State Operations Manual

Chapter 6 - Special Procedures for Laboratories

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(Rev. 35, 04-18-08)

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6000 - Background

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 i*n 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.

6002 - CLIA Applicability

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The *complexity* or volume of testing conducted does not exclude an entity from being subject to CLIA, but these factors determine which requirements a laboratory must meet for CLIA certification, and the fees to be paid by the laboratory. These requirements apply whether or not the laboratory or entity bills the patient for the services or is paid for the services by Medicare or Medicaid.

Certain types of laboratories and laboratory tests are NOT subject to meeting CLIA requirements. These include:

- Any facility or component of a facility that performs testing strictly for forensic purposes;

- Research laboratories that do not report patient specific results (although they test human specimens) for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individuals;

- Components or functions of laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed that meets SAMHSA guidelines and regulations. (However, all other testing conducted by a SAMHSA certified laboratory is subject to this rule.);

- Laboratories under the jurisdiction of the Department of Veterans Affairs;

- Department of Defense (DoD) laboratories *are subject to requirements that CMS has determined to be comparable to those in CLIA*. The DoD is responsible for *assuring compliance with these requirements and for oversight of its laboratories under a Memorandum of Understanding (MOU) between the Secretary of HHS and the Secretary of DoD*. (See §6022 for discussions on Federal laboratories.);

- Laboratory testing conducted in conjunction with the provision of home health or hospice care in an individual's home, where the home health agency or hospice employee merely **assists** the individual in performing a test, since tests performed by individuals in the home are not subject to CLIA;

- Laboratories licensed in a State whose laboratory licensure program is approved by CMS, (i.e., CLIA exempt as approved under 42 CFR part 493, Subpart E);

- Facilities which serve only as collection stations. A collection station receives specimens to be forwarded to a laboratory performing diagnostic tests;

- Radiological facilities that perform only imaging procedures (e.g., x-rays, ultrasounds, Magnetic Resonance Imaging, Computerized Tomography);

- Facilities performing only physiological testing, e.g. spirometry, slit-lamp test for eyes*, breath analysis, pulse oximetry;* and

- Any facility or component of a facility that performs testing for drugs of abuse for employment purposes.

NOTE: In the preamble to the January 19, 1993, "Federal Register" notice (HSQ-202-FC), the application of CLIA requirements to employee workplace drug testing subject to CLIA was deferred until the issue could be studied further. Until such time as a final determination is made, CLIA regulations do not apply to testing conducted for workplace drug testing for employment purposes, including components or functions of any employer entity that performs substance abuse testing for any purpose **other** than as part of a treatment program. The CLIA rules do not apply to testing that results in disciplinary, administrative, or legal action if the test result is positive, or to testing for the presence or absence of substances of abuse involving an employee. This would include employer-testing programs, which might lead to disciplinary action, whether or not there is an associate referral to an employee assistance program (EAP). Positive tests that result in the employee's referral to an EAP do not make the EAP subject to CLIA unless the program actually does testing for substances of abuse itself as a part of a substance abuse treatment program. Testing for drugs of abuse is covered by CLIA when the testing is part of a treatment program.

If a laboratory is performing testing subject to CLIA and does not obtain the appropriate certificate, it is in violation of Public Law 100-578, §353, and subject to specified penalties. Such cases or suspected cases should be referred to the RO for referral to OIG. (See §6030.)

6004 - Consultative CLIA Activities

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Centers for Disease Control and Prevention (CDC) assists 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 - Application and Certificate Process

(Rev. 1, 05-21-04)

It is the responsibility of the laboratory to obtain and submit the CLIA application (Form CMS-116, Exhibit 125) and necessary personnel information for a CLIA certificate. The CLIA application collects information about a laboratory's operation that is necessary to determine the fees to be assessed, to establish baseline data and to fulfill the statutory requirements for CLIA. The information will provide an overview of a facility's laboratory operation. A laboratory cannot perform testing or claim Medicare and/or Medicaid payment for services performed without a CLIA certificate and/or valid CLIA identification number. (See Chapter 2, §2005, for additional information pertaining to "Medicare Health Care Provider/Supplier Enrollment.")

CMS (directly or through its agents or contractors) is responsible for providing, collecting, and processing CLIA applications (Form CMS-116); collecting registration and compliance fees; and entering application and fee data into the CLIA database. A CMS contractor issues the CLIA certificate through the CLIA data system.

6006.1 – Certificate of ***Registration***

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A Certificate of Registration is *issued initially to any laboratory that applies for* a *C*ertificate of *C*ompliance or *C*ertificate of *A*ccreditation 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.

6006.2 – Certificate of Waiver

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A Certificate of Waiver (COW) is issued to a laboratory that *performs* only waived tests *as listed at 42 CFR Part 493.15* and pays the appropriate fee. Waived tests are those tests that have been determined to be so simple that *if performed incorrectly will pose no risk of harm*. Tests approved for COW status can be viewed at CMS'CLIA website (http://www.cms.gov/clia). A COW is valid for a 2-year period. Upon certificate expiration, and after payment of appropriate fees, the laboratory's certificate will be renewed for another 2-year period. While the laboratory with a COW is not subject to *routine inspections, the laboratory must comply with CLIA registration and certificate requirements and* follow the manufacturer's instructions for test performance.

6006.3 – Certificate for Provider-Performed Microscopy (PPM) Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A Certificate for Provider-Performed Microscopy (PPM) procedures is issued to a laboratory *in which* a physician or practitioner performs only the microscopy tests listed at 42 CFR 493.19(c) or performs only the listed microscopy tests in any combination with waived tests. A certificate for PPM procedures is valid for a 2-year period. Upon expiration, and after payment of appropriate fees, the laboratory's certificate will be renewed for another 2-year period. The laboratory that holds a PPM certificate is subject to *nonwaived* quality system requirements. *H*owever, such a laboratory is not routinely surveyed and may be included in a *survey sample of* non-waived laborator*ies*.

