



**American Hospital  
Association**

Liberty Place, Suite 700  
325 Seventh Street, NW  
Washington, DC 20004-2802  
(202) 638-1100 Phone  
[www.aha.org](http://www.aha.org)

November 13, 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 21244-1850

***RE: CMS-1443-P, 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; Proposed Rule; (Vol. 78, No.184), September 23, 2013.***

Dear Ms. Tavenner:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule regarding changes to the *Clinical Laboratory Improvement Amendments of 1988* (CLIA) enforcement actions for proficiency testing (PT) referral and changes to contracting policies for rural health clinics (RHCs). The AHA appreciates CMS's proposal regarding alternate sanctions for PT referrals, although we are concerned that several of the proposed sanctions are unduly severe. Further, the AHA is pleased that CMS has proposed more flexibility for RHCs in meeting the employment requirements of the law. We believe the proposal will provide RHCs with regulatory relief and allow them to utilize individualized approaches to appropriately staff their facilities with non-physician practitioners (NPPs).

## **CHANGES TO CLIA ENFORCEMENT ACTIONS FOR PT REFERRAL**

**Overall, the AHA believes that the proposed rule largely aligns with the guidance that hospital and laboratory organizations have provided to CMS and Congress regarding sanctions for PT referrals. While the categories that CMS establishes are reasonable, we are concerned that some of the corresponding sanctions remain too severe.** In addition, the AHA requests additional explanation and clarification for some of CMS's proposed regulatory language.



CLIA requires laboratories that engage in moderate or high-complexity testing to enroll in a PT program that covers all the specialties and subspecialties for which the laboratory is certified and all analyses listed in the CLIA regulations. PT is a tool to ensure the accuracy and reliability of laboratory test results. Laboratories are required to test PT samples in the same manner as patient specimens, except that they may not refer these samples to another laboratory for testing for any reason.

The CLIA statute, until recently, required the revocation of a laboratory's CLIA certificate and a subsequent two-year ban of the owner or operator of the laboratory from owning or operating any CLIA-certified laboratory when a PT referral had been confirmed. These automatic and severe sanctions effectively shut down laboratories for even minor or inadvertent PT referrals. The two-year ban for the owner and operator has been especially problematic for hospitals and health systems because they may have multiple laboratories that share a common owner or operator. Additionally, hospitals and health systems often have many laboratories operating under a single CLIA certificate. In these circumstances, if a PT referral violation occurred in a single laboratory within the hospital or health system and the CLIA certificate was revoked, all laboratories under that hospital or health system's certificate would be banned from performing laboratory testing, a situation that poses severe risk to patient safety and quality of care.

Over the past several years, the AHA has urged Congress to address the severe sanctions that laboratories faced for inadvertent PT referrals. Laboratories should not be punished for following their standard operating procedures, which may result in the unintentional referral of a PT sample to another laboratory. In 2012, the AHA supported the passage of the *Taking Essential Steps for Testing Act of 2012* (TEST Act), which gave CMS greater discretion in determining sanctions for PT referrals. These sanctions would be in lieu of the automatic revocation of the CLIA certificate and subsequent imposition of the two-year ban.

In implementing the provisions of the TEST Act, CMS proposes to establish three categories of sanctions for PT referral to be applied under certain specified conditions and based on the severity and extent of the PT referral. The agency would reserve revocations and the most serious sanctions for the most egregious violations while assigning lesser sanctions and civil monetary penalties (CMPs) to cases involving less serious violations.

**Category 1: Revocation of CLIA Certificate.** CMS proposes the most severe sanctions for the most egregious violations. This would include cases of repeat PT referral or where a laboratory reports another laboratory's test results as its own. In these cases, CMS proposes that the CLIA certificate be revoked, and the owner and operator be banned from owning or operating a CLIA-certified laboratory for at least one year. These cases could also result in a CMP.

**The AHA generally agrees with CMS's approach for category 1 violations.** However, we are concerned that CMS's proposal to impose a mandatory one-year prohibition on the owner and operator of the responsible laboratory from owning or operating any CLIA-certified laboratory will have a devastating impact on the patients served by large national health systems that often own and operate many laboratories in many locations. **The AHA believes that the**

**violations described in this category are deserving of severe sanctions, but we strongly recommend that CMS allow itself some discretion, particularly in instances in which imposing an ownership ban across an entire health system would endanger the public's health.** This could be accomplished by indicating that in category 1 violations, CMS "may" prohibit the owner and operator from owning or operating a CLIA-certified laboratory for at least one year.

With regard to CMS's proposal to impose the most severe sanctions on cases of repeat PT referrals, we request that CMS clarify that a "second instance" of a referral only includes an entirely different and separate set of PT samples sent to the laboratory on a different date. A request to perform multiple analyte testing on a referred specimen during the same PT event should not be considered to be a "second instance" of referral.

