



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 14-23-CLIA

DATE: May 2, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Publication of Final Rule CLIA "TEST ACT" for Proficiency Testing (PT)
Referral - *Informational Only*

Memorandum Summary

- **Publication of Final Rule:** CMS-1443-FC published on May 2, 2014. The effective date for the Changes to Clinical Laboratory Improvement Amendments (CLIA) of 1988; Enforcement Actions for Proficiency Testing Referral provisions is July 1, 2014.
- **Effect of Changes:** The changes provide the Secretary with discretion as to which sanctions may be applied to cases of intentional PT referral.

The rule for the prospective payment system for the Federally Qualified Health Centers (FQHCs) was published on May 2, 2014. One part of this rule implements major parts of recent legislation that permits the Centers for Medicare & Medicaid Services (CMS) to exercise greater discretion in enforcing PT requirements under CLIA. The federal legislation is entitled, "Taking Essential Steps for Testing Act ("TEST Act") (Pub. L. 112-202)." The law was enacted in December 2012. It amended section 353 of the Public Health Service Act (the CLIA statute) to provide the Secretary with discretion as to which sanctions may be applied to cases of intentional PT referral. Such discretion may in some circumstances replace the automatic revocation of the laboratory's CLIA certificate and subsequent imposition of the two-year ban on the laboratory's owner or operator, which would prevent them from owning or operating a CLIA-certified laboratory. This final rule implements the TEST Act and provides the prescriptive framework for the application of sanctions in PT referral cases. The rule allows for a better fit between the nature and extent of an intentional PT referral violation and the penalties that are imposed.

This final rule includes the three tiered categories of sanctions for a PT referral (including revocation of the CLIA Certificate and/or alternative sanctions) to be applied under certain specified conditions, based on the severity and extent of the violation. These categories reserve revocations and the most serious sanctions for the most egregious violations while assigning lesser sanctions and civil monetary penalties to cases involving less serious violations.

The current process for PT referral cases remains in effect. All PT referral cases are referred to CMS Regional Office and then the cases and supporting documents must be forwarded to Melissa

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Singer, Melissa.singer@cms.hhs.gov, for review by Central Office. Additional guidance will be forthcoming.

Final rule, CMS-1443-FC, published on May 2, 2014. The publication can be viewed at: <http://www.gpo.gov/fdsys/pkg/FR-2014-05-02/pdf/2014-09908.pdf>.

The effective date for the Changes to Clinical Laboratory Improvement Amendments of 1988; Enforcement Actions for Proficiency Testing Referral provisions is July 1, 2014.

Effective Date: July 1, 2014

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management