6006.4 – Certificate of Compliance

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A *C*ertificate of *C*ompliance 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 *C*ertificate of *C*ompliance will reflect the effective date for each approved specialty/subspecialty. A *C*ertificate of *C*ompliance 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 *C*ertificate of *C*ompliance 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 *C*ertificate of *C*ompliance 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.

6006.5 – Certificate of Accreditation

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A *C*ertificate of *A*ccreditation is issued to a laboratory once the accreditation organization verifies to CMS the accreditation status of the laboratory. The *C*ertificate of *A*ccreditation will reflect the effective date for each specialty/subspecialty approved by the accreditation organization.

Upon a certificate's expiration, and after payment of appropriate fees, the laboratory's certificate will be renewed with a new 2-year effective date unless CMS is notified by the accreditation organization of a laboratory's non-accreditation status.

In the event of a Condition-level noncompliance determination as a result of a random sample validation or complaint survey, a laboratory with a *C*ertificate of *A*ccreditation is subject to a full review by CMS or its designee. A *C*ertificate of *A*ccreditation may be issued to an accredited laboratory that is out of compliance at the Condition-level provided an acceptable Plan of Correction (PoC) is received by CMS or its designee, and the compliance does not constitute immediate jeopardy, even if a hearing is pending.

6006.6 – Effective Dates

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The effective date of the initial *C*ertificate for PPM procedures, *Certificate of Registration*, or a *C*ertificate of *W*aiver for new laboratories is the date the CLIA application, Form CMS-116 *(Exhibit 125)* is entered into the CLIA data system.

The effective date of the *C*ertificate of *C*ompliance is the date the laboratory is surveyed and found in compliance with the CLIA requirements.

The effective date of the *C*ertificate of *A*ccreditation is the date the organization verifies to CMS that the laboratory is accredited. This date can be no earlier than the accreditation organization initial approval date. Once the effective dates are established, the laboratory's 2-year certificate cycle is set.

6006.7 – Verification of Laboratory Director Qualifications

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Laboratories applying for a Certificate of PPM procedures, Certificate of Compliance or Certificate of Accreditation must meet the qualifications of Laboratory Director as found in Sections 493.1357, 493.1405, 493.1406 and 493.1443. Before the CLIA application (Form CMS-116) is approved, the SA is responsible for verifying that the Director meets the appropriate personnel qualifications. The SA may request the Director to provide the following documentation: evidence of meeting state licensure requirements (if applicable), copy of diploma, transcripts from accredited institution, evidence of Continuing Medical Education (CME) credits in laboratory practice, appropriate laboratory experience, etc.

6007 - CLIA Certificate Status Changes

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Laboratories operating under a COW or *C*ertificate 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 *C*ertificate of *C*ompliance or *C*ertificate of *A*ccreditation 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 *C*ertificate of *C*ompliance to a *C*ertificate of *A*ccreditation 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 *C*ertificate of *C*ompliance until the certificate expiration date and subsequently change the certificate status. *I*f 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 f*ees will be system generated. The *C*ertificate *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 *C*ertificate of *A*ccreditation to a *C*ertificate of *C*ompliance will have its survey authority transferred to the appropriate State Agency. The CLIA system must be updated, 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 - Laboratory Location - Criteria for Meeting the Exceptions

(Rev. 1, 05-21-04)

Each location where laboratory tests are performed must file a separate application to be separately certified 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.

Consider the following guidance for HHAs with multiple sites having the following options when applying for CLIA certification. Each site or office may apply for its own individual certificate, or multiple sites may apply for one CLIA certificate as long as

these sites are under one provider number, i.e., parent branch. Since subunits by definition operate independently and have a unique provider number, each subunit must apply for a unique CLIA identification number.

NOTE: A primary site or home base is responsible for the day-to-day operation, supervision and administration of laboratory testing, including the employment of qualified personnel. Multiple sites are allowed under one certificate providing the laboratory director is identical for all affiliated testing sites.

6010 - Assignment of CLIA Identification Numbers

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CLIA identification numbers are 10-digit alphanumeric numbers issued by the CLIA *data s*ystem. This is assigned at the time of initial entry of the CLIA application and included with the mailing of the remittance fee coupon. The 10-digit number consists of the following fields:

- Positions 1 and 2 in most cases identify the State in which the laboratory was located when it initially applied for a CLIA certificate. (A laboratory that relocates to another State retains its original CLIA number.);

- Position 3 is the alpha letter "D" to identify the provider/supplier as a laboratory under CLIA; and

- Positions 4 through 10 are the unique facility number identifiers.

Laboratories which are CLIA-exempt and those designated as VA laboratories do not have a CLIA certificate, but are assigned a CLIA identification number using the 10-digit number.

Once a laboratory is assigned a number, it retains this number even if it withdraws from CLIA, has its license revoked, changes its certificate type or ownership, location (i.e., relocates to another State), name, or operator. A CLIA number will not be reassigned to another laboratory for any reason.

6012 - CLIA Information in OSCAR System

(Rev. 1, 05-21-04)

The Online Survey Certification and Reporting System (OSCAR) includes information on laboratories that participate under CLIA. Some of the information is comparable to what is collected in OSCAR on other suppliers of services and providers. The entry and reporting of surveys, Federal surveys, and complaint investigations on CLIA laboratories are maintained in OSCAR's subsystems. Additionally, OSCAR captures unique data

such as approved specialties/subspecialties of testing and CLIA certificate history that is collected in conjunction with laboratories that participate in CLIA.

6014 - CLIA Data System

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The CLIA data *system*, which is a subsystem of OSCAR, is a computerized subsystem that maintains *demographic and billing* data on every laboratory in the nation that is required to participate in the CLIA program. The data *system* supports CLIA program operations, including the *entry* and display of the CLIA application (Form CMS-116) *(Exhibit 125)*, the billing and collection of laboratory user fees *and the* issuance of certificates.

