CMS Manual System

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Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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SUBJECT: Revisions to Chapter 6 - "Special Procedures for Laboratories"

I. SUMMARY OF CHANGES: This revision contains editorial changes to Chapter 6, Sections 6000 – 6316. In addition to these editorial changes, we have corrected the acronym "TJC" for the Joint Commission as the acronym was incorrect. We have also included clarifications to the Limited Public Health testing and Home Health Agencies and Hospices. There are no policy changes in this document.

NEW/REVISED MATERIAL--EFFECTIVE DATE: May 8, 2009
IMPLEMENTATION DATE: May 8, 2009

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

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***Unless otherwise specified, the effective date is the date of service.**

State Operations Manual

Chapter 6 - Special Procedures for Laboratories

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(Rev.45, 05-08-09)

Program Background and Actions Related to Certification

6000 - Background

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, amended §353 of the Public Health Service Act (42 U.S.C. 263a), to extend jurisdiction of the Department of Health and Human Services (HHS) to regulate all laboratories that test human specimens for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. CLIA mandates that virtually all laboratories, including physician office laboratories, meet applicable Federal requirements and have a CLIA certificate in order to operate.

Regulations implementing CLIA are codified under 42 CFR Part 493. These regulations require that all laboratories or entities that perform laboratory testing:

- Pay user fees as assessed by CMS to finance the entire cost of administering the CLIA program;
- Submit specific information to HHS or its designee;
- Comply with specific administrative and program requirements;
- Submit to surveys to assess compliance with CLIA requirements;
- Be subject to specified enforcement actions; and
- Apply for CLIA certificates based on the complexity of testing performed in the laboratory or based on accreditation by a CMS-approved accreditation organization, or
- Be *located* in a State with a CMS approved State laboratory licensure program, be licensed or approved in accordance with State requirements.

Section 6141 of the Omnibus Budget Reconciliation Act of 1989, Public Law 101-239, requires that laboratories participating in the Medicare program comply with CLIA requirements. Therefore, all laboratories, with the exception of laboratories licensed by a State with a CMS-approved State laboratory licensure program (CLIA-exempt laboratories) must obtain a CLIA certificate to operate and to be eligible for payment under Medicare and Medicaid. Although CLIA-exempt laboratories do not need a CLIA certificate to operate, they are assigned a CLIA identification number for Medicare and Medicaid payment purposes.

6004 - Consultative CLIA Activities

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The Centers for Disease Control and Prevention (CDC) assists *the* CMS CO CLIA component in evaluating and approving proficiency testing programs, accreditation programs and State laboratory licensure programs.

Clinical Laboratory Improvement Advisory Committee (CLIAC) – CLIAC is a committee that consists of experts knowledgeable in all scientific areas of the laboratory disciplines, the field of medicine, public health, manufacturers, clinical practice and consumers. The authority for this committee is 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. This committee provides scientific and technical advice and guidance to HHS regarding the need for, and the nature of:

- Revisions to the standards under which clinical laboratories are regulated;
- The impact on medical and laboratory practice of proposed revisions to the standards; and
- The modification of the standards to accommodate technological advances.

CDC oversees the CLIAC and provides CMS with any other required scientific and technical expertise.

6006.1 – Certificate of Registration

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

A Certificate of Registration is issued initially to any laboratory that applies for a Certificate of Compliance or Certificate of Accreditation and pays appropriate registration fee(s). For laboratories applying for a Certificate of Compliance, a Certificate of Registration is temporary and indicates only that the laboratory is registered with CMS and does not indicate approval or compliance with CLIA requirements. It permits the laboratory to operate until CMS or its designee determines through a survey that all applicable requirements are met. A Certificate of Registration can be reissued if a laboratory requests an appeal of a sanction imposed as a result of noncompliance with one or more CLIA conditions, which does not pose immediate jeopardy. In such a case, a Certificate of Registration is reissued and remains effective until an Administrative Law Judge (ALJ) of the Departmental Appeals Board (DAB) makes a decision. All sanctions imposed against the registration certificate carry forth when reissued.

For laboratories applying for a Certificate of Accreditation, a Certificate of Registration is temporary and indicates only that the laboratory is registered with CMS. It permits the laboratory to operate until CMS receives verification of accreditation approval. The

Certificate of Registration is valid for a period of no more than 2 years. Such laboratories must provide CMS with proof of accreditation by an approved accreditation program within 11 months of issuance of the Certificate of Registration.

6006.4 – Certificate of Compliance

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

A Certificate of Compliance is issued to a laboratory once it is determined through a survey to be in compliance with applicable requirements for laboratories performing nonwaived tests. The Certificate of Compliance will reflect the effective date for each approved specialty/subspecialty. A Certificate of Compliance may also be reissued to a laboratory that has one or more Condition-level deficiencies that do not pose immediate jeopardy (see §6262).

If a Certificate of Compliance is due to expire prior to a hearing date, it may be reissued if CMS finds that conditions in the laboratory do not pose immediate jeopardy. It remains effective while awaiting the hearing decision. All sanctions imposed against the certificate carry forth when the certificate is reissued. A Certificate of Compliance is valid for a period of two years. Upon certificate expiration, and after recertification and payment of appropriate fees, the laboratory's certificate will be renewed for another 2-year period.

6007 - CLIA Certificate Status Changes

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Laboratories operating under a COW or Certificate for PPM procedures must notify HHS or its designee prior to performing and reporting results for any test not covered under their certificate. The laboratory must submit a new CLIA application (Form CMS-116). For specific instructions on the application process, see §6006. A fee coupon will be system generated once the data is entered into the CLIA data system. The certificate is issued once the appropriate fees are paid.

A laboratory operating under a Certificate of Compliance or Certificate of Accreditation and that is no longer performing nonwaived testing (excluding PPM procedures), may request to change to either a COW or a certificate for PPM procedures. However, the laboratory is not required to change its certificate. The laboratory may decide to retain its current certificate and change the type of certificate upon its certificate expiration. If the laboratory elects to change the certificate, the data must be updated in the CLIA data system; therefore, a new certificate and fees will be system generated. The certificate will be issued after the fees are paid.

A laboratory requesting a change from a Certificate of Compliance to a Certificate of Accreditation remains under CMS jurisdiction until its deficiencies are corrected. Once the PoC has been accepted, the certificate change data may be entered into the CLIA data system. A laboratory can elect to retain the Certificate of Compliance until the certificate expiration date and subsequently change the certificate status. If the laboratory elects to change its certificate status prior to the expiration date of the current CLIA certificate the data system must be updated. A new certificate will be generated once the data is entered into the data system; therefore, a Certificate of Registration and fees will be system generated. The Certificate of Registration will be issued once the appropriate fees are paid. The laboratory then continues the process for a Certificate of Accreditation.

A laboratory requesting a change from a Certificate of Accreditation to a Certificate of Compliance will have its survey authority transferred to the appropriate State Agency. The CLIA system must be updated *and* a Certificate of Registration with appropriate fees will be system generated. The Certificate of Registration will be issued after the fees are paid. The laboratory then continues the process for a Certificate of Compliance.

NOTE: The CLIA Data Entry Users Guide contains a comprehensive chart with all of the above situations described in detail. The users' guide should be consulted prior to making any changes for any certificate types.

6008 – *Criteria for One Certificate for Multiple Sites*

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Location

Each location where laboratory tests are performed must file a ***separate*** application, unless it meets one of the following exceptions as ***outlined*** in 42 CFR 493.35(b), 493.43(b), or 493.55(b):

- Laboratories that are not at a fixed location, i.e., laboratories that move from testing site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the CLIA certificate and address of the designated primary site or home base.

- Not-for-profit or Federal, State, or local government laboratories that engage in limited (not more than a combination of 15 moderately complex or waived tests per certificate) public health testing may file a single application.

- Laboratories within a hospital that are located at contiguous buildings on the same campus and under common direction may file a single application or multiple applications for CLIA certificate(s) for the laboratory sites within the same physical location or street address.

Home Health Agencies (HHAs)

A parent HHA with multiple branches may apply for one CLIA certificate as long as these sites are under one HHA provider number, i.e., parent branch. Subunits by definition operate independently and have a unique provider number; therefore, each subunit must apply for a separate CLIA certificate.

***NOTE**: The parent or provider location must perform laboratory testing. Since branches cannot operate independently, the parent defines the services provided in the branches and is responsible for the day-to-day operation, supervision, and administration of laboratory testing, including the employment of qualified personnel.*

For consistency, the Medicare designated terms parent and branches are used for this policy.

Hospices

The guidance as for HHAs applies to Hospices. The Medicare designated term for the hospice multiple sites is multiple locations instead of branches.

6022 - Laboratories Under Direct RO Jurisdiction

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The following facilities fall under the direct jurisdiction of the RO. All survey and certification activities are to be performed by RO staff.

- **Federal laboratories**

  Survey and Certification of Federal laboratories is the responsibility of the RO except as noted below:

  - Laboratories owned or operated under the jurisdiction of the VA are subject to the requirements the VA establishes through rulemaking. They are not subject to CLIA requirements.

  - Laboratories under the jurisdiction of the Department of Defense (DOD) are subject to requirements that CMS has determined to be comparable to those in CLIA. DOD is responsible for oversight of its laboratories.

6036.2 - Laboratories Performing Limited Public Health Testing

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Not-for-profit or Federal, State, or local government laboratories engaged in limited public health testing, (e.g., WIC clinics), may file a single application for multiple sites regardless of the physical location. The limited public health CLIA certificate includes a combination of no more than 15 tests, waived or of moderately complexity. The location designated as the primary site on the CLIA application/certificate must perform testing and hold the certificate. Each site may perform different test(s), but the total test menu for all sites must not exceed the 15 moderate complexity or waived tests specified in the CLIA application/certificate. The primary site must also identify the type of testing performed at each site. If any of the multi-site laboratories are located in more than one State, the State Agency (SA) contacts the Regional Office to determine which State conducts the inspection.

Proficiency Testing (PT) is required "per certificate," and the primary location must enroll in PT for any non-waived analyte listed in Subpart I of the regulations. The PT samples may be rotated among the multiple sites under the single certificate; however, all five samples from each event must be tested at a single location.

