



November 18, 2013

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1443-P,
P.O. Box 8013,
Baltimore, MD 21244-8150

Re: Comments on the proposed rule: Medicare Program; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral: File Code CMS-1443-P.

Dear Ms. Tavenner:

The Association of Public Health Laboratories (APHL) is in favor of the proposed changes to the Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing (PT) Referral. Allowing the Secretary discretion in dealing with "unintentional referrals" allows laboratories that have made an honest mistake to continue the important work that they do. APHL appreciates CMS's efforts to make the enforcement process as fair as possible.

We believe that the three-tiered approach to enforcement of the PT referral rule is a step in the right direction, but unfortunately, the new rule provides only a "narrow exception" to CMS's longstanding interpretation of what constitutes "intentional" PT referral. APHL believes that clarification, education and examples on what exactly constitutes an intentional and unintentional referral will be necessary.

For example, would the following potential referral scenarios be "unintentional"?:

- A sample has been rendered to appear as a patient sample to meet the CLIA regulations that calls for PT samples to be treated like patient samples. An abnormal result could result in the blinded sample being referred to another laboratory.
- A sample was referred to another laboratory, but a supervisor caught the mistake and promptly contacted the receiving laboratory to discard the sample(s).

Given the varying circumstances in which a PT sample might be referred unintentionally, we hope that CMS will consider each situation closely and with standard criteria before deciding what sanctions to levy.

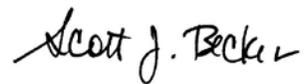
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APHL appreciates the opportunity to comment on the proposed rule: Medicare Program; Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral. We would be happy to provide any information that would be helpful as you write the final rule.

Sincerely,

A handwritten signature in black ink that reads "Scott J. Becker". The signature is written in a cursive style with a small checkmark at the end.

Scott J. Becker, MS Executive Director
Association of Public Health Laboratories