Authorized users can query the CLIA data *system to review* CLIA certificate data and laboratory accounts data. A browse feature allows users to *view* certificate/laboratory data and laboratory accounts data within the CLIA data *system*. A specific record from a list of available records or data for a specific laboratory within the data *system* may be selected. Additional features (such as adding or updating information) are available based upon the security authorization of the individual user.

Standard or user defined reports that provide general information that users request are available through the OSCAR system. Consult with your OSCAR Coordinator to obtain specific directions on how to use the system, or any of the current available OSCAR or CLIA Users' Guide(s).

6016 - Revised Certificates

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The laboratory must report any changes to its name, location, specialty *and/*or subspecialt*ies of testing* (if applicable), or director (operator *or owner*) once the laboratory is issued any certificate. *A laboratory holding a Certificate for PPM Procedures or Certificate of Compliance must report a director change using a CLIA application (Form CMS-116). The SA is responsible for ensuring that the new director meets the personnel qualifications (see §6006.7).* Provisions have not yet been implemented to issue and charge a fee for revised certificates. *T*he ROs *and CO* have been given approval to issue revised or misplaced certificates without corresponding fees.

6018 - *Fee* Adjustments

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO/SA should contact the CO CLIA component for *guidance*.

6020 - Regional Office (RO) Role

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO is responsible for:

- The certification of Federal laboratories and some State operated laboratories within each region (see §6022);

- Oversight and monitoring of CLIA certification and enforcement activity for the States within the region, e.g., performance of Federal Monitoring Surveys (FMS) (see §6232), Alternative Quality Assessment Survey Protocol *(AQAS)* (see §6112), CLIA State Agency Performance Review (SAPR) (see §6230); and

- Performing validation and complaint surveys of laboratories in States whose laboratory licensure programs have been approved by CMS. (See Chapter 5 regarding additional information about complaint investigations of laboratories)*; and*

- *Identifying administrative/program problems at the State, regional or national level.*

6022 - Laboratories Under Direct RO Jurisdiction

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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*.

- **Laboratories outside the United States**

  A laboratory outside the United States is also required to possess an appropriate CLIA certificate if it performs laboratory tests on human specimens referred to it by a CLIA laboratory in the U.S. or its territories. CO will determine survey responsibilities for laboratories *that are* located outside of the U.S. and its territories that must comply with CLIA requirements. CLIA applications (Forms CMS-116, *Exhibit 125*) for laboratories located outside of the U.S. are forwarded to the New York RO for processing. For specific instructions for *the* CLIA application *process*, see §6006.

- **State operated laboratories**

  Laboratories owned or operated by the State represent a possible conflict of interest for survey purposes. Those State-operated laboratories where there is a conflict of interest will be surveyed by the RO.

  The RO uses the following criteria to determine if a conflict of interest exists in State operated laboratories for CLIA survey and certification purposes.

    State surveyors work under the supervision of the same individual who is directly responsible for operating the State operated laboratory or laboratories; and/or

    State surveyors work in a State laboratory that is subject to CLIA.

A conflict of interest may not exist if the State funds local public health laboratories but does not operate them directly, or if one department of State government operates the laboratory and another department surveys them (e.g., Department of Public Health vs. Department of Mental Health).

Survey and certification functions are performed for laboratories under RO jurisdiction using the procedures in §§6100 - 6138 (monitoring of proficiency test scores) and Appendix C of the SOM, *"Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services."*

6024 - RO Review of SA Certification Activities

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CLIA has a single set of regulations applicable to all types of laboratories or entities performing laboratory tests based on test complexity. The RO is responsible for reviewing certification activity of the SA. The primary objective of this review is to ensure that the certification decision is supported by appropriate documentation that serves as sufficient evidence of the laboratory's compliance with the laws and regulations governing program participation.

In meeting this objective, the RO reviews the SA's certification process. The RO review will ensure that the SA's:

- Certification of compliance is consistent with the documented findings, taking into account the impact of deficient requirements on the respective conditions;
- Recommendation of compliance or noncompliance is appropriate;
- Interpretation of reasonable time and reasonable plans for the correction of deficiencies is appropriate; *and*
- Processing of CLIA certifications (including entering information into the CLIA data *system and* OSCAR is efficient, accurate, and timely.

If the RO determination disagrees with the SA, the decision must be supported by evidence. The RO justifies the determination in writing and attempts to resolve the disagreement. To foster continuous quality improvement, the RO communicates the resolution to CO. *If a disagreement involves* interpretive policy *that* cannot be resolved, it should be referred to the CO for resolution.

6026 - State Agency (SA) Role

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

State agencies are responsible for survey and certification activity (including data entry) for non-Federal laboratories within its State. Lists of laboratories ready to be inspected are available to SAs through the CLIA data *system*. The SA recommends to the RO whether to certify laboratories.

6028 - CLIA Laboratories - Compliance With Civil Rights Requirements

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CLIA laboratories are required to comply with certain requirements enforced by the Office for Civil Rights (OCR), including the Americans with Disabilities Act, but are not subject to traditional pre-certification assurance investigations. These requirements are enforced only on the basis of complaints. The OCR makes any necessary investigations and determinations related to compliance with civil rights requirements.

The SA forwards complaints concerning a CLIA laboratory's noncompliance with Federal civil rights requirements to the RO. The complaint should be forwarded to OCR for review and investigation. As necessary, OCR forwards the complaint to the Department of Justice (DOJ) for evaluation, investigation, and disposition. *T*he RO *does*

not investigate Federal civil rights complaints *under any circumstances*. OCR or the DOJ is responsible for investigating Federal civil rights complaints. CMS is not authorized to bill the laboratory for the cost of a complaint survey for noncompliance with civil rights as part of the laboratory's fee obligation.