In contrast to the allowance for limited testing sites, not-for-profit or Federal, State or local government laboratories that perform high complexity testing must file a separate application for certification of each laboratory performing high complexity testing regardless of their profit or government status.

At a minimum, the SA verifies that all laboratory sites are included in a laboratory's comprehensive Quality Assessment program that monitors the correlation of each site's results with the instruments, test systems, and methods covered by the PT program. Failure of a laboratory to monitor and evaluate the quality of testing at each location is a deficiency.

6038.2 – Additional Survey Requirements Under the CMS/FDA MOU

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Under the CMS/FDA MOU, the SA is required to survey transfusion services for compliance with all applicable CLIA regulations, including those FDA regulations cited in the CLIA regulations. The MOU requires three additional survey activities:

1. SA surveyors must determine whether the facility is properly registered with FDA as a blood establishment if required. A blood establishment is defined as a facility that collects, manufactures, prepares, stores under controlled conditions for further distribution, or processes blood and blood products. Blood establishments include community blood banks, hospital blood banks, and blood product testing laboratories. (**NOTE:** Establishments that solely prepare Red Blood Cells or recovered plasma, pool Platelets or Cryoprecipitated AHF for ease of transfusion, or issue bedside leukocyte reduction filters with blood components, are considered to be transfusion services and are exempt from FDA registration.) If the facility is not properly registered, the SA surveyor must notify the RO. The RO will then notify the FDA district office. To find out the FDA contact for blood establishment registration, go to *http://www.fda.gov/ora/inspect_ref/iom/iomoradir_monitors.html* and click on Blood Registration Monitors.

2. For laboratories that meet the definition of transfusion service, and are therefore exempt from registration, the MOU requires that the SA surveyor give the laboratory material about FDA requirements on labeling and product expiration dating for blood products. This material will be provided by FDA.

3. Transfusion services are subject to FDA's Biologic Product Deviation (BPD) reporting requirements. Under the MOU, SA surveyors are required to provide transfusion services with a copy of FDA-prepared material on BPDs. This material is given to transfusion services when CLIA surveys are performed. It includes FDA contact information for laboratories with questions about the BPD requirements. If CLIA surveyors receive specific questions from laboratories about the BPD regulations, they should refer laboratories to the FDA for further information and guidance.

6042 - Proficiency Testing (PT)

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

42 CFR Part 493 Subpart H, Participation in Proficiency Testing for Laboratories Performing Non-waived Testing, provides laboratories with the PT requirements they must follow to comply with CLIA. The subpart specifies requirements for PT enrollment, testing, PT sample handling, and documentation. The prohibition of referral of PT samples to another laboratory is found at 42 CFR Part 493.801(b)(4) and, if

identified, carries one of the most severe sanctions in the CLIA law and regulations. The subpart also identifies successful participation in a CMS-approved PT program and how a laboratory may be reinstated when it has performed unsuccessfully. (Please see 42 CFR Part 493.2, Definitions, for unsatisfactory participation and unsuccessful participation.)

If laboratories perform any of the specific tests (analytes) that are listed in Subpart I, Proficiency Testing Programs for Nonwaived Testing, they must enroll in a CMS-approved PT program for each of these tests. Laboratories may enroll in more than one approved program. A condition level deficiency (42 CFR Part 493.801) is cited if a laboratory has not enrolled for even one of these tests if performed in the laboratory.

NOTE: The referral to another laboratory of a sample from a PT program (samples for tests listed in 42 CFR Part 493 Subpart I and all other tests for which PT samples are available) by ANY laboratory of ANY certificate type is considered PT referral. Notify the RO if PT referral is identified.

All sanctions are taken in accordance with 42 CFR Part 493 Subpart R and ONLY by the RO or with the RO's review and concurrence. A State surveyor may not initiate an action without the RO's permission.

PT Program Approval: Not-for-profit organizations or States may apply to CO to become a CMS-approved PT program for specific subspecialties and analytes. CO PT specialists perform an in-depth review of application submitted for approval to determine whether the program meets the requirement of 42 CFR Part 493 Subpart I. The CLIA statute requires annual review of approved programs. Re-approval reviews are also conducted by CO specialists. Approved PT programs and the subspecialties and analytes for which they are approved are listed on the CMS CLIA Web site each year.

6048 – PT Enrollment, Participation, and Testing Requirements

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

A laboratory must meet the CLIA regulatory requirements for enrollment, participation, and testing as specified in *S*ubpart H at 42 CFR Part 493.801. The SA, adhering to the *time frames* and guidelines in Appendix C of the SOM, reviews all related documentation. If failure to meet the specific requirements of 42 CFR Part 493 Subpart H is identified by the SA, appropriate actions may be initiated and sent to the RO for review and concurrence. If a laboratory has not enrolled in an approved PT program, the technical assistance and training sanction cannot be imposed when noncompliance with the condition, 42 CFR Part 493.801 is found, but instead the SA may recommend to the RO appropriate sanctions if the non-enrollment isn't corrected in a timely manner.

If the SA identifies any information on survey or by any other means that indicates the possibility that a PT sample for regulated analytes has been referred to another laboratory for testing, the RO must be notified immediately. The RO will instruct and advise the SA

surveyor of the appropriate actions the surveyor must take. The RO may contact CO with any questions.

6052 - PT Monitoring System Reports

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

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

The SA or RO has access to the following reports from the PT Monitoring System:

- OSCAR Report 150 – PT program names, addresses and telephone numbers, program demographics and tests for which the program is approved;
- OSCAR Report 152 – Listing of corrected scores;
- OSCAR Report 153 – Listing of laboratories by state or region with unsuccessful performance;
- OSCAR Report 155 – An individual laboratory's PT scores; and
- OSCAR Report 157 – Laboratories requesting excused participation (See example of this exception at 42 CFR Part 493.841(c)(1-3)).

To obtain directions on how to use the PT Monitoring system, consult the OSCAR Report User's Guide or the CO OSCAR coordinator.

6056 - Excused Failure to Participate in a Testing Event for a Particular Analyte

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

If a laboratory has received a score of zero due to failure to participate in a testing event for an analyte or subspecialty without analytes, the laboratory may request excused participation. This request is usually made when instrumentation is inoperative or reagents for testing are unavailable during the testing event. An excused participation may be granted only if:

- Patient testing for the specialty, subspecialty, analyte was suspended during the time frame allotted for testing and reporting of PT results;

- The laboratory notifies SA/RO and the PT program within the *time frame* for submitting PT results of the suspension of patient testing for that specialty, subspecialty, or analyte and of the circumstances that led to failure to perform testing on the PT samples; and

- The laboratory participated in the previous two testing events for the specialty, subspecialty, or analyte.

A regulatory example of these requirements may be found at 42 CFR Part 493.845(c)(1)-(3).

If the SA/RO accepts the circumstances given by the laboratory for not participating, the score of 100 percent given by the program is allowed to remain. If the SA/RO does not accept the circumstances given by the laboratory to justify its lack of participation, the SA/RO will notify the PT program to change the 100 percent score to a zero to indicate lack of participation. Only the PT program can change a laboratory's PT score in the PT Monitoring System.

6058 - Unsuccessful Participation in PT

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Unsuccessful PT performance under CLIA is defined as unsatisfactory performance in two consecutive or two out of three events for a specialty, subspecialty, or analyte and requires follow-up action by the surveyor. The SA (and RO for Federal jurisdictional laboratories) initially identifies a laboratory's noncompliance with the PT requirements through monitoring the OSCAR PT Monitoring System report on unsuccessful participation (OSCAR Report 155) and during the onsite survey.

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 immediate jeopardy, 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 – NOTE: This may be a blanket consent for SAs for all initial unsuccessful PT) sends the laboratory a letter proposing T&TA with a Form CMS-2567 citing the Condition-level deficiency. The letter should also include the consequences of another PT failure.

- 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, 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 for its PT program, but it may order them 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 OSCAR 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.

If an initial unsuccessful performance by a laboratory (the laboratory has never performed unsuccessfully for any specialty, subspecialty, or analyte) is confirmed, the SA may recommend to the RO that the laboratory undertake additional training, obtain

technical assistance, or both, rather than recommending the imposition of alternative or principle sanctions. No on-site survey is necessary to initiate this action.

NOTE: The SA may recommend training and/or technical assistance for initial unsuccessful PT EXCEPT when one or more of the following exists:

- There is immediate jeopardy to patient health or safety;
- The laboratory fails to adequately correct the problem causing the unsuccessful performance;
- The laboratory has a history of poor compliance with CLIA requirements.
- See 42 CFR Part 493.803(c) for regulatory specifications.

After the RO agrees with the imposition of technical assistance and/or training, an acceptable plan of remedial action to correct the problem that caused the unsuccessful performance should be obtained from the laboratory. Documentation of the SA determinations and follow-up should be maintained.

To initiate the appropriate enforcement actions, use the guidance at §§6262 - 6294 Please see the Notice of Proposed Limitation of the CLIA Certification and Suspensions of Medicare Payments When a Laboratory Has Failed to *Participate* Successfully in a Proficiency Testing Program.

6060 - Reinstatement After Failure to Successfully Participate in Proficiency Testing

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The laboratory must meet the requirements for reinstatement when:

- A laboratory has been required to cease testing an analyte or subspecialty without analytes or a specialty;
- The laboratory's certificate has been suspended or limited; or
- The laboratory voluntarily withdraws testing of the unsuccessful area of participation.

Reinstatement requires satisfactory performance on two consecutive PT events for the specialty, subspecialty, or analyte that the laboratory previously failed. Sustained satisfactory performance (two consecutive events) demonstrates that the laboratory has identified and corrected the area of failure that caused the original unsuccessful performance. A laboratory that has had its certificate suspended, limited or cancelled due

to unsuccessful PT participation may not be reinstated or receive Medicare or Medicaid payments in less than six months. The laboratory must re-apply to CMS to have the specialty, subspecialty, or analyte recertified. A revised application and certificate are necessary during the period of suspension or limitation. The laboratory must pay a fee to cover the cost of issuing the revised certificate.

