less than 90 percent on the second test are subsequently retested with a 20-slide test set and are required to complete 35 hours of continuing medical education each time they fail the 20-slide test. To ensure annual testing of individuals, an announced or unannounced testing event is conducted on-site in each laboratory at least once each year. Stakeholders suggest that the CLIA does not stipulate how the periodic confirmation and evaluation is to be conducted, what the evaluation should consist of, or who should perform or confirm the evaluation.

The CLIA also mandated that CMS study the validity between the regulatory approach undertaken by the agency and the impact on the reliability/accuracy of the test results. According to stakeholders, since the testing was instituted in 2005, and despite the fact that the testing slides were not quality controlled or field tested, the percentage of persons passing the test each year has continued to rise. In 2008 virtually every pathologist and cytotechnologist passed the test the first time, and no one failed the second test. While these results are promising, it calls into question the utility of the testing and begs the question whether cytotechnologists are provided with slides that provide them with challenging, borderline examples of Pap smears.

Industry representatives note that CMS has apparently not undertaken the study required by the CLIA to determine the validity of the regulatory approach, yet it has now published the proposed rule seeking to modify the pre-existing regulatory PT approach. Industry representatives point to an independent study that confirms that there is no link

between CMS' regulatory approach and the accuracy and reliability of the test results.[10] The study concluded that under the current regulatory approach, the number of slides in the test is insufficient to determine proficiency and that only a 100-slide PT model can assess the skills of a pathologist or cytopathologist to within 90 percent confidence. Industry representatives concede that a 100-slide test is both cost-prohibitive and administratively impossible to implement, hence their request that CMS entertain a more cost effective education-based regulatory scheme as an alternative to the proposed regulation.

The stakeholders told Advocacy that they are committed to putting a PT regimen in place that ensures the health of the nation's women, yet is fair to the laboratory personnel that interpret the cytological preparations. They encourage CMS to study the impacts of this regulation to determine if the regulatory scheme is beneficial and cost-effective, and/or whether an alternative approach may be more conducive to the legislative intent of the CLIA, and is less burdensome for small businesses.

Conclusion

In summary, Advocacy requests that CMS give consideration to the issues raised herein. Advocacy believes there is value bringing these industry concerns to CMS' attention in an attempt to balance industry concerns with the agency's regulatory policy. Advocacy encourages CMS to better analyze the possible effects of this regulation on the affected industries. Advocacy appreciates being given a chance to provide CMS with these comments. If you have any questions or concerns, please do not hesitate to contact me, or Assistant Chief Counsel Linwood Rayford, at (202) 205-6533.

Sincerely yours,

/s/

Shawne Carter McGibbon
Acting Chief Counsel Advocacy

/s/

Linwood L. Rayford, III
Assistant Chief Counsel for Food, Drug
and Health Affairs

cc: Kevin Neyland, Acting Administrator, Office of Information and Regulatory Affairs

[10] The Dysfunctional Federally Mandated Proficiency Test in Cytopathology: A Statistical Analysis, Cancer Cytopathology 111:467-476, 2007.