6030 - Referrals to the Office of Inspector General (OIG)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If a laboratory is operating without a CLIA certificate, the SA or RO as applicable, notifies the laboratory that it is violating CLIA requirements (see Exhibit 110), and warns the laboratory of the consequences of such violations. The laboratory is afforded an opportunity to respond within 14 days. If it does not respond, or does not cease testing without a certificate within 30 days of the date of the notification to the laboratory, the RO will notify the OIG of the violation. *If applicable, t*he SA forwards documentation to the RO within 20 days of the date the violation notice was sent to the laboratory. In addition, the RO also refers to the OIG:

- Cases of misrepresentation in obtaining a CLIA certificate;
- Laboratories that perform or represent the laboratory as entitled to perform tests not authorized by its CLIA certificate; and
- Laboratories that violated or aided or abetted in the violation of any provision of CLIA and its implementing regulations.

6032 - Notification of Change in Laboratory Operations

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When a laboratory provides written notification of a change in location, director, laboratory name, technical supervisor and deletion of specialties or subspecialties, the SA enters the information into the *CLIA* data system *(or OSCAR system, as necessary)* and retains a copy of the laboratory's letter of request. The SA must not accept oral notices of change or intents to change. *When a laboratory holding a Certificate for PPM Procedures or Certificate of Compliance reports a change in director, the laboratory must complete and sign a CLIA application (Form CMS-116). The SA is responsible for ensuring that the new director meets the personnel qualifications (see §6006.7).* Once a compliance determination has been made on an addition of a specialty or subspecialty, the SA agency enters the information into the *OSCAR* system. For further information refer to §6102.2.

For information concerning change of ownership see Chapter 2, §2005.

6034 - Mobile Laboratories

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A mobile laboratory is defined as a movable, self-contained operational laboratory with its own personnel, equipment, and records. It is not a vehicle that only transports laboratory equipment, supplies or personnel from one location to another, such as a vehicle used for transporting instruments, specimens, and supplies to or from a health screening fair. Mobile laboratories *may use the multiple site exception and file a single application for the appropriate CLIA certificate using the address of its home base.*

If a mobile laboratory operates in more than one State and does not obtain a separate certificate *for* each State, the SA contacts the RO to determine which State conducts the inspection. A mobile laboratory may perform testing only when the laboratory is stationary.

Each mobile vehicle and each laboratory that moves from testing site to testing site or has a temporary testing location, should provide *the* SA with the home base or central dispatch phone number, so that *the SA can obtain* an updated schedule of the location of testing and the hours of operation. Records may be maintained in the *mobile vehicle* or at the home base. Reports should reflect the home base address and indicate which mobile unit performed the test. The vehicle identification number distinguishes mobile laboratory vans. Concerns unique to mobile laboratories are addressed throughout Appendix C.

6036 - Facilities With Multiple Sites

(Rev. 1, 05-21-04)

6036.1 - Hospitals

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Laboratories within a hospital that are located *in* contiguous buildings on the same campus and under common direction may file a single application or multiple applications for the laboratory sites within the same physical location or street address. Hospital satellite or auxiliary laboratories located outside a hospital (at a different physical location) must each make a separate application. "Under common direction," means the hospital laboratory director is responsible for the quality of laboratory testing in all laboratories within the hospital that are covered by a single application and certification. "Street address" is the address assigned by the post office and is the physical location of the main laboratory. The street address may be different from the mailing address, which can be a post office box or a billing address. For large hospitals, such as a university campus facility that may contain laboratories in separate buildings,

the SA consults with the RO to determine if the hospital is eligible for a single certificate. A single individual may be named as director of up to five laboratories. A certificate may include more than one laboratory using the above criteria. The SA refers questions regarding multiple sites status to the RO.

The SA surveys in its entirety each laboratory site within a hospital seeking a single certification for all applicable conditions and standards. Proficiency testing (PT) is the only exception. Every laboratory site within a hospital is not necessarily required to perform PT. However, all analytes tested within the hospital laboratory's certification must be enrolled in an appropriate PT program. Appendix C has additional guidance concerning PT coverage at multiple sites.

Each certified laboratory must have a comprehensive quality system designed to continually monitor and evaluate the overall quality of testing. The SA verifies that the laboratory quality assessment (QA) program includes all laboratory testing locations covered under the laboratory's certification.

6036.2 - Laboratories Performing Limited Public Health Testing

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Not-for-profit or Federal, State, or local government laboratories with multiple sites that engage in limited public health testing may file a single application for a certificate regardless of the physical location. Multiple laboratories may be covered under one certificate as long as they are not-for-profit or Federal, State, or local government laboratories and collectively perform no more than any 15 tests categorized as moderate or waived. If a laboratory system performing limited public health testing operates in more than one State and does not obtain a separate certificate *for* each State, the SA contacts the RO to determine which State conducts the inspection. The laboratories may choose to apply for more than one certificate, and may want to do so based on the ramifications of any PT failures (for *moderate complexity testing*), or any deficiencies cited during a compliance survey which would in any way limit the laboratory's certificate.

Not-for-profit or Federal, State, or local government laboratories that perform **high** complexity testing must file a separate application for certification for each laboratory performing high complexity testing regardless of their profit or government status.

Each separate location of a not-for-profit or Federal, State, or local government laboratory covered under a single certificate must meet all the applicable requirements of 42 CFR 493. The only exception is Subpart H, Participation in PT. All specialties, subspecialties, analytes or tests performed by that public health laboratory system must be enrolled in an approved PT program, if one is available. At the laboratory's discretion, PT samples may be distributed to all testing locations, restricted to certain locations, or performed at one location. (See Appendix C.)

At a minimum, the SA verifies that all laboratory sites are included in a laboratory's comprehensive QA program that monitors the correlation of 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.