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 considered as back in compliance. The SA will monitor this in coordination with the RO and utilize 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 voluntarily stops testing in the area of failure, it may resume testing when it has demonstrated sustained satisfactory performance for two consecutive testing events; the PT samples may be tested as soon as the laboratory has identified and corrected the cause of the original unsuccessful performance. Reinstatement samples (referred to as non-routine in the PT Monitoring System) should be purchased from the program in which the laboratory is enrolled for the failed analyte. If samples are not immediately available, the laboratory may purchase the samples from another approved program. The RO will make the final determination whether reinstatement requirements are met.

6061 – PT Referral

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

If it is determined that PT samples or PT results have been intentionally referred to another laboratory, 'PT Referral' is called. The sanctions for proven PT referral are revocation of the entire certificate for *1* year and the owner/operator (director) cannot own or operate (direct) another laboratory for a period of two years.

Do not solicit a Plan of Correction from a laboratory when it has been determined that the laboratory intentionally referred its PT samples to another laboratory for analysis and submitted the other laboratory's results as its own. Immediately notify the RO recommending revocation of the certificate (a statutory requirement) and forward to the RO all documentation necessary to support the findings.

Immediate Jeopardy is called for every intentionally (improperly) referred PT sample or event.

Laboratories experiencing poor performance for analytes using a PT program other than the one that is designated for CLIA compliance purposes or for unregulated analytes, should address the failures via their own internal quality assurance protocol.

To avoid implications of PT referral, laboratories using previously tested PT samples for competency assessment, training or other in-house purposes should wait until after the PT program returns the event's results.

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 42 CFR 493.801(b)(4), it will have its certificate revoked as stated in 42 CFR 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 that must be checked for accuracy twice per year for quality assurance and/or assessment (QA) purposes.

6063 – Survey Protocols for Compliance with Cytology Proficiency Testing

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

During surveys, SAs must accomplish the following:

- Enrollment: Confirm by review of enrollment documentation that the individuals examining gynecologic cytology slides (Pap smears and liquid based technologies) are enrolled in a CMS-approved cytology PT program for the calendar year and that all individuals at all laboratory cytology testing sites are enrolled.

- Testing: Ask the laboratory director the status and outcome of each individual's testing to ensure that the laboratory is following the regulatory protocol. Do not request copies of individual results.

    - **NOTE:** For laboratories that will not be surveyed in the current calendar year, the SAs will receive guidance from CMS Central office (CO), based on monitoring of enrollment *and* testing performance data from the Survey & Certification Group.

- Approved State Programs (Exempt States) & Approved Accrediting Organizations (AOs): CLIA-exempt laboratories and accredited laboratories will be overseen by their respective State Agencies or AOs.

- System of Re-testing: Confirm that individuals who fail the initial proficiency test are being re-tested in a timely manner in conformance with the procedures at §493.855.

- Additional Systems of Controls: Individuals have multiple opportunities to take the proficiency test and any retest, if necessary. Initially, individuals are required to take a 10-slide test within 2 hours, provided in sets.

    - If an individual passes the first 10-slide test, he/she has successfully participated for the year and need not be tested again until the following year.

    - If the individual fails the first 10-slide test, he/she must take a 10-slide retest within 45 days after notification of test failure. Surveyors must confirm that the individual was retested within the 45 day time frame.

    - When an individual passes the second 10-slide test, he/she has successfully participated for the year and need not be tested again until the following year.

    - If the individual fails the 10-slide retest:

        - The individual must obtain documented, remedial training in the area of test failure, which will be noted on the test results letter. Confirm via review of laboratory documentation that remedial training did occur.

        - All Pap smears screened by the individual subsequent to the notification of failure must be reexamined. Surveyors should review the documentation of reexamined slides, and

        - The individual must successfully participate in a 20-slide proficiency test within 4 hours. Confirmation of scheduled retesting must be reviewed.

    - If the individual fails the 20-slide test:

        - He/she must cease examining Pap smears immediately upon notification of failures. Surveyor confirmation of individual cessation of examining gynecologic cytology specimens is necessary;

        - The individual must obtain at least 35 hours of documented, formally structured, continuing education in diagnostic Cytopathology which focuses upon the examination of gynecologic cytology. Surveyor confirmation of continuing education is necessary; and

- The individual must successfully participate in another 20-slide proficiency test. Confirmation of scheduled retesting must be reviewed.

- This final cycle could continue until the individual successfully participates in another 20-slide proficiency test.

- Verification of Compliance: For laboratories that will not be surveyed in the current calendar year, CO will monitor their performance and provide additional guidance to the ROs. CO will also monitor the performance of individuals in accredited laboratories and CLIA-exempt laboratories and will notify the AO or approved State program of any necessary follow-up.

Enforcement Actions

The RO, in conjunction with the SA, will initiate intermediate sanctions that may include Civil Money Penalties of up to $10,000, limitation of the laboratory's CLIA certificate for cytology, and, if applicable and serious, suspension of the laboratory's Medicare and Medicaid payments for gynecologic cytology testing in accordance with Subpart R of the CLIA regulations if the laboratory fails to accomplish any of the following:

- Ensure Enrollment: Fails to enroll all gynecologic cytology testing sites in a CMS-approved cytology PT program for each calendar year beginning in CY 2005;

- Ensure Testing: Fails to ensure that all individuals examining gynecologic cytology slides in the current calendar year are enrolled in a CMS-approved cytology PT program and are tested in a timely manner. The regulatory protocol under §493.855 identifies the extent to which additional testing, education or limitations must be put in place with regard to individuals who do not pass the test initially.

  Individuals have multiple opportunities to take the proficiency test and any retest, if necessary. Initially, individuals are required to take a 10-slide test within 2 hours, provided in sets.

  - If an individual passes the first 10-slide test, he/she has successfully participated for the year and need not be tested again until the following year.

  - If the individual fails the first 10-slide test, he/she must take a 10-slide retest within 45 days after notification of test failure. Surveyors must confirm individual was retested within the 45 day time frame.

- When an individual passes the second 10-slide test, he/she has successfully participated for the year and need not be tested again until the following year.

- If the individual fails the 10-slide retest:

    - The individual must obtain documented, remedial training in the area of test failure, which will be noted on the test results letter. Confirm via review of laboratory documentation that remedial training did occur.

    - All Pap smears screened by the individual subsequent to the notification of failure must be reexamined. Surveyors should review the documentation or reexamined slides, and

    - The individual must successfully participate in a 20-slide proficiency test within 4 hours. Confirmation of scheduled retesting must be reviewed.

- If the individual fails the 20-slide test:

    - He/she must cease examining Pap smears immediately upon notification of failure. Surveyor confirmation of individual cessation of examining gynecologic cytology specimens is necessary;

    - The individual must obtain at least 35 hours of documented, formally structured, continuing education in diagnostic Cytopathology which focuses upon the examination of gynecologic cytology. Surveyor confirmation of *continuing* education is necessary; and

    - The individual must successfully participate in another 20-slide proficiency test. Confirmation of scheduled retesting must be reviewed.

- This final cycle would continue until the individual successfully participates in another 20-slide proficiency test.

- Ensure Retesting: Fails to ensure that an individual who fails a cytology PT test takes any required additional education or remedial actions, and is retested, as specified in the CLIA requirements, if such individual continues to examine slides for the laboratory.

Complete Testing: Fails to ensure that the testing for the current calendar year has been completed by April 2nd of the following calendar year. Please contact your RO in the event you identify any other questionable practices.

6102.1 – Scheduling Priorities

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

When scheduling surveys use the following priorities:

- Complaint surveys indicating possible immediate jeopardy;
- Laboratories with other complaint investigations pending;
- Follow-up surveys;
- Initial surveys;
- Recertification surveys; and
- Validation (non-complaint) surveys.

Scheduling surveys – There are *three* activities associated with scheduling surveys: the intention to survey which is the in-office formulation of a workplan, announcing the surveys which is notifying the laboratory (when applicable) *of* the survey date and time, and performing the survey which is the actual on-site inspection. For efficiency when scheduling, attempt to cluster surveys geographically, to include initials, recertifications, complaints and validations. Extenuating circumstances require RO review. In instances where the State requires a laboratory survey at a different time frame than CLIA, the State must meet both survey scheduling requirements as efficiently as possible.

For example: The State requires a survey before the laboratory can operate in that State. The SA can survey the laboratory for compliance with the State requirements, and return in the appropriate time frame to survey for compliance with the CLIA requirements.

1. Initial Surveys: In order to permit observation of actual testing during the initial survey, schedule the initial survey to occur at least 90 days after the data entry date of the CMS Form-116, but no later than 12 months after the data entry of the CMS Form-116.

For example: CMS-116 data entry date is May 10, 2006. Initial survey should be conducted between August 8, 2006 (90th day after May 10, 2006) and May 9, 2007 (365th day after May 10, 2006).

2. Recertification Survey: Schedule the recertification survey to occur at least 6 months (180 days) prior to the expiration date of the laboratory's current certificate, but no earlier than 12 months prior to the expiration date of the current certificate.

For example: Current certificate expiration date is December 31, 2006. Recertification survey should be conducted between December 31, 2005 and July 3, 2006.

If after the 90 days a representative from the laboratory states that laboratory testing is not being performed because equipment is not ready, etc., advise the laboratory that the CLIA number will be terminated until such time testing is being performed. If there is suspicion that the laboratory is being operated in a manner that constitutes a risk to human health, schedule an unannounced survey. An unannounced survey could be an option for either case.

Establish a date and time for the survey once the schedule has been completed. If a laboratory operates more than one shift or location, schedule survey hours to include a representative cross-section of shifts or locations, as necessary.

All surveys of accredited laboratories must have prior approval from the RO.

6114 - AQAS Verifications and Summaries

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

AQAS Verification Surveys - Each RO determines the number of laboratories in its jurisdiction that will receive the AQAS form based on the criteria described at §6112. An approximate percentage of the total number of laboratories that receive the AQAS, as a self- assessment, will be selected for an onsite survey for verification purposes (*r*efer to the current budget call letter). *The* AQAS verification surveys are conducted onsite after the AQAS has been returned to the SA to substantiate the laboratory's responses on the form. Using the completed AQAS form as a guide, the verification process should focus on verifying the laboratory's responses. If deficiencies are noted during the AQAS onsite verification survey, the SA issues a deficiency report Form CMS-2567 (Exhibit 7) and solicits an appropriate PoC. Verification information cannot presently be entered into the OSCAR system.

