DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and State Operations/Survey & Certification Group

Ref: S&C-07-02

DATE: **November 16, 2006**

FROM: Director
Survey and Certification Group

TO: State Survey Agency Directors

SUBJECT: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Additional Topics Concerning Proficiency Testing (PT) Policies – **Action**

Letter Summary

- This letter transmits a summary of current policies and guidance that updates previous memoranda relating to the determination of compliance with CLIA PT requirements. These policies and guidance will also be specified within the State Operations Manual (Chapter 6 Special Procedures for Laboratories) and Appendix C (Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services).

- The Centers for Medicare & Medicaid Services (CMS) regional offices (RO) and State Survey Agencies (SA) have mutual roles regarding monitoring and review of laboratory enrollment and successful PT performance as a part of determining compliance with the CLIA requirements.

The following incorporates the policies and activities that are to be considered when determining laboratory compliance with PT enrollment, participation, and/or performance:

- A rolling timeframe is used to determine **unsuccessful PT** performance wherein the laboratory incurs either 2 of 3 or 2 consecutive unsatisfactory scores; that is, for any 2 out of the 3 most recent PT events, in an analyte, subspecialty, or specialty. The timeframe does not stop, nor does it re-set annually. It will be based on information available in the CLIA PT monitoring system.

- Immediate jeopardy (IJ) is defined as an egregious situation in which results or practices in a laboratory are or could lead to real or potential harm to a patient(s) or the public, and immediate action is necessary to correct the problem. IJ is not called for every unsuccessful PT; however, the SA should gather sufficient information to determine if patient results are in significant risk of error. In this case, an onsite survey may be warranted. This determination should be made in consultation with the RO.

- IJ is called for every intentionally (improperly) referred PT sample or event.

- Unacceptable PT performance means unsatisfactory performance for a single analyte. "Unacceptable performance" is not used to describe an unsatisfactory score for a subspecialty (such as bacteriology or virology) that does not contain analytes.

- The terms PT performance and participation are interchangeable; surveyors should routinely use 'performance.'

- All SAs are required to conduct PT desk reviews for their certificate of compliance laboratories at least every 30-45 days using the PT monitoring system reports #155 and #153. The SA must verify the scores using information from the PT provider and/or the laboratory prior to recommending an action, and take any necessary follow-up actions based on their findings in collaboration with their RO. PT must also be reviewed during the on-site survey. The SA must ensure that the laboratory has effectively corrected all problems that lead to an unsatisfactory or unsuccessful PT performance and has taken steps to **prevent a recurrence of the problem(s) that caused the unsatisfactory or unsuccessful performance. The SA should also review quality control results with patient results during the period of time when the poor performance occurred.**

- For the **initial unsuccessful PT**, the RO may allow the SA to request that a laboratory undertake training and technical assistance (T&TA) provided: 1) the laboratory has a good history of compliance; 2) there is no IJ, no PT referral, no current significant quality problems; and 3) the laboratory has agreed to correct the problem causing the unsuccessful PT.

    - The SA must first verify that the PT scores are correct by contacting either the PT program or the laboratory to review the results of the testing that caused the unsuccessful performance. After verification of the scores, the SA with RO consent, sends the laboratory a letter proposing T&TA with a Form CMS-2567 citing the condition-level deficiency. NOTE: This can be a blanket consent for SAs for all initial unsuccessful PT. The letter should also include the consequences of another PT failure.

    - This information is entered into Automated Survey Processing Environment (ASPEN) or ASPEN Central Office (ACO) under "other." Please note that the system part of this guidance may change when CLIA converts to Quality Improvement & Evaluation System (QIES).

    - The laboratory may continue testing during this period.

    - The laboratory must document completion of the T&TA and correction of the problem(s) that caused the unsuccessful PT performance. The documentation must be submitted promptly to the SA.

    - When the laboratory completes the T&TA and notifies the SA, it is placed back into compliance by the SA.

