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Center for Clinical Standards and Quality/Survey & Certification Group

S&C: 18-07-CLIA

DATE: **December 15, 2017**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing (PT) Referral Categories

Memorandum Summary

- **Clarification of Proficiency Testing (PT) Referral:** The final regulations implementing the *Taking Essential Steps for Testing Act ("TEST Act")* include three categories for PT Referral which are based on severity and extent of the violation.

Background

The *Taking Essential Steps for Testing Act of 2012 ("TEST Act")* (Pub. L. 112-202, enacted on December 2012) 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 for two years.

In final rules published on May 2, 2014 (79 Fed. Reg. 25,436, and on May 12, 2014 (79 Fed. Reg. 27,106), the Centers for Medicare & Medicaid Services (CMS) promulgated regulations to implement the TEST Act and provided the prescriptive framework for the application of sanctions in PT referral cases. These regulations allow for a more appropriate enforcement action based upon the nature and extent of an intentional PT referral violation and the penalties that are imposed. These regulations include three categories of sanctions for a PT referral to be applied under certain specified conditions, based on the severity and extent of the violation. These categories reserve revocation and the resulting laboratory director/owner/operator prohibition for the most egregious violations while permitting less serious sanctions in cases where circumstances warrant.

Category 1 (42 C.F.R. §493.1840(b)(1))

Category 1 is for the most egregious violations, encompassing cases of repeat PT referral, regardless of circumstances revolving around the violation, and cases where a laboratory reports

another laboratory's PT results as its own to the PT program on or before the PT event close date. This category includes the revocation of the laboratory's CLIA certificate for at least one year, bans the owner and operator from owning or operating a CLIA-certified laboratory for at least one year, and may include the imposition of a CMP.

For example, a laboratory may have two distinct sites, Laboratory A and Laboratory B, that operate under different CLIA numbers, where Laboratory A has received PT samples to be tested as part of their enrollment in PT as required by the CLIA regulations. If Laboratory A were to refer PT samples to Laboratory B, receive test results from Laboratory B prior to the event cutoff date, and report those results to the PT program, the scores for the PT event would not reflect the performance of Laboratory A. Since the PT scores would actually reflect the accuracy and reliability of Laboratory B rather than Laboratory A, the purpose of the proficiency testing would be undermined.

Note: The CLIA statute and regulations generally prohibit a person who has owned or operated a laboratory which has had its certificate revoked from owning or operating a CLIA-certified laboratory for <u>two years</u> (*see,* 42 C.F.R. § 493.1840(a)(8)). However, if the revocation occurs due to intentional PT referral, and certain findings are made, the Secretary may substitute intermediate sanctions instead of the otherwise applicable two-year prohibition (42 U.S.C. § 263a(i)(3), *see* 42 C.F.R. § 493.1840(b)). Regardless, when revocation does occur, the prohibition applies to the laboratory director as the operator of the laboratory (*see,* 42 C.F.R. §493.2, definition of "operator") and generally applies to the owner as well.

The owner may be exempt from ban if, after review, CMS finds that there is no evidence that:

- Patients would be put at risk by the owner being exempted from ban;
- The owner participated in or was otherwise complicit in the PT referral; and,
- The laboratory received a PT sample from another laboratory within 2 previous survey cycles and failed to immediately report the receipt to CMS or to the appropriate CMS-approved Accreditation Organization (AO).

Thus, the application of the owner exemption from the ban is determined on a case-by-case basis (*see,* 42 C.F.R. §493.1840(b)(ii)).

Repeat proficiency testing referral means a second instance in which a proficiency testing sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory's proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved AO). This means that if a laboratory has been sanctioned for <u>any</u> category of PT referral in the prior to survey cycles, the second, or "repeat", referral will considered a Category 1.

<u>Category 2 (42 C.F.R. §493.1840(b)(2))</u>

The second category of PT referral applies to cases where a laboratory refers its PT samples to another laboratory for analysis and obtains test results for the PT samples

from the other laboratory on or before the cut-off date for the PT event, but reports its own PT sample results to the PT program. In these cases, the laboratory's CLIA certificate is suspended or limited in combination with the imposition of alternative sanctions. At a minimum, the alternative sanctions would include a CMP as well as directed plan of correction (dPOC) which requires staff training in addition to other necessary requirements as determined by CMS.

In determining whether to recommend the suspension or limitation of the CLIA certificate, apply the criteria of 42 C.F.R. §493.1804(d). CMS Central Office and ROs will work together to determine the course of action based on the circumstances of each case.

For example, Laboratory A has been having technical issues with a particular test so it refers PT samples to Laboratory B to "check" its results and receives the results back from Laboratory B *prior* to the event cut-off date. In this case, Laboratory A reports its own results to the PT program.

Category 3 (42 C.F.R. §493.1840(b)(3))

The third category includes cases of PT referral where the laboratory refers its PT samples to another laboratory for analysis and obtains test results for the PT samples from the other laboratory after the cut-off date for the PT event. In these cases, alternative sanctions should be imposed, and will always include the imposition of a CMP as well as dPOC which requires staff training in addition to other necessary requirements as determined by CMS.

If CMS determines that a PT sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the PT referral is not a repeat PT referral, CMS may impose alternative sanctions in accordance with 42 C.F.R. §493.1804(c). It is important to note that in this specific case, CMS will consider the PT referral to be improper rather than intentional. Any laboratory that receives a PT sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason (42 C.F.R. §493.801(b)(4)).

For example, Laboratory A has been having technical issues with a particular test so it refers PT samples to Laboratory B to "check" its results and receives the results back from Laboratory B *after* to the event cut-off date. In this case, Laboratory A reports its own results to the PT program.

Category 3 would also apply if the laboratory's procedure manual, at the time of referral, stated that specific samples would need to be sent to another laboratory for confirmation or additional testing. This scenario would also apply if Laboratory A sent PT samples to Laboratory B and Laboratory B recognized the samples as PT samples and destroyed the samples upon receipt. In this case, Laboratory A would not be able to receive results for the PT samples from Laboratory B prior to the event close date.

Please note: The current process for PT referral cases remains in effect. All PT referral cases are sent by the SA to CMS RO, and then the cases and supporting documents must be forwarded to Sarah Bennett at Central Office for review.

Additional information on PT and PT referral can be found in CLIA Brochure #8, "Proficiency Testing and PT Referral" on the CLIA website at: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html.

Contact: For questions, please contact the LabExcellence mailbox at LabExcellence@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

cc: Survey and Certification Regional Office Management