Selection of laboratories for verification is at the discretion of the RO and/or unless the laboratory strongly requests that an onsite survey be performed. If the laboratories meeting the criteria for receipt of the AQAS *request* an onsite survey and agree to also fill out the AQAS, such laboratories can be considered part of the AQAS verification pool. Laboratories meeting the criteria for receipt of the AQAS and do not wish to complete the form will be removed from the AQAS pool and be surveyed onsite.

AQAS verification surveys will be announced and will be conducted within 60 days after the AQAS is returned to the SA.

AQAS Summaries - ROs/SAs should compare the data from the AQAS received by those laboratories selected for verification with the onsite verification data and prepare a summary of the comparison results. The RO forwards this summary to the CO CLIA component on an annual basis. Contact CO to obtain guidance on how to prepare the summary.

6116 - Laboratory Refuses to Allow Survey

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Section 353(g) of the PHSA permits authorized officials to make announced or unannounced surveys of laboratories holding any type of CLIA certificate, at any time during the laboratory's normal hours of operation. If access is refused, the SA documents the identity (name and title) of the individual refusing admission and the reasons given, and submits this documentation immediately to the RO, i.e., by telephone or fax. In addition, *the* regulation at 42 CFR 1001.1301 permit*s* the OIG to exclude a laboratory from the CLIA program if it fails to grant immediate access upon reasonable request. The exclusion may be in effect up to a period equal to the sum of the length of the period during which immediate access was not granted, plus an additional 90 days. The RO will make the referral to the OIG. (See §6270.)

6120.2.3 – Deficiencies

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The surveyor uses the Interpretive Guidelines of Appendix C, "Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services," during the survey and notes the *D*-tag numbers relating to any deficiencies observed along with data and evidence supporting the findings on the surveyor worksheet. There are four CLIA Condition-level requirements that must be cited if noncompliance is determined, regardless of any negative outcome or potential harm. They are: Personnel qualifications, PT enrollment, unsuccessful PT participation, and PT referral. (See the Mandatory Citation chart in Appendix C, "Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services.") It is important to maintain accurate notes of observations, since the information is used to prepare a Form CMS-2567.

6124 - Preparation for Exit Conference

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The surveyors hold a survey team meeting prior to the exit conference and come to a consensus on the seriousness and extent of the deficiencies and whether the number, character, or combination interferes with accurate and reliable laboratory test results. Deficiencies found in more than one Condition or standard may be cumulative and interrelated and result in general, pervasive inadequacies in determining test results.

6130 - Statement of Deficiencies and Plan of Correction, Form CMS-2567

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The Form CMS-2567 (Exhibit 7) serves several important functions. *They are as* follows:

- Documents that specific deficiencies were found. If there are no citations, the surveyors indicates this in the left-hand column of the Form CMS-2567;
- Documents the laboratory's receipt of the deficiency notice;
- Discloses to the public the laboratory's deficiencies and what is being done to remedy them;
- Provides an opportunity for the laboratory to refute survey findings and to furnish documentation that requirements are met; and
- Documents the laboratory's plans and time frames for correcting the deficiencies.

The SA mails the laboratory a copy of the Form CMS-2567 within 10 calendar days of completing the survey. If there are citations, the SA allows the laboratory 10 calendar days to complete and return a PoC or credible AoC. If immediate jeopardy is identified, the SA follows the time frames in §6282.

The Form CMS-2567 may be disclosed to the public in accordance with the instructions in Chapter 3, "**Additional Program Activities**." The following sections contain information on disclosure: §§3308, 3308A, 3310, 3312, 3314, 3316 and 3318.

6130.1 – Statement of Deficiencies

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The Form CMS-2567 (Exhibit 7) can be generated using the Automated Survey Processing Environment computer program (ASPEN). Direct references to regulations are shown with a corresponding D-tag *(*data tag*)* number. In the summary statement column at the appropriate D-tag number, the surveyor includes the regulatory citation along with the description of the laboratory's deficient practices. The surveyor should refer to the Principles of Documentation manual for preparing a defensible citation.

Positive findings noted on the Form CMS-1557 (Exhibit 12) are not to appear on the Form CMS-2567.

The SA must always obtain and maintain thorough and comprehensive documentation to support the survey findings and certification decisions to sustain the action in the event of a hearing or judicial review. The SA must use all available sources of information to assist with completing the Form CMS-2567.

6130.4 - Strategy for Repeat Deficiencies

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

A repeat deficiency is defined as a deficient practice cited on a current Form CMS-2567, Statement of Deficiencies, that was also cited during a prior CLIA survey of the laboratory. If during a recertification, complaint, or validation survey of the laboratory it is determined that a repeat deficiency exists, use the following strategy to help ensure the receipt of an acceptable plan of PoC or a credible AoC that will result in effective, meaningful, and sustained corrective actions by the laboratory.

Laboratories must not be given multiple opportunities to correct repeat deficiencies. If repeat deficiencies are not corrected quickly, the SA should refer the laboratory to the RO for possible enforcement action. (This strategy may not be applicable to certain repeat deficiencies, e.g., the laboratory's failure to have appropriately qualified laboratory personnel in rural areas.)

Strategy for Repeat Deficiencies:

1. Cite each repeat deficiency and, if found, all other deficient practices on Form CMS-2567. Principles of Documentation do not preclude the surveyor from identifying a deficient practice as a repeat deficiency on Form CMS-2567.

2. Using *the* routine process, request the laboratory to submit an acceptable PoC or a credible AoC.

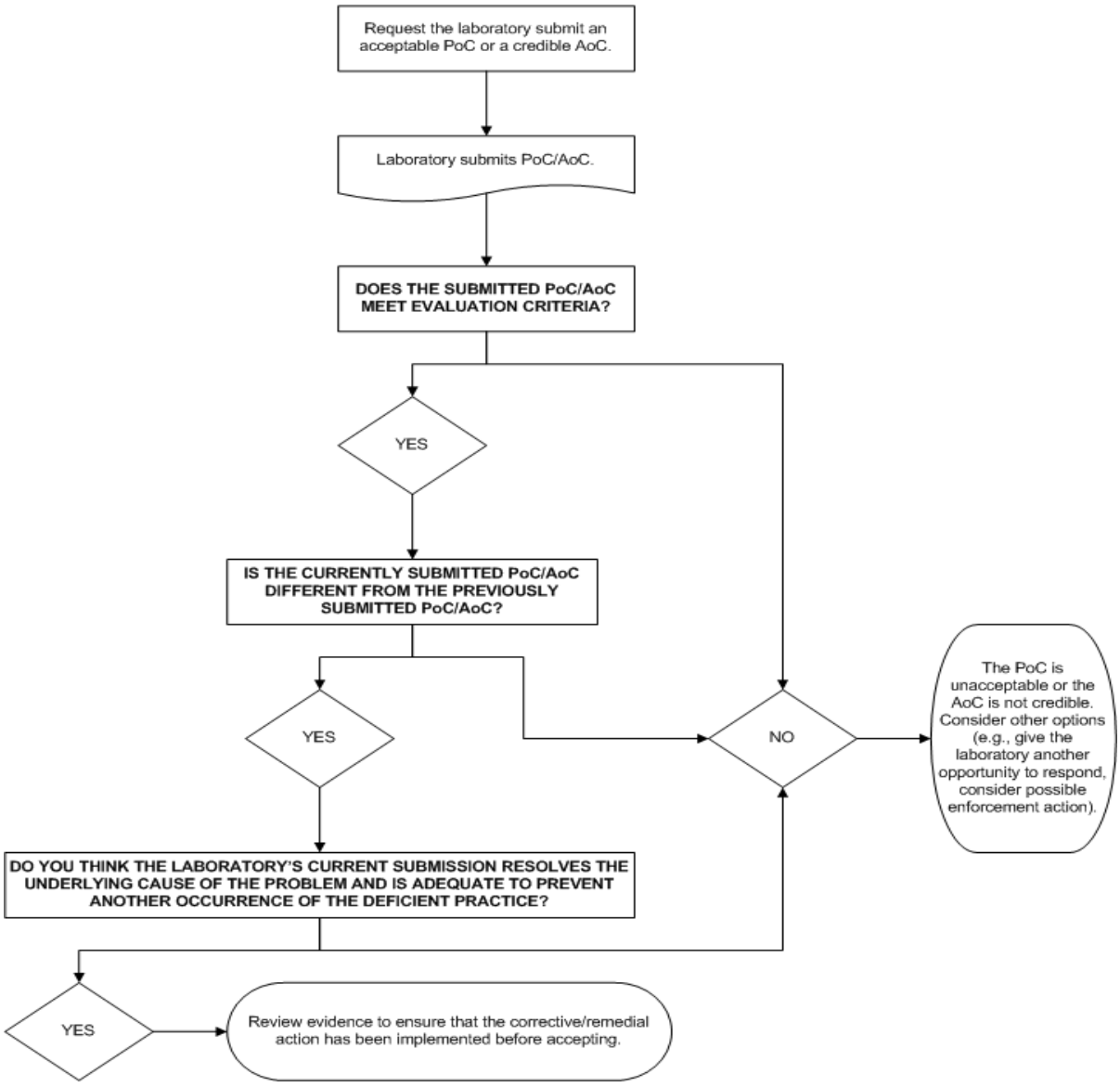
3. Review the submitted plan of correction or allegation of compliance and determine whether the laboratory's submission meets the criteria for an acceptable plan of correction or a credible allegation of compliance. Based on established criteria, if the plan of correction is not acceptable or the allegation of compliance is not credible, give the laboratory no more than one additional opportunity to provide an acceptable or credible submission, or forward the case to the Regional Office for possible enforcement action. Consideration should be made to the laboratory's compliance history, seriousness of the deficient practice, and the degree to which the laboratory's submission has met established criteria.