- These actions for the initial unsuccessful PT performance must be entered into the CLIA enforcement data base in a timely manner by the RO.

- For a non-initial (subsequent—not the first) unsuccessful PT performance, the SA must verify that the scores are correct by contacting either the PT program or the laboratory to review the results of the testing that caused the unsuccessful performance.

- If the subsequent unsuccessful PT performance is confirmed, in a different analyte, subspecialty or specialty, the RO has the option, based on the laboratory's compliance history, SA recommendation, and the specific circumstances that caused the failure, to impose another T&TA rather than impose a sanction as specified in subpart R. If the RO determines that another T&TA is warranted, follow the procedure noted above for an initial unsuccessful performance.

- If the failure is for the same analyte, specialty or subspecialty, then a more stringent sanction, as noted below, is imposed.

- If the imposition of a more stringent sanction is decided, the SA refers the Form CMS-2567 with condition-level noncompliance to the RO.

- The RO then sends a letter along with the Form CMS-2567 citing the condition level deficiency to the laboratory that proposes sanctions, including a limitation of the laboratory's certificate in the area of failure for six months, and proposes cancellation of their Medicare and/or Medicaid payment immediately for no less than six months.

- If the laboratory does not appeal the sanctions, they are imposed.

- In order to come back into compliance and remove the sanctions, the laboratory must obtain satisfactory scores in 2 consecutive re-instatement PT events.

- The laboratory should purchase the re-instatement PT samples from any CMS-approved PT program.

- The scores of the re-instatement PT are entered into the CLIA PT data base as "non-routine" by the PT program and may be found at the bottom of report # 155**.** The laboratory will receive copies of their re-instatement scores from the PT program from which it purchased the two re-instatement events.

- The laboratory may **voluntarily withdraw** from testing prior to the RO sending the letter to impose a sanction or limitation to the laboratory if it notifies the SA that it has stopped testing the unsuccessful analyte(s), subspecialty, or specialty. The laboratory must still complete the two consecutive re-instatement PT events with satisfactory scores and correct the problem that caused the unsuccessful performance. If the laboratory satisfactorily completes the two re-instatement events (which may be completed in less than 6 months), it will be back in compliance. The SA will monitor this in coordination with the RO and use the same procedure as indicated for all unsuccessful PT performance.

- Re-instatement (non-routine in the PT system) PT samples are NOT included in the grading for routine PT events that are sent 3 times per year and are, therefore, not counted toward a determination of PT performance.

- If a laboratory chooses to use PT samples from a CMS-approved PT program for the purpose of meeting the quality assurance requirements at 42 CFR §493.1236(c) and intentionally refers those samples to another laboratory, as stated at §493.801(b)(4), it will have its certificate revoked as stated in §493.1840. This refers to **ALL** samples purchased from a PT program; samples for tests listed in Subpart I AND samples for tests not listed in subpart I.

- Laboratories experiencing poor performance for analytes using a PT program other than the one that is designated for CLIA compliance purposes or for analytes not listed in Subpart I, should address the failures via their own internal quality assurance protocol.

- To avoid any implication of PT referral, laboratories using previously tested PT samples for competency, training, and other purposes should wait until after the PT program returns the results on these samples prior to re-testing them.

The FY 2007 CLIA budget call memorandum, released on June 13, 2006, explains that the States have been provided funding for PT desk review activities. This workload should not be entered into OSCAR/ODIE, i.e., the 670 data base. Information regarding recording of the 2567 information will be forthcoming.

States should notify their ROs and ROs should report to CMS central office PT staff any problems they encounter with PT programs and include the corresponding reports.

Please contact Judy Yost at (410) 786-3407, Harriet Walsh at (410) 786-7304, or a member of the CLIA team at (410) 786-3531 if you have any questions about this memo.

Effective Date: Immediately. The State survey agency should disseminate this information within 30 days of the date of this memorandum.

Training: This information should be shared with all CLIA survey and certification staff, their managers, and the State/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)
RO CLIA Consultants