6036.3 – Temporary Testing Sites

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A temporary testing site is where, at various intervals of time, an entity that is not at a fixed or permanent location performs laboratory testing. The laboratory moves from testing site to testing site. The laboratory's certificate is in the name of the home base or designated primary site.

6038 - Transfusion Services Covered by CMS/FDA Memorandum of Understanding (MOU)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CMS and FDA have a MOU concerning transfusion services. For the purposes of the MOU, a transfusion service is defined as an establishment which is engaged in the compatibility testing and transfusion of blood and blood components, but which neither routinely collects nor processes blood and blood components. Transfusion services are exempt from FDA registration and are not routinely inspected by FDA.

Transfusion services are allowed to perform certain specified blood processing activities. Transfusion services may prepare Red Blood Cells or recovered plasma from Whole Blood, pool Platelets or Cryoprecipitated AHF for ease of transfusion, or issue bedside leukocyte reduction filters with blood components.

However, if an establishment performs any other blood processing activity, including but not limited to freezing, deglycerolizing, washing, irradiating, rejuvenating, or leukocyte-reducing Red Blood Cells, it is not considered to be a transfusion service. Blood establishments performing these functions are required to register with FDA and are routinely inspected by FDA.

NOTE: The definition of transfusion service for the purposes of the CMS/FDA MOU is different than the CLIA definition of transfusion service.

The scope of the CMS/FDA MOU is limited to transfusion services that are CLIA-certified and are exempt from FDA registration as blood establishments. Facilities that are both CLIA-certified and registered with FDA as blood establishments are outside the scope of the MOU.

6038.1 – Inspections of Transfusion Services

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA routinely conducts CLIA surveys of non-accredited immunohematology laboratories that meet the definition of a transfusion service under the CMS/FDA MOU. These transfusion services are not registered with FDA and FDA does not routinely inspect these facilities. An example of this type of facility is a hospital transfusion service that obtains its blood products from an outside provider.

Under the MOU, the SA must survey transfusion services for compliance with all applicable CLIA regulations, including those FDA regulations that are cited in 42 CFR Part 493, Subparts J and K. It is not required that the SA survey transfusion services for any other FDA regulations, except as noted below in §6038.2.

Blood establishments that are registered with FDA are routinely inspected by FDA. Non-accredited immunohematology laboratories located within these blood establishments are also routinely surveyed by the SA for CLIA. Because these facilities receive inspections by both agencies, they are not covered by the CMS/FDA MOU. An example of this type of facility is a community blood center in which blood is collected, processed, tested and distributed to hospitals.

The following table summarizes the different types of facilities:

Non-Accredited Immuno hematology Laboratory?	Blood Establishment		Surveyed by State Agency for CLIA?	Inspected by FDA?	Covered by MOU?
	Registered with FDA?	FDA Registration Exempt?			
Y	Y	N	Y	Y	N
Y	N	Y	Y	N	Y

6038.2 – Additional Survey Requirements Under the CMS/FDA MOU

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Under the CMS/FDA MOU, the SA is required to survey transfusion services for compliance with all applicable CLIA regulation, 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.*

6040 - Transfusion-Related Fatalities

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Facilities, including laboratories, involved in the collection or transfusion of blood or blood products must report transfusion-related fatalities to FDA's Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality *by E-mail at fatalities2@cber.fda.gov or by telephone/voice mail at* 301-827-6220.

*FDA notifies CMS CO of all transfusion related fatalities. (**NOTE**: The reports from the FDA are considered confidential and may only be shared within CMS or the SA. They may not be shared with any other party, including accreditation organizations.) CMS CO evaluates the information received from the FDA. As applicable, CO may request that a survey of the facility be performed. The request is made in a letter that is sent from the Director, Division of Laboratory Services, to the appropriate area administrator. Depending on the circumstances of the fatality, a CLIA survey, a survey by another CMS program (e.g., hospital), or both, may be necessary. The surveys may be performed simultaneously or separately. Either the RO or SA (including CLIA exempt states) may perform the survey, but the survey may not be delegated to an accreditation organization. For investigations involving staff from more than one program unit (e.g., CLIA and hospital), it is important to work as a team to coordinate activities. Within CLIA, the RO is the point of contact for coordinating the investigation.*

For CLIA purposes, transfusion-related fatalities that warrant surveys are considered to be complaints. The policies and procedures that apply to complaint investigations apply to transfusion-related fatality investigations. The investigations are entered and tracked in the ASPEN Complaint Tracking System (ACTS). When performing investigations in accredited laboratories or laboratories in exempt states, follow standard policies and procedures for RO authorization, review of deficiencies, and communication with the laboratory, the accreditation organization, and the exempt state.

The RO or SA will schedule and conduct the survey within 45 days of the notice from CO, with a report to CO within 60 days. (For CLIA investigations, the information entered in ACTS is sufficient for reporting to CO; no additional report is necessary. However, for investigations involving hospital conditions, a report is required.) Investigations of transfusion-related fatalities are generally scheduled, since the facility is aware of the possibility of a follow up after the report is made to FDA. These investigations are an exception to the general policy that complaint surveys are not announced. However, if the report of the fatality originates with any other source, e.g., media or anonymous complaint, the SA or RO conducts an unannounced survey.

*The RO or SA will assess the facility's compliance with applicable CLIA conditions and standards during the onsite review. If condition-level deficiencies are found, a full CLIA inspection is conducted. The survey may uncover problems that warrant investigation of departments outside the laboratory, e.g., Operating Room, Emergency Room, nursing services, or medical records, to follow up on problems that may have led to the fatality. Since CLIA is specific only to laboratory testing, the RO forwards relevant information to other programs, e.g., hospital, for follow up as necessary. (**NOTE:** When citing deficiencies related to a CLIA survey, only D-tags should be used on the 2567. A-tags should not be used on the 2567 given to the laboratory for the CLIA survey.)*

The RO or the SA will issue deficiencies and document the survey in ACTS using standard policies and procedures.