4. If the laboratory's submission meets established criteria for an acceptable plan of correction or a credible allegation of compliance, compare the currently submitted plan of correction or allegation of compliance for the repeat deficiency to the plan of correction or allegation of compliance the laboratory submitted when the deficiency was previously cited. If the currently submitted plan of correction or allegation of compliance for the repeat deficiency is the same as the previously submitted plan of correction or allegation of compliance, the plan of correction is not acceptable or the allegation of compliance is not credible. Give the laboratory no more than one additional opportunity to provide an acceptable or credible submission, or forward the case to the Regional Office for possible enforcement action. Consideration should be made to the laboratory's compliance history, seriousness of the deficient practice, and the degree to which the laboratory's current submission is the same as the laboratory's previous submission.

5. If the laboratory's submission for the repeat deficiency is different from the plan of correction or allegation of compliance submitted by the laboratory for the prior survey, consider whether the laboratory's current submission resolves the underlying cause of the problem and is adequate to prevent recurrence of the deficient practice. If it is determined that the laboratory's current submission does resolve the underlying cause of the problem or is not adequate to prevent the deficient practice from recurring, give the laboratory no more than one additional opportunity to provide an appropriate submission, or forward the case to the Regional Office for possible enforcement action. Consideration should be made to the laboratory's compliance history, seriousness of the deficient practice, and the degree to which the laboratory's current submission is likely to resolve the underlying cause of the problem(s) and prevent recurrence of the deficient practice.

6. If it is determined that the laboratory's current submission resolves the underlying cause of the problem and is adequate to prevent the deficient practice from recurring, review evidence from the laboratory to ensure that the corrective/remedial action has been implemented before determining that the laboratory's submission is acceptable or credible.

The above strategy is summarized in the following flow chart:



6135 – Data Management

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The following CLIA data entry actions contain reasonable time frames that should be adhered to:

- Form CMS-116 (Exhibit 125) entered up to 30 days after receipt by the SA. (Before entering the *Form* CMS-116 data into the system, the SA verifies that the laboratory director is qualified. See *§6006.7*)

- Form CMS-2567, Form CMS-670 (Exhibit 74), Form CMS-209 (Exhibit 106), and Form CMS-1557 (Exhibit 12) entered up to 45 days after the survey.

- Certificate changes and updates entered up to 45 days after receipt by the SA.

6138 - Retention of CLIA Certification Records

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Essential data from all CLIA forms can be captured electronically in *the* CMS mainframe data system, *and* will maintain *the* data for *3* years following the year in which the record is created, pursuant to Subpart R of the Federal Acquisition Regulations (incorporated by reference in Article XII.A of the §1864 agreement). The 1864 agreement and Subpart R do not preclude limiting data captured to "essential" elements. For example, the deficiency codes and correction dates from the Form CMS-2567 are essential, but the narrative description of deficiencies or corrections are not.

Article XII.A of the §1864 agreement requires retention of survey and certification records for three years following the year in which the record is created. This provision permits retention of the records in electronic form.

Additional expectations are found in the CMS Records Schedule, which provides record descriptions and mandatory disposition instructions for the retention, transfer, retirement or destruction of Agency records as approved by the National Archives & Records Administration. See Section XI for specific CLIA-related information.

However, where State law requires retention of records for a longer period or in specific formats, State law is controlling.

The following sections specify record retention requirements for different compliance situations.

6150 - Background - CMS Approval of Accreditation Organizations

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Section 353(e) of the PHSA permits the Secretary to approve private nonprofit accreditation organizations and thereby determine that laboratories accredited by the approved accreditation organization are deemed to meet CLIA requirements. An accreditation organization may be approved for a maximum of *6* years and must re-apply for each succeeding approval. When CMS approves an accreditation organization, a notice is published in the "Federal Register" stating the name of the organization, the specialties and subspecialties for which it is approved, and the basis for the approval of that accreditation organization. If it is later determined that the accreditation organization no longer meets the applicable requirements set forth in 42 CFR Part 493, Subpart E of the regulations, CMS will publish a notice in the "Federal Register" containing a justification of the basis for removing deeming authority from an accreditation organization.

The approved organizations are:

- AABB,
- American Osteopathic Association (AOA),
- American Society for Histocompatibility and Immunogenetics (ASHI),
- COLA,
- College of American Pathologists (CAP), and
- *the* Joint Commission.

6156.2 - Criteria for Selection - Laboratories Accredited by COLA, CAP, and *the Joint Commission*

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The CO periodically forwards the COLA, CAP and *the Joint Commission* inspection schedules to each RO, usually on a quarterly basis. The RO, with SA input about travel

schedules and other administrative matters, selects laboratories to receive validation surveys using the following criteria:

- Select from small, medium and large volume laboratories *to* encompass, to the extent possible (in whole or in part), the entire range of specialty and subspecialty testing;

- Select laboratories that are geographically dispersed and generally proportionate to the number of laboratories located in urban and rural areas; and

- To the extent possible, select from each organization roughly proportionate to the *total number* of accredited laboratories -- approximately 45-50% COLA, 25-30% CAP and 25% *the Joint Commission*.

6164.1 - SA Responsibilities

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

- Upon receipt of Form CMS-2802A (Exhibit 242) from the RO, scheduling validation survey(s) to take place no later than 90 days after the accreditation organization's survey;

- Assignment of surveyors on *a* rotating basis to perform the validation survey, as available;

- Performance of the validation survey (complete survey of all specialties per certificate) using the same survey process and the same objectivity as in a survey of a non-accredited laboratory;

- Performance of an exit conference which outlines the survey findings and informs the laboratory of any follow-up actions or correspondence

- Upon completion of the survey forwards *to the RO* the *following* validation survey package:

    - Form CMS-2802A (Exhibit 242) - Request for Complaint Investigation or Validation Survey of Accredited Laboratory;

    - Form CMS-1539 (Exhibit 9) - Certification and Transmittal;

    - Form CMS-1557 (Exhibit 12) - Survey Report Form;

    - Form CMS-209 (Exhibit 106) - Laboratory Personnel Report;

- Form CMS-2567 (Exhibit 7) - Statement of Deficiencies and Plan of Correction; and

- Form CMS-670 (Exhibit 74) - Survey Team Composition and Workload Report.

Include the following forms, when applicable:

- Form CMS-2567B (Exhibit 8) - Post-Certification Revisit Report, and

- Form CMS-562 (Exhibit 75) – Medicare/Medicaid/CLIA Complaint Form.

6164.2 - Discrepancy With CLIA Data Information

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

If, during the course of a validation survey in an accredited laboratory, the laboratory is found to be performing more or less tests and/or specialties than reflected in the CLIA data system, i.e., the laboratory is in a higher or lower schedule, the discrepancy must be corrected. (See Appendix C.)

The SA completes the Form CMS-1557 (Exhibit 12), reflecting all changes, including the true volume of testing being performed. The laboratory director or designee must sign or initial a Form CMS-116 (Exhibit 125). A notation is made on the new Form CMS-116 clearly indicating it is for *a* change in test volume only. The SA enters the corrected data into the CLIA data system.

6166.1.1 - The SA

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

- At the exit conference informs the laboratory of its noncompliance status; its recommendation to the RO that the laboratory no longer meets the CLIA Condition-level requirements by virtue of accreditation; and that the laboratory is subject to the same enforcement actions as non-accredited laboratories;

- Prepares a Statement of Deficiencies, Form CMS-2567 (Exhibit 7), and/or clearly documents the nature of the jeopardy and immediately (within 2 days) notifies the RO with the recommended action. The SA does not leave the Form CMS-2567 with the laboratory at the time of the exit conference.

- Within *three* working days of the last day of survey, forwards the validation survey certification package to the RO. (See §6164.)

6166.1.2 - The RO

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

NOTE: *F*or accredited laboratories, the RO rather than the SA is responsible for processing the enforcement actions listed in §6282 and §6284.

- Receives the SA recommendations and determines the appropriate actions according to the policies outlined in §6282. The RO initiates immediate action to suspend or limit the laboratory's certificate of accreditation, and may also impose one or more alternative sanctions as necessary to encourage compliance.
- Notifies the laboratory of the immediate jeopardy situation by overnight mail or facsimile (followed up by mail) and of the actions being initiated (Exhibit 237). A copy of this communication is sent to the SA, CO, and the applicable accrediting organization. (Call CLIA component at CO for current contact and address.)

- On or before the 23rd day, the RO assures that the immediate jeopardy has been removed and follows procedures for Condition-level deficiencies with no immediate jeopardy. If the immediate jeopardy has not been removed, the RO follows the procedure for immediate jeopardy enforcement actions in §6282. The RO also updates the AO regarding the immediate jeopardy situation and/or findings.

- Sends copies of selected documents and correspondence to CO for performing the validation review. (See §6170.)

6206 - Preparing for Sample Validation Survey of CLIA-Exempt Laboratories

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Validation surveys are typically announced unless performed simultaneously with CAP or *the Joint Commission*, which have policies of unannounced surveys. Sometimes COLA surveys are unannounced. (See *§6227.3.1* for complete guidance on when to refrain from announcing CLIA validation surveys.) The RO laboratory surveyors should conduct validation surveys, to the extent possible, on a rotating basis so that no one surveyor conducts all the validation surveys.

The RO completes the survey in approximately the same time frame required for a laboratory of similar size and complexity undergoing a CLIA certification survey. To permit an independent compliance decision, the RO does not obtain a copy of the licensure survey findings until the validation survey is completed.

If a laboratory representative refuses to permit a validation survey, the RO requests the State to explain the protocol to the laboratory. If the laboratory still refuses, the RO requests the State to take enforcement action under their licensure program.

6227.3 - Pre-Survey Arrangements for Accredited Laboratories

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

When a laboratory is selected for a simultaneous validation survey, the special tasks listed below are performed in addition to the usual survey scheduling tasks, in order to fully coordinate among all the parties. Note the special instructions in the subsections below pertaining to all simultaneous validation surveys performed with *AABB,* CAP and *the Joint Commission,* and some simultaneous validation surveys performed with COLA.