**Category 2: Suspension or Limitation of CLIA Certification.** CMS proposes an intermediate category of sanctions that would be applied to certain PT referral situations in which a laboratory refers out a PT sample to another laboratory, receives the result before the PT cutoff date, but does not use the other laboratory's result as its own. Unless this is a repeat PT referral, CMS proposes to suspend or limit the CLIA certificate for less than one year rather than revoke it. In determining whether to suspend or limit the CLIA certificate, CMS would consider criteria such as the extent of the PT referral practice and its duration. If CMS surveyors determine that there were prior PT referrals that occurred but were not cited by CMS, then the CLIA certificate would always be suspended rather than just limited.

In the proposed rule's preamble, CMS notes that one difference between a suspension and a revocation is that a suspension "usually" applies to only the individual laboratory in question rather than all laboratories that are under the control of the owner or operator. Part of the reason that the TEST Act was enacted was to ensure that an error made by a single laboratory within a health system would not cause all the laboratories within the system to be shut down.

**Therefore, the AHA urges CMS to clarify that a suspension would not apply to laboratories other than the individual laboratory involved in the PT referral unless CMS surveyors determine that prior referrals not previously cited by CMS occurred in more than one laboratory under the control of the owner or operator.**

CMS also states that the duration of a suspension would reflect the number of samples referred, the period the referrals had been occurring, the extent of the practice and other criteria. **The AHA requests that CMS provide additional detail about how the duration of a suspension would be determined. For consistency, the AHA recommends that CMS, in consultation with the laboratory and hospital community, define reasonable criteria to determine the duration of a suspension rather than leaving that decision up to the individual CMS surveyor.**

CMS proposes that if the CLIA certificate is suspended, the agency would impose "state on-site monitoring" of the laboratory. **The AHA requests that CMS explain what is involved in state on-site monitoring and whether there are costs associated with such monitoring.**

**Category 3: General Sanctions.** CMS proposes that the least severe level of sanctions would be applied to laboratories that refer PT specimens that are not tested by another laboratory. In these cases, the laboratory in violation would always be required to pay a CMP and comply with a directed plan of correction, including staff training on proper procedures.

The AHA is concerned that CMS's proposal to require CMPs even for minor, unintentional infractions is excessive and should be reconsidered. CMS describes an example whereby the laboratory realizes it has accidentally sent out a PT specimen and calls the reference laboratory to which a specimen was referred to stop any analysis and reporting. The AHA recommends that CMS acknowledge that these types of referrals "without intent" sometimes occur. **Thus, the agency should not require the imposition of CMPs for such category 3 violations, but rather should mandate only education of the staff in the laboratory where the accidental referral occurred.**

CMS also seeks comments about other scenarios in which lesser sanctions may be appropriate. The AHA requests that CMS finalize its proposal made in the February 7, 2013 Program Efficiency, Transparency, and Burden Reduction Proposed Rule to establish a narrow exception to what CMS would consider an "intentional" PT referral. In this proposed exception, lesser alternative sanctions would be imposed when there is a single instance of PT sample referral related to reflex or confirmatory testing, as long as the sample referral is consistent with the laboratory's written standard operating procedure. This would be another example of a situation in which the AHA recommends against the imposition of CMPs, and instead supports mandatory staff education.

## **CHANGES TO CONTRACTING POLICIES FOR RHC**

**The AHA supports CMS's proposal to provide more flexibility for RHCs in meeting the employment requirements under the law.** Specifically, the *Rural Health Clinic Services Act of 1977* requires RHCs to employ a physician assistant (PA) or nurse practitioner (NP). However, CMS interprets the term "employ" to mean that the employer issues a W-2 form to the employee. Yet, current Medicare regulations prohibit RHCs from being paid for services furnished by contracted individuals other than physicians and do not authorize RHCs to contract with RHC practitioners other than physicians. The AHA has long believed that these regulations are an over-interpretation of the law and an unnecessary restraint of a hospital's ability to staff its RHC to best meet the needs of its patients and community. Therefore, we are pleased that CMS now proposes to allow RHCs to contract with NPPs as long as the RHC meets the statutory requirement that at least one PA or NP is employed by the RHC. The ability to contract with PAs, NPs and other NPPs would allow hospitals to utilize individualized approaches to appropriately staff their RHCs.

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Thank you again for the opportunity to comment. If you have any questions, please contact me or Roslyne Schulman, director for policy development, at (202) 626-2273 or [rschulman@aha.org](mailto:rschulman@aha.org).

Sincerely,

/s/

Rick Pollack  
Executive Vice President