6042 - Proficiency Testing (PT)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 493.901(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.*

6044 - Enrollment Information

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Each calendar year the PT programs transmit enrollment records to the OSCAR PT Monitoring System for each laboratory participating in their program. Laboratory demographics and every test for which the laboratory has enrolled are listed on OSCAR Report 155, PT Individual Laboratory Profile. This information is transmitted just prior to the first testing event of the year. Additional enrollments (usually for new

laboratories) are sent to the system as enrollment occurs throughout the year. The surveyor must verify that laboratories are correctly enrolled during the on-site survey. If the SA or RO wishes to verify enrollment more frequently, they may print out OSCAR Report 155 for the prior year and compare it to new enrollment for the current year. If there are tests missing on the current year's enrollment when compared to the prior year, the SA or RO should call the laboratory to ask for proof of enrollment for the missing tests or ask for a written statement from the laboratory director that it has discontinued performing the missing tests.

6046 - PT *(*Excluding Cytology*)* for Non-Accredited and Non-CLIA Exempt Laboratories

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Title 42 CFR 493.801(a)(1) requires laboratories performing moderate and/or high complexity tests to enroll in one or more CMS approved PT programs for each specialty, subspecialty, analyte, or test listed in 42 CFR 493, Subpart I. The laboratory must designate a specific survey (as well as PT program) for each specialty, subspecialty, analyte, or test for regulatory purposes, so that only one score is considered for that area per testing event. The specialty, subspecialty, analyte or tests for PT are listed in 42 CFR 493.909 through 493.959. If a laboratory fails to enroll and/or appropriately test PT samples, the RO may impose any of the sanctions described in 42 CFR 493, Subpart R.

6048 – PT Enrollment*, Participation,* and Testing Requirements

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A laboratory must meet the CLIA regulatory requirements for enrollment, participation, and testing as specified in subpart H at 42 CFR Part 493.801. The SA, adhering to the timeframes 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.

6050 – Monitoring *of* PT *Scores*

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA routinely monitors their state's laboratory performance by reviewing OSCAR Report 153, PT Unsatisfactory/Unsuccessful Report, from the PT Monitoring System. The RO will determine how frequently the SA will review the performance. The SA (and RO for Federal jurisdictional laboratories) identifies a laboratory's noncompliance with requirements for successful participation from this report. Prior to on-site survey, the SA will review OSCAR Report 155, PT Individual Laboratory Profile, which will display the individual laboratory's PT performance. The PT system holds reports for just over two years. The SA may print the reports on prior individual laboratory performance to take with them on survey and compare any specific PT results that the PT system scores indicate as unsatisfactory or unsuccessful.

The SA will recommend sanctions or enforcement actions to the RO for failure to meet PT requirements for successful participation. This may only be done after the SA has verified the PT results from the PT program or from the laboratory. Specifically, SA follow-up action for unsuccessful PT performance should consist of:

- *Obtaining the results for each unsatisfactory analyte, subspecialty, or specialty that contributed to the laboratory's unsuccessful performance from the laboratory or from the PT program; and*
- *Reviewing the PT performance reports and determining if the unsatisfactory results truly represent the laboratory's failure to perform and report the test(s) satisfactorily. For example, clerical errors and delays in reporting still constitute failure; however, an instrument failure, a PT program data input error, or a backorder of necessary reagents may not be within the laboratory's control. Careful reviews will provide a fair evaluation of the laboratory's performance and insight into the reason(s) for the PT failure. Problems regarding PT samples such as matrix effects and scoring are to be handled between the laboratory and the PT program.*

6052 - PT *Monitoring System* Reports

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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

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.

6054 - Unsuccessful Performance in Proficiency Testing

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If *it is determined that* a laboratory has *performed unsuccessfully*, the SA follows the procedures in §6058.

Unsuccessful participation, unsatisfactory performance and unsuccessful performance are defined at 42 CFR Part 493.2, Definitions.

Unsuccessful participation *is defined as follows*:

Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events; unsatisfactory overall testing event scores for two consecutive, or two out of three testing events; *or a*n unsatisfactory testing event score for those subspecialties not graded by analyte (i.e., bacteriology, mycobacteriology, virology, parasitology, mycology, unexpected antibody detection, *and* compatibility testing) for the same subspecialty for two consecutive, or two out of three testing events.

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

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

Unsuccessful performance may be used interchangeably with unsuccessful participation for non-cytology PT. (Please 42 CFR Part 493.2)

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

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 timeframe allotted for testing and reporting of PT results;

- The laboratory notifies *SA/RO* and the PT program within the timeframe 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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Unsuccessful PT performance under CLIA is defined as unsatisfactory performance in two consecutive or two out of three events for an 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 S*ystem 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 cuased 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 Participated Successfully in a Proficiency Testing Program.

6060 - Reinstatement After Failure to Successfully Participate in Proficiency Testing

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 withdraw*s 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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 one 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 §493.801(b)(4), it will have its certificate revoked as stated in §493.1840. This refers to **ALL** samples purchased from a PT program; samples for tests listed in subpart I AND samples for tests not listed in subpart I that must be checked for accuracy twice peryear for quality assurance and/or assessment (QA) purposes.*

6062 - Onsite Observation of Proficiency Testing

(Rev. 1, 05-21-04)

RO/SA Surveyors may elect to observe PT performance onsite as part of the survey process or because of failure in PT by the CLIA laboratory.

6063 – Survey Protocols for Compliance with Cytology Proficiency Testing

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 atn 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 individual 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 continuine 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.*

6100 - The Survey Process - Emphasis, Components, and Applicability

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Survey protocols and Interpretive Guidelines provide guidance to personnel conducting surveys of laboratories. *Surveys are conducted using an* outcome-oriented survey process*, which* places emphasis upon performance or outcome measurements to ensure accurate and reliable test results and other related activities. The purpose of the protocols and guidelines is to provide suggestions, interpretations, and other tools to use in preparing for and conducting the survey and for analyzing and evaluating survey findings. (See Appendix C). Both the SA and RO use the same survey protocol.