6227.3.1 - Coordinating With Accreditation Organization (AO) Contact Person

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The surveyor telephones the accreditation organization's designated contact person (current names and telephone numbers can also be obtained from the RO.) The surveyor:

- Verifies the date of the organization's inspection;
- Obtains the name and telephone number of the AO inspector; and
- If the accreditation organization's policy is to announce the inspection, requests the AO contact person to advise both the inspector and the laboratory that a CLIA validation survey will be conducted simultaneously with the accreditation inspection. Notifying the inspector and the laboratory, in advance of the surveyor's contact, facilitates the surveyor's coordination efforts with those parties.

  EXCEPTION: CMS has agreed to honor *AABB's,* CAP's and *the Joint Commission*'s policies of unannounced surveys; therefore, request the *AABB,* CAP or *the Joint Commission* contact person to advise their inspector only (not the laboratory) that the CLIA validation survey will be conducted simultaneously.

  NOTE: COLA's policy is to announce inspections; however, COLA honors *the Joint Commission*'s policy of unannounced inspections when performing inspections of laboratories deemed to meet *the Joint Commission* accreditation requirements by virtue of their COLA accreditation. ALWAYS VERIFY WITH THE COLA CONTACT PERSON WHETHER THEIR INSPECTION WILL BE

ANNOUNCED OR UNNANOUNCED. If unannounced, request the COLA contact person to advise their inspector only (not the laboratory) that the CLIA validation survey will be performed simultaneously.

6227.3.2 - Arrangements With Laboratory

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The surveyor verifies that the laboratory received the SA notification about the validation survey and apprises the laboratory that it will be performed simultaneously with the accreditation inspection.

EXCEPTION: Do not have any pre-survey contact (written, electronic or oral) with a laboratory accredited by *AABB,* CAP or *the Joint Commission*, in order to conform with those organizations' policies of unannounced inspections. If the COLA inspection will be unannounced (see §*6227.3.1*) , do not have any pre-survey contact with the laboratory.

6238 – Completion of FMS Workload and Time Expenditures

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

To provide accurate information on both the number and types of monitoring surveys the RO completes the Form CMS-670 *which* is entered into the system for each survey performed, regardless of the type or extent of the survey, or the size of the survey team. For CLIA surveys, the Form CMS-670 will capture SA time, RO time, CO (administrative) time, and appeals time expenditures. This more comprehensive accounting of time is necessary to meet the self-funding requirement of CLIA.

6240 - Other Special Purpose Federal Surveys - Definitions

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

- **Federal jurisdictional survey** is a Federal survey to assess laboratory performance and to determine whether a laboratory meets all CLIA requirements for the tests that the laboratory conducts. It is used as the basis for approving a laboratory where CMS has indicated that the SA should not have jurisdiction over the laboratory. Surveys conducted by Federal personnel include federally operated laboratories and State operated laboratories. When conducting these surveys, the RO performs all functions performed by the SA for CLIA laboratories, including ensuring that the laboratory is enrolled in an approved PT program and monitoring their performance in the PT program. CO will determine whether or not a laboratory outside the U.S. should be surveyed under

CLIA if the laboratory performs laboratory tests on human specimens referred to it by a laboratory in the U.S. or its territories.

- **Complaint survey** is a survey conducted to investigate an allegation of laboratory noncompliance with one or more CLIA requirements. The SA or RO may conduct complaint surveys. Refer to Chapter 5, "*Complaint* Procedures," for additional information about complaint investigations in a laboratory.

- **Follow-up survey** is conducted to determine the status of corrective action, based on deficiencies cited on the Form CMS-2567 (Exhibit 7). If appropriate, a contact (i.e., telephone or mail) in lieu of an on-site follow-up survey may be conducted to ascertain the status of a facility that has received notice from the RO and has alleged correction of the deficiency or deficiencies.

6250.2 - Basis for Enforcement

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

CLIA enforcement actions are based on:

- Deficiencies found during an onsite laboratory survey or through review of materials submitted by the laboratory, e.g., personnel qualifications;

- Unsuccessful participation in PT;

- Improper referral of PT;

- Failure to comply with notification requirements; or

- Improper actions of laboratory's owners, operators or employees, which can include:

    - Misrepresentation in obtaining a CLIA certificate;

    - Performance of, or representing the laboratory as entitled to perform, a laboratory examination or other procedure that is not within a category of laboratory examinations or other procedures authorized by its CLIA certificate;

    - Failure to comply with the certificate requirements and performance standards;

    - Failure to comply with reasonable requests by CMS or its designee for any information or work on materials that is necessary to determine the laboratory's continued eligibility for CLIA certification or continued compliance with performance standards set by CMS;

- Refusal of a reasonable request by CMS or its agent for permission to inspect the laboratory including its operation and pertinent records during the hours that the laboratory is in operation;

- Violation or aiding and abetting in the violation of any provisions of CLIA and its implementing regulations; and

- Owning or operating, within the preceding 2-year period, a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

6252 - Definitions/Terminology - Enforcement

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

- Credible Allegation of Compliance – A credible allegation is a statement or documentation that:

    - Is made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;

    - Is realistic in terms of the possibility of the corrective action being accomplished between the last day of the survey and the date of the allegation; and

    - Indicates that the problem has been resolved.

- Day - Unless otherwise stated, day always means calendar day.

- Foreign Laboratories – CLIA-certified laboratories operating outside the United States or its territories.

    NOTE: All enforcement actions on foreign laboratories are handled by the CMS New York Regional Office.

- **PT Scores** - The CMS approved PT program will determine the overall and individual analyte scores following the grading criteria defined in 42 CFR Part 493, Subpart I.

- **PT Survey** - A module or grouping of samples marketed as a unit by PT programs. Programs typically offer several survey kits that include different samples for the same specialty, subspecialty, analyte, or test.

- **Repeat Deficiencies** - The same Condition-level deficiencies found in three consecutive surveys of any type, for the purposes of suspension of all Medicare payments.

- **Significant Hazard to the Public Health** - This is a deficiency that may cause harm to members of the community who are not necessarily patients served directly by the laboratory, e.g., incorrect reporting of accurate test results with respect to communicable diseases. The term is equivalent to immediate jeopardy for patients served by the laboratory.

- **Testing Event** - This is a PT program's scheduled submission to a laboratory of survey samples for a regulated specialty, subspecialty, analyte, or test. A minimum of two testing events per year are required for the mycobacteriology subspecialty. All other specialties, subspecialties, analytes, and tests require three testing events per annum except cytology.

Training and Technical Assistance - This is a sanction option separate from principal and alternative sanctions that may be applied alone or in addition to other sanctions when a laboratory is not in compliance with the CLIA PT requirements. CMS may require the laboratory to undertake formal training of its personnel or to obtain necessary technical assistance, or both, in order to resolve the noncompliance successfully. An educational focus is recommended for initial unsuccessful PT performance if it has not resulted in an immediate jeopardy situation.

6264.1.1 - Basis for Cancellation

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

CMS always cancels a laboratory's approval to receive Medicare payment for its services if CMS suspends or revokes the laboratory's CLIA certificate.

Cancellation of Medicare approval to receive Medicare payment for its services is applied to those specialties and subspecialties that are affected by a limited CLIA certificate.

CMS may cancel the laboratory's approval to receive Medicare and Medicaid payment for its services under any of the following circumstances:

- The laboratory is out of compliance with a Condition including failure to meet PT requirements;

- The laboratory fails to submit an acceptable PoC within an appropriate *time frame;* or

- The laboratory fails to correct lower level deficiencies within the *time frames* specified in the PoC, which cannot extend beyond 12 months from the last date of survey that identified the deficiencies.

6264.1.2 - Effective Date

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Medicare cancellation takes effect after proper written notice to the laboratory (at least *5* days before the effective date of the sanction for immediate jeopardy and at least 15 days before the effective date if there is no immediate jeopardy), which includes the opportunity to respond. The cancellation is **not** delayed because the laboratory has appealed and the hearing or hearing decision is pending.

6264.1.3 - Effect of Cancellation on Other Medicare Payment Sanctions

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Cancellation of Medicare approval terminates any other Medicare payment sanction, i.e., suspension of all or part of Medicare payments, regardless of the *time frames* originally specified for the other sanction.

6264.2.1 - Suspension of Part of Medicare Payments

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

CMS may impose this sanction in the following situations:

- The laboratory has Condition-level deficiencies with respect to tests in one or more specific specialties or subspecialties; and

- The laboratory agrees not to charge Medicare beneficiaries, their private insurance carriers, the fiscal intermediary (FI), or carrier for those services for which payment is suspended. The laboratory may choose to make this agreement in return for not having its Medicare approval canceled immediately.

After proper written notification, the RO will inform the appropriate Medicare carrier, intermediary, or Medicare Administrative Contractors (MACs) to suspend Medicare payment for services furnished on and after the effective date of the sanction for those specialties or subspecialties for which the laboratory is out of compliance. The sanction remains in effect until the laboratory corrects the Condition-level deficiencies or CMS cancels the laboratory's approval to receive Medicare payment, but never beyond 12 months from the last date of the survey that identified the deficiencies; one or the other

must occur. If the laboratory corrects all Condition-level deficiencies, the RO resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected. If all deficiencies are not corrected within the *time frames* specified in the PoC, which cannot exceed 12 months, the RO cancels the laboratory's approval to receive Medicare payment for its services.

6276.1 - Basis for Action

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The RO imposes a directed PoC for a laboratory that has Condition-level deficiencies. Under this sanction, the laboratory is directed to take specific corrective action within specific time frames in order to compel the laboratory to achieve compliance. The laboratory must correct every deficiency addressed in the directed PoC. If the RO does not impose a directed PoC as an alternative sanction, it imposes at least a directed **portion** of a PoC when any of the following alternative sanctions are imposed:

- State onsite monitoring;
- Civil money penalty; or
- Suspension of all or part of Medicare payments.

6276.2.1 – Notice of Proposed Sanction(s)

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The RO provides written notice of the proposed sanction(s) and gives the laboratory *at least* 10 days to respond. [See updated sample letters at *http://www.cms.hhs.gov/clia*.]

