D2016
(Rev. 140, Issued: 05-29-15, Effective: 05-29-15, Implementation: 05-29-15)

§493.803 Condition: Successful participation

(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA.

(b) Except as specified in paragraph (c) of this section, if a laboratory fails to

participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part.

(c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists:

(1) There is immediate jeopardy to patient health and safety.

(2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance.

(3) The laboratory has a poor compliance history.

Interpretive Guidelines §493.803

Only the PT program has the capability to correct scores in the CMS PT monitoring system.

No single PT enforcement protocol is universally applicable for all situations. Unique circumstances may require special considerations or actions that may not conform to the general approach outlined below. The laboratory's compliance history, its willingness to take remedial actions, and the professional judgment of surveyors, RO CLIA laboratory consultants and enforcement personnel may be factors in determining an appropriate PT enforcement plan.

Careful review of PT performance reports and other available information should always be performed to determine whether the PT results truly represent failed PT. The potential of a PT program data input error or other factors beyond the laboratory's control should be considered. If the laboratory has made a transcription error(s), it is considered erroneous PT result(s).

If review and verification of PT performance reports confirm unsuccessful PT, cite as a Condition-level deficiency (use D2016 on the Form CMS-2567).

NOTE: The CMS PT monitoring system may NOT be used alone to determine unsuccessful participation. Surveyors must verify any unsuccessful participation indicated in the PT monitoring system. This may be done by reviewing PT results supplied by the approved PT program (they will send copies to the surveyor if requested) or from results sent to the laboratory by the PT program.

If the unsuccessful PT participation is the first occurrence for the laboratory, and none of the exceptions listed at §493.803(c)(1)-(3) exist, notify the laboratory and instruct them to seek training of its personnel, obtain the necessary technical assistance to correct the problem causing the unsuccessful participation, or both. SAs may initiate training and/or technical assistance after first obtaining RO concurrence. No on-site review is required to initiate this action.

The laboratory must submit an acceptable plan of remedial action, listing projected completion dates and other pertinent information for its training and/or technical assistance efforts. Follow-up is necessary to verify that the laboratory has carried out its plan. Satisfactory participation in the next PT event would provide verification that the laboratory's remedial action, training and/or technical assistance were successful. The remedial action plan should demonstrate that the laboratory will correct its problems within 3 months, although special circumstances may be considered. If a laboratory refuses to take acceptable training and/or technical assistance actions (including failure to submit an acceptable plan of remedial action, or failure to complete its plan), sanction action may be initiated with concurrence from the RO.

When the unsuccessful PT participation is not the first such occurrence for the laboratory, cite as a condition-level deficiency and take appropriate enforcement action. For immediate jeopardy cases, the procedures in Subpart R apply. For non-immediate jeopardy situations, enforcement procedures should be completed within 90 days from the date that the unsuccessful PT was first identified. In immediate jeopardy situations, enforcement procedures should be completed within 23 days from the date unsuccessful participation of PT is first identified.

Example:

A laboratory scores 60% on a testing event in mycobacteriology. On the next testing event, the laboratory fails to participate in mycobacteriology. The citations are D2030 (§493.825), D2037 (§493.825) and D2016 (§493.803). (Note: It is not necessary to cite the standard for unsatisfactory analyte performance. However, it is necessary to cite the standard when the laboratory fails to participate in a testing event so that the laboratory is made aware that such deficient practice results in a score of 0 for the testing event.)

Example:

A laboratory scores 60% on uric acid PT samples. On the next testing event, the laboratory scores 40% on the same analyte. The citations are §§493.841(f), and 493.803. (Note: Cite the standard for unsuccessful performance and the condition for unsuccessful participation. It is not necessary to cite the standard for unsatisfactory analyte performance.)

When recommending to the RO that a laboratory be subject to sanctions, submit copies of the laboratory's testing event or analyte score(s) that were unsatisfactory and the correct responses provided by the PT program. Also, enclose copies of any correspondence sent

to or received by the laboratory concerning its PT performance.