6102 - Scheduling Surveys

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6102.1 – Scheduling Priorities

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 3 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) or 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 timeframe 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 timeframe 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.

6102.2 – Survey Due to Unanticipated Events

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA or RO conducts a survey at an earlier date than planned if there is reason to believe the laboratory is being operated in a manner that constitutes a risk to human health. Possible reasons for this would be a complaint about deteriorating standards of operations, results of an accreditation survey of an accredited laboratory, loss of laboratory accreditation, substantial changes in managerial personnel, *continued unsatisfactory PT performance,* or a significant change (e.g., from moderate to high complexity) in the type of testing performed. The decision to conduct a survey at an earlier date than originally planned depends upon whether there is likelihood that certification status could be changed. Such surveys must be unannounced.

6102.3 – Change of Location of Laboratory

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Changes in location of a laboratory within a State do not ordinarily require a special on-site survey. The laboratory is expected to continue to uphold the standards of operation detailed in its most recent survey. An on-site survey is to be performed only when the relocation raises significant questions as to the laboratory's ability to maintain standards. In these situations, the SA considers when the last recertification survey was performed. If a recertification survey is due within the next six months, the SA advances the entire

resurvey. If the recertification survey is not due, and an on-site visit is performed, the SA conducts a limited review focusing on the issues that led to question the laboratory's ability to maintain standards. The SA documents the justification for performing special on-site surveys and maintains this documentation in the laboratory's official file.

6102.4 – Change of Testing Performed by a Laboratory

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If a laboratory, other than a laboratory with a *C*ertificate of *W*aiver, begins to perform additional tests, a SA survey or resurvey may be required. (For laboratories with a *C*ertificate of *W*aiver that want to expand services to include nonwaived testing, see §6007 and §6016). The regulations permit laboratories with a certificate to add services for *6* months prior to notification to CMS, although laboratories will not be eligible for Medicare or Medicaid payments until they have made the notification and their certificate has been revised. If a regularly scheduled survey occurs during the 6-month period a laboratory has added services but has not notified CMS, the SA surveys the added services.

6106 – Policy *On Announcing Surveys*

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

It is CMS' policy to give advance notice to laboratories (up to two weeks) when conducting surveys to determine compliance. However, HHS or its designee may conduct announced or unannounced survey of any laboratories at any time during its hours of operation to assess compliance with the applicable requirements within 42 CFR Part 493. If there is any conflict with internal State policies and practices, the SA discusses it with the RO.

The complaint or revisit/follow-up surveys must be conducted on an unannounced basis. Validation surveys of accredited or CLIA-exempt laboratories are typically announced, *except for simultaneous validation surveys of laboratories accredited by certain accreditation organizations (See §§6227.3.1 - 6227.3.2). I*n cases where there is significant evidence of non-compliance in the survey findings of the accreditation organization or CLIA-exempt State agency, the RO has the latitude to treat such a survey as a complaint *survey, which is unannounced. (See SOM Chapter 5 for guidance regarding complaint investigations.)*

6106.1 – Follow-Up Surveys

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In many circumstances, a mail or telephone contact may be sufficient in lieu of an on-site revisit. *When possible, revisit surveys should be conducted by the surveyor who made the findings.* (See §6132.)

6106.2 – Testing Outside the Certificate Type

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In accordance with 42 CFR 493.1775, if it is verified that the laboratory is *testing outside of its certificate type*, the laboratory is in violation of CLIA. *The SA allows the laboratory the opportunity to submit a new Form CMS-116 (Exhibit 125) requesting an appropriate certificate. If the laboratory fails to do so in a timely manner, t*he SA completes a Medicare/Medicaid Certification and Transmittal (Form CMS-1539, *Exhibit 9*), and in Item 16 (State Survey Agency Remarks) recommend referral to OIG. The SA completes a Statement of Deficiencies and Plan of Correction (Form CMS-2567, Exhibit 7), to indicate the findings of the survey, and does not solicit a PoC from the laboratory. The SA attaches any documentation that can be used in the adverse action process to substantiate the recommendation and submits all of the documentation, including the completed Form CMS-1539 and Form CMS-2567, to the RO. The SA refers to §6016 if the laboratory wants to add nonwaived tests.

6106.3 – Accredited Laboratories

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Laboratories accredited by a CMS approved organization are deemed to meet the requirements of 42 CFR Part 493. When the RO/SA receive*s* notification from a laboratory, which was previously inspected by the RO/SA, that it has been accredited, the SA verifies the laboratory's accreditation status *by asking the laboratory for documentation of its application to the accreditation organization* before removing the laboratory from the RO/SA's biennial survey schedule. If any standard-level deficiencies are still pending on this laboratory, the SA discontinues any follow-up on the deficiencies and forwards the pending deficiencies to the laboratory's accreditation organization. If the pending deficiencies are serious and represent a threat to the quality and reliability of the laboratory's testing, i.e., Condition-level non-compliance exists, the matter is referred to the RO. A laboratory's accreditation cannot be recognized until it has corrected its Condition-level deficiencies.

6106.4 – CLIA-exempt Laboratories

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Laboratories exempt through an approved State licensure program are subject to validation surveys conducted by the RO or its designee.

6108 - Survey Responsibilities

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA*/RO* uses Appendix C for guidance in conducting the on-site survey, and entering the information concerning the results of the survey into the *Online Data Input and Edits (ODIE) subsystem of OSCAR* if the laboratory is in compliance. In the event of a noncompliance determination, see §6134.

6110 - Survey Team Size and Composition

(Rev. 1, 05-21-04)

Each SA surveyor must meet the education and training qualifications in §4009. If more than one surveyor is performing the survey, all surveyors are to survey together during the same time interval. (See Appendix C, **"**Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services.")