6276.3 - Processing Directed PoC

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

When imposing this sanction, the RO takes the following actions:

- **Specific Corrective Action and Time Frames** - Directs the laboratory to take specific corrective action within specified *time frames.*
- **Submission of Names of Laboratory Clients (Optional)** - The RO may direct the laboratory to submit to the SA or another CMS agent the names and addresses

of its clients so they can be notified of sanctions being imposed and make decisions regarding retesting.

- **Duration and Effect of Sanction** - If a revisit or other written documentation confirms that the laboratory has not corrected its deficiencies within 12 months from the survey date, the RO cancels the laboratory's approval to receive Medicare payment for its services and notifies the laboratory of its intent to impose a principal sanction against its CLIA certificate. The directed PoC remains in effect until the effective date of the principal sanction against the laboratory's CLIA certificate.

6276.4 - Processing Directed Portion of PoC

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

It may be necessary to notify clients, i.e., physicians, providers, and suppliers, and in some cases, individual patients, of a sanctioned laboratory, because of the seriousness of the noncompliance (e.g., immediate jeopardy) or for other reasons. In these cases, the RO directs the SA to notify the laboratory's clients. When the RO imposes this sanction, the following procedures apply:

- The RO directs the laboratory to submit to the SA, within 10 days after the date of its notice, a list of the names and addresses of all physicians, providers, suppliers, and other clients who have utilized some or all of the laboratory's services since the last survey or within any other *time frame* the RO specifies.

- Within 30 days of the date the SA receives this information, the RO may direct the SA to provide a notice to each of the laboratory's clients which contains the following:

    - The name and address of the laboratory;

    - The nature of the noncompliance; and

    - The type and effective date of the alternative sanction or principal sanction.

The notice will also indicate that the client may contact the SA if additional information is needed. It is the SA's responsibility to obtain information or needed clarification in order to respond to clients' concerns about making an informed decision regarding patient notification and retesting or the use of another laboratory's services. If the RO determines that it is necessary to provide notice to each of the laboratory's clients, they will also arrange for a public notice to be published in the newspaper.

If the enforcement action is subsequently rescinded, the RO directs the SA to provide written notice of the action to the laboratory's clients and the newspaper within 30 days of the rescission.

If a principal sanction is imposed following imposition of an alternative sanction for which a listing of the laboratory's clients has already been obtained, the SA may use that same listing to notify the laboratory's clients of the imposition of the principal sanction.

6280.4.1 - Notice of Intent

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The RO will notify the laboratory in writing of its intent to impose a civil money penalty at least 15 days before the effective date of the sanction if there is no immediate jeopardy situations and at least five days before the effective date when immediate jeopardy exists. The notice includes the following information [see updated sample letters at *http://www.cms.hhs.gov/clia*]:

- The statutory basis for the penalty;
- The proposed daily or per violation amount of the penalty;
- The factors considered in determining the penalty amount;
- The laboratory's opportunity to respond within ten days of receipt of the notification, which includes the opportunity to submit additional information or a credible allegation of compliance; and

The laboratory's appeal rights, including the criterion that, if the laboratory does not request a hearing, RO may reduce the proposed penalty amount by 35 percent.

6282.1 - Processing Immediate Jeopardy Enforcement Actions

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

When immediate jeopardy is documented, the RO completes enforcement procedures within 23 calendar days. The RO does not postpone or stop the procedure unless the removal of the immediate jeopardy is achieved and verified.

1. **Survey Date -** The survey date is the date on which the entire onsite survey process is completed.

2. **Second Working Day -** No later than 2 working days following the survey date, the SA will telephone the RO to advise that it is making a determination of noncompliance and that immediate jeopardy exists.

3. **Third Working Day -** No later than three working days following the survey date:

   - The SA sends written notice, i.e., a warning letter (see updated sample letters at *http://www.cms.hhs.gov/clia*) to the laboratory (by overnight mail or facsimile) which includes the following:

     - The Conditions out of compliance and their determination that these deficiencies constitute immediate jeopardy;

     - The sanction or sanctions recommended. The sanction(s) must consist of at least suspension or limitation of the laboratory's CLIA certificate and may include one or more alternative sanctions. If the laboratory participates in Medicare, all (or, in the case of the limitation of a CLIA Certificate, part of) Medicare payments must be canceled or suspended. If the laboratory unsuccessfully participated in PT, the training and technical assistance requirement may also be imposed. If a civil money penalty is recommended, the daily or per violation amount recommended must also be specified;

     - The rationale for the proposed sanction(s);

     - The projected effective date and duration of the proposed sanction(s);

     - The authority for the proposed sanction(s);

     - The time allowed (ten calendar days from the date of the notice) for the laboratory to respond to the notice, which includes the opportunity to submit additional information or a credible allegation of compliance to the RO (see updated sample letters at *http://www.cms.hhs.gov/clia*);

     - The CMS authority at 42 CFR 493.643(b) to assess additional fees for costs incurred to verify compliance;

     - The opportunity for the laboratory to notify the RO and/or the SA immediately if the jeopardy has been removed or the deficiencies have been corrected and there is evidence to support the allegation of compliance and;

     - The intent for the RO to publish a public notice in the local newspaper; and

- The SA forwards all supporting documentation to the RO by overnight mail.

6284.1 - Procedures

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

Enforcement procedures cannot exceed 12 months in cases where alternative sanctions are utilized. The RO or SA does not postpone or stop the procedure unless compliance is achieved and verified.

1. **Survey Date –** The survey date is the date on which the entire onsite survey process is completed.

2. Tenth Calendar Day - No later than ten days following the survey date, the SA will notify the laboratory in writing by overnight mail or facsimile of the cited deficiencies, including Condition-level noncompliance (see updated sample letters at *http://www.cms.hhs.gov/clia*). The SA will inform the laboratory that the enforcement process provides the opportunity for correction and that, if compliance is achieved, the laboratory is to notify the SA immediately and furnish evidence to support its allegation. The SA will state that they will make a determination of compliance within 45 days of the survey, if an acceptable PoC and a credible allegation of compliance is received and verified.

3. **Twentieth Calendar Day -** The laboratory must submit an acceptable PoC to the SA.

4. **Forty-Fifth Calendar Day to the Fifty-Fifth Day -** If the laboratory has submitted an acceptable PoC and a credible allegation of compliance, the SA will determine whether compliance has been achieved. If compliance can be verified based on evidence presented by the laboratory, the SA will certify compliance, notify the laboratory, and transmit the certification information to the RO. If compliance cannot be verified based on the evidence presented, the SA will conduct a revisit.

If the laboratory fails to submit an acceptable PoC and a credible allegation of compliance, a revisit is not required. In these cases and those in which a revisit found continued noncompliance, the SA will prepare and send via overnight mail or facsimile a warning letter to the laboratory [see updated sample letters at *http://www.cms.hhs.gov/clia*] which includes the following information:

- The cited deficiencies, including the Condition-level noncompliance identified;

- The sanctions recommended for imposition against the laboratory. (If a principal sanction is not imposed an alternative sanction must be put in place.) If the laboratory unsuccessfully participated in PT, the training and technical assistance requirement may be imposed in lieu of any sanction or in addition to a sanction. If a civil money penalty is recommended, the daily or per violation amount recommended will be specified;

- The rationale for the proposed sanction(s);

- The projected effective date and duration of the proposed sanction(s);

- The authority for the proposed sanction(s);

- For alternative sanctions, the time allowed (ten calendar days from the date of the notice) for the laboratory to respond to the notice and the instruction for the laboratory to notify the SA if the deficiencies have been corrected and there is evidence to support the allegation. (See updated sample letters at *http://www.cms.hhs.gov/clia*);

- The CMS authority at 42 CFR 493.643(b) to assess additional fees for costs incurred to verify compliance;

- The sanction(s) which will take effect if compliance is not achieved; and

- The intent to publish a public notice in the local newspaper.

Subsequent SA revisits are subject to the RO's approval. Usually revisits occur between the first and 45th day and between the 45th and 90th day. If subsequent SA revisits are necessary they may be done with RO approval.

5. **Sixtieth Calendar Day -** The SA will review any response received from the laboratory or from the revisit and determine whether compliance has been achieved. If compliance can be verified on the basis of evidence presented by the laboratory or from the revisit, the SA will certify compliance and transmit the information to the RO. If compliance cannot be verified on the basis of evidence submitted by the laboratory or from the revisit, the SA will certify noncompliance. They will also transmit the certification, supporting documentation and sanction recommendation to the RO.

6. **Seventieth Calendar Day -** If the RO's review concludes that the laboratory still has Condition-level deficiencies, it sends an official enforcement action notice to the laboratory which includes the following information (see updated sample letters at *http://www.cms.hhs.gov/clia*):

    - The cited deficiencies, including the Condition-level noncompliance identified;

- The outcome of the RO's review of any evidence presented by the laboratory as the result of the SA's warning letter and/or any revisit conducted by the SA;

- The sanctions it will impose against the laboratory. If the laboratory unsuccessfully participated in PT, the training and technical assistance requirement may be imposed in lieu of any sanction or in addition to a sanction. If a civil money penalty is recommended, the daily or per violation amount recommended will be specified;

- The rationale for imposing the sanction(s);

- The projected effective date and duration of the sanction(s), and the effective date of the sanction(s) if Condition-level compliance is not achieved;

- The authority for imposing the sanction(s);

- The opportunity for the laboratory to notify the RO immediately if the Condition-level deficiencies have been corrected and there is evidence to support the allegation;

- The CMS authority at 42 CFR 493.643(b) to assess additional fees for costs incurred to verify compliance;
- The laboratory's right to appeal; and

- The intent to publish a public notice in the local newspaper.