6112 - Laboratory Self-Assessment

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

For those laboratories that continue to pose potential risks to the public health and safety, judging from their compliance history, regular onsite inspections present the most viable course of assuring that these laboratories maintain compliance with the CLIA requirements. On the other hand, for those laboratories that have sustained record of maintaining compliance, the need to have a constantly recurring onsite presence is not as compelling. For those laboratories a self- assessment would be used between onsite inspections.

The "Alternative Quality Assessment Survey (AQAS)," is the self- assessment document designed to be used by RO*s* and SA*s* in nonwaived and non-accredited laboratories. The SA should reassure the laboratory that the AQAS is a reward for exceptional performance. However, no laboratory will receive the AQAS for two consecutive certification cycles.

NOTE: Due to publication of the Final Rule, CMS-2226-F (Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and

Certain Personnel Qualifications, 68 FR 3640), *the AQAS will be placed on hold until quality control policies are resolved. AQAS will not be conducted until notified by CO*.

The criteria for using the AQAS is based on past laboratory performance. If the laboratory meeting the criteria below is in receipt of the AQAS and requests that an onsite survey be performed, the RO or SA confirms whether the laboratory agrees to also complete the form. Such laboratories can be considered part of the AQAS verification pool. Laboratories meeting the criteria for receipt of the AQAS and that do not wish to complete the form will be removed from the AQAS pool and be surveyed onsite. The SA uses the AQAS when laboratories meet the following criteria:

- Have been surveyed onsite during the certification period prior to being considered for receipt of the AQAS.

- Have zero or few minor deficiencies cited during the previous certification period. The RO will determine what constitutes a minor deficiency in order to qualify a laboratory for receipt of the AQAS.

- Have enrolled and satisfactorily participated, (i.e., attained a minimum satisfactory score for each analyte, test, subspecialty, or specialty for each testing event), in the three proficiency testing (PT) events prior to the upcoming survey. The SA requests that the laboratory submit a copy of its PT results for the last three PT events.

- Laboratories performing pathology, histocompatibility and/or cytogenetics will not be eligible for the AQAS because of the nature and complexity of the testing and the impact on health care. These areas will be surveyed on their biennial schedule. Facilities that include pathology, histocompatibility and/or cytogenetics could receive the AQAS for other specialty areas provided they meet the criteria.

- Laboratories with substantiated complaints will not be eligible for the AQAS.

- No laboratory will receive the AQAS for two consecutive certification cycles.

The SA conducts AQAS surveys no later than 6 months (180 days) prior to the expiration of the current certificate.

Mailing the AQAS Form

Before mailing the AQAS form to eligible laboratories, the SA ensures that the appropriate SA telephone number and contact person is included in the cover letter (the cover letter is not part of the AQAS form). Also, the SA ensures that the SA address is written or stamped on a label for fixing to the return envelope provided in the AQAS form packet.

Reviewing the Completed Form

The purpose of the AQAS is to reward good performing laboratories, provide an educational tool for laboratories to use in preparation for the next onsite CLIA survey, and finally to be used as a mechanism to recertify laboratories. The form is designed to be consistent with current policy for the survey process onsite that focuses on a quality system approach for evaluating laboratories for compliance with CLIA. This approach reflects the quality assessment requirements of the CLIA regulations which require laboratories to develop, monitor, and evaluate the effectiveness of their policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the staff.

The SA should use demographic, personnel and test information submitted on the AQAS form to update the current CLIA data *system*. The *SA* will determine whether any changes in the laboratory's personnel or type, volume and location of testing since the previous survey constitutes the need to perform a survey onsite. No question specifically flags an automatic survey onsite.

The laboratory director or appropriate designees should answer the AQAS questions and the laboratory director should sign the form. Along with the completed form, laboratories must submit documentation solicited by certain questions. The AQAS form directs the laboratory and reviewer to ensure that appropriate copies of documentation are submitted to the SA. Appendix A of the AQAS form provides a summary of those tests that a laboratory performs that are required to be enrolled in PT. Appendix B of the AQAS provides a summary of test counting policies to assist the laboratory in answering questions about test volume.

In the event that a laboratory communicates deficient practice via the AQAS, the decision to perform an onsite survey based on the completed form and supplemental documentation is left to the RO in consultation with the SA. If the AQAS is acceptable, the SA notifies the laboratory in writing of its recertification status.

Data Management

The SA notes the date the AQAS form is mailed to the facility *in the CLIA data system*. Because the CLIA law requires issuance of certificates every 2 years, ODIE entry of a basic certification kit is required for AQAS (See Appendix C for the applicable CMS forms).

Where a prompt appears in ODIE for the AQAS form, the SA enters YES. Certificates of *C*ompliance for the next 2-year certification period will be issued after appropriate review of the AQAS form and documentation, payment of applicable fees, and data entry into ODIE. The following examples provide instructions for kits involving the AQAS form where:

AQAS responses indicate continued compliance:

Note administrative time on the *Survey Team Composition and Workload Report*, Form CMS-670 *(Exhibit 74)*.

The SA enters into ODIE the basic certification kit using the AQAS information.

AQAS data indicates that a survey onsite is needed:

AQAS becomes part of the pre-survey activity/history;

The SA conducts onsite survey and enters information in usual manner;

Survey time is entered on Form CMS-670 and may be billed as follow-up.

6114 - AQAS Verifications and Summaries

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 (Refer to the current budget call letter). 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 requests an onsite survey *and agree to also fill out the AQAS*, *s*uch 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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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, regulations at 42 CFR 1001.1301 permit 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.)

6118 - During the Survey

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The surveyor(s) may allow or refuse to allow laboratory personnel to accompany surveyor(s) during certain phases of the survey. The surveyors must not allow managerial personnel to be present during staff interviews. The SA should exercise discretion in each case. Laboratory personnel may be helpful, answer questions, or point out certain