The newspaper notice must also explain that when the principal sanction of limitation is imposed, if the laboratory participates in Medicare, its Medicare participation will be affected. If the sanction of suspension of Medicare payment is recommended, the RO includes in the notice a statement asking the laboratory whether or not it intends to continue charging Medicare beneficiaries, their private insurance, fiscal intermediary, or carrier for those specialties and subspecialties for which testing is being limited. The RO informs the laboratory that if it agrees not to charge its Medicare beneficiaries, their private insurance, fiscal intermediary, or carrier, it will have its payment for affected Medicare covered laboratory services suspended on the effective date of the sanction. The RO ensures that the laboratory understands that its Medicare approval will be canceled, as opposed to being suspended, if it does not agree not to charge its Medicare beneficiaries, their private insurance, fiscal intermediary, carrier, or MAC. (The principal sanctions of suspension and revocation always result in a cancellation of Medicare participation.) The RO includes in the notice that the laboratory must respond within 15 days. If no response is received, the RO assumes the laboratory has not agreed to cease charging for Medicare covered services. Therefore, action will be taken to cancel the

Medicare approval for payment on the effective date of the sanction. (See 42 CFR Part 493.1826(a)(ii).) **NOTE:** The intent is to cancel Medicare approval.

If the laboratory makes a credible allegation of compliance, the RO determines whether the SA can certify compliance on the basis of the evidence presented by the laboratory in its allegation or if a revisit must be made to verify that the laboratory has, in fact, achieved compliance. If the RO determines a revisit is needed, it instructs the SA to conduct it prior to the effective date of the sanction. The RO also instructs the SA to notify it of the outcome immediately upon completion of the revisit.

If the RO concurs on the basis of evidence presented or the outcome of a revisit that there are no remaining Condition-level deficiencies, it certifies compliance and ensures that a CLIA certificate is issued or reissued to the laboratory, if appropriate. The RO advises the laboratory that compliance has been achieved.

If the laboratory fails to make a credible allegation of compliance, no revisit is necessary and enforcement procedures continue.

7. **Ninetieth Calendar Day -** If compliance has not been achieved, the CLIA sanctions may take effect, however, the Medicare sanctions must take effect on the 90th day. If a principal sanction is imposed, the RO arranges to publish a public notice immediately. In the public notice, the RO states the type of adverse action, the reason for the adverse action, the effective date, and effect of the action. When a certificate is limited, the RO outlines in the public notice those specialties or subspecialties of tests that the laboratory is no longer authorized to perform and, therefore, are no longer approved for payment under Medicare.

    a. Laboratory Participated in Medicare, Has Its Certificate Limited, and Does Not Agree Not to Charge Medicare Beneficiaries, Their Private Insurance, the Fiscal Intermediary (FI), or Carrier - Payment for all Medicare-covered laboratory services is canceled on the effective date of the sanction.

    b. Laboratory Participated in Medicare, Has Its Certificate Limited, and Agrees Not to Charge Medicare Beneficiaries, Their Private Insurance, the FI, or Carrier

        (1) Suspension of All Medicare Payment - Payment for all Medicare covered laboratory services is suspended on the effective date of the sanction, if the laboratory agrees not to charge Medicare beneficiaries, their private insurance, the FI, carrier, or MAC for services for which Medicare payment is suspended, i.e., specialties, subspecialties out of compliance. The laboratory may choose to make this agreement in return for not having its Medicare approval canceled immediately.

(2) Duration and Effect of Sanction - The sanction remains in effect until the laboratory corrects all Condition-level deficiencies, but never beyond 12 months from the last date of the survey which identified the deficiencies.

If the laboratory corrects all Condition-level deficiencies and participates in Medicare, the RO resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected. If all deficiencies are not corrected by the end of the 12-month period specified above, the RO cancels the laboratory's approval to receive Medicare payment for its services. The RO may impose a principal sanction against the laboratory's CLIA certificate. The RO notifies the laboratory in writing via overnight mail or facsimile of the sanction and its right to due process. [See updated sample letters at *http://www.cms.hhs.gov/clia*.]

NOTE: Due to the additional administrative process which requires a cytology contractor to send survey findings to the RO once the cytology survey is completed, the effective date of any adverse action imposed against a laboratory based on a cytology contractor's survey begins on the date the RO receives the official survey report.

6286.5 - Revocation of CLIA Certificate

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

If the RO decides to revoke a noncompliant laboratory's CLIA certificate, it may do so within the *time frames* that the RO communicate to the laboratory in the notice of sanction if the laboratory does not request a hearing. If the laboratory requests a hearing, the CLIA certificate may not be revoked until the decision is rendered by the ALJ.

6290.1 - General

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The validation program is designed to evaluate the premise that a laboratory that receives accreditation is, in fact, meeting CLIA requirements. Validation surveys of accredited laboratories should be conducted in strict accordance with established procedures for SA certification surveys of nonaccredited laboratories to ensure a fair and consistent basis for evaluating the effectiveness of approved accreditation organizations.

In the case of a complaint against an accredited laboratory, the RO may choose to carry out its own investigation, or refer the complaint to the SA or accreditation organization, depending on the nature of the complaint. The RO reviews each complaint and determines whether a complaint investigation is warranted.

6290.2.3 - Notification of Accreditation Organization

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The RO will notify the Division of Laboratory Services at CO and the appropriate representative of the laboratory's accreditation organization within 60 days of completion of the survey when the laboratory is placed under your monitoring jurisdiction. The RO copies all written communications to CO and the accreditation organization. The laboratory continues to be accredited. However, it is subject to the same requirements, survey, and enforcement procedures applied to nonaccredited laboratories found out of compliance following a survey. The facility is monitored until it reaches Condition-level compliance or when its certificate of accreditation is revoked.

6292.1 - Initial Action

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The laboratory must submit a PoC that is acceptable in terms of both its contents and the *time frames* for correction.

For the PoC to be acceptable, it must show that the laboratory can achieve compliance and that compliance can be **verified** within 12 months from the survey date.

If a laboratory fails to submit an acceptable PoC, and subsequent requests for an acceptable PoC are unsuccessful, the RO may cancel the laboratory's approval to receive Medicare payment for its services in accordance with 42 CFR Part 493.1842(a)(2)(ii). In addition, the RO may consider the laboratory's failure to comply with reasonable requests for information for purposes of 42 CFR 493.1840(a)(4) and may initiate a principal sanction, i.e., suspension, limitation, revocation of the CLIA certificate, on the basis of this failure.

6292.2 - Ensuring Timely Corrections

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

If the laboratory has not corrected its deficiencies within 12 months after the last date of the survey that identified the deficiencies, the RO cancels the laboratory's approval to receive Medicare payment for its services and imposes a principal sanction against the laboratory's CLIA certificate.

6297 - Summary of RO Responsibilities during CLIA Adverse Action Process

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

During an adverse action or civil suit against a laboratory, the RO has the following responsibilities:

- Notifies the laboratory of the exact enforcement action to be imposed against it, the authority for the action, and the effective dates;
- Generates revised CLIA certificates, if necessary;
- Suspends or limits *the* CLIA certificate if a laboratory's noncompliance poses immediate jeopardy;
- Assists in the collection of evidence and other information related to criminal actions by the laboratories;
- Notifies carriers and fiscal intermediaries or MACs of Medicare payment sanctions imposed against laboratories; and
- Provides appropriate notice to Medicaid State Agencies.

6306.4 - Relationship of Action on Laboratory's CLIA Certificate to Timing of Hearing

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

In cases where a laboratory's deficiencies do not constitute immediate jeopardy, action against a laboratory's CLIA certificate occurs after the administrative hearing if one is requested. In cases of immediate jeopardy, a CLIA certificate may be suspended or limited prior to an ALJ hearing. Civil money penalties, which accrue during periods of noncompliance prior to the hearing, are collected following a hearing decision favorable to CMS. Alternative sanctions other than civil money penalties and cancellation of the laboratory's Medicare/Medicaid approval may be imposed prior to an ALJ hearing.

If a laboratory's CLIA certificate is due to expire prior to the hearing date, CMS will reissue it for a 2-year period in order for the laboratory to remain operational except for cases of immediate jeopardy or when the criteria at 493.1840(a)(4) or (a)(5) are met.

6310.2 - Relationship of Cancellation of Medicare Approval to the Timing of the Hearing

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

If a laboratory does not correct its Condition-level noncompliance within 12 months from the date of the survey that identified the noncompliance, approval for Medicare payment for its services may be canceled at any time during those 12 months. Since laboratories receiving Medicaid payments in each State must be Medicare-approved, Medicaid payments under the State plan may not be made to those laboratories for which Medicare approval has been canceled. Subsequent to Medicare cancellation, the administrative hearing (if the laboratory had requested one *within* the appropriate time frame) is held.

6314 - Readmission to CLIA Program

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

If an administrative hearing decision upholds CMS' determination to revoke a laboratory's CLIA certificate, the owner and operator of the laboratory may not own or operate a laboratory for *2* years as outlined *at* 42 CFR 493.1840(a)(8). If the laboratory is taken over by another owner and/or operator who does not meet the criteria in 42 CFR 493.1840(a)(8), the laboratory must submit another CLIA application according to the procedures outlined *at* 42 CFR 493.45.

When a previously sanctioned laboratory seeks readmission or reinstatement, it may be necessary to survey the laboratory prior to reissuance (or reinstatement) of a CLIA certificate, regardless of the certificate type. The purpose of the survey would be to establish reasonable assurance that the prior deficient practices which resulted in the sanction action have been corrected and will not recur.

6316 - Laboratory Registry

(Rev.45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

The CLIA statute and 42 CFR 493.1850 require CMS to make information available to physicians and to the general public that is useful in evaluating the performance of laboratories. The laboratory registry is compiled for the calendar year preceding the date the information is made available *and* includes appropriate explanatory information to aid in the interpretation of the data. The categories included in the registry are:

- A list of laboratories that have been convicted under Federal or State laws relating to fraud and abuse, false billing or kickbacks;

- A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reason for the adverse actions;

- A list of persons who have been convicted of violating CLIA requirements, as specified in §353(1) of the PHSA, together with the circumstances of each case and the penalties imposed;

- A list of laboratories on which alternative sanctions have been imposed, showing:

    1. The effective date of the sanctions;

    2. The reasons for imposing them;

    3. Corrective action taken by the laboratory; and

    4. If the laboratory has achieved compliance, the verified date of compliance;

- A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation;

- All appeals and hearing decisions;

- A list of laboratories against which CMS has brought suit under 42 CFR 493.1846 and the reasons for the actions; and

- A list of laboratories that have been excluded from participation in Medicare and Medicaid and the reasons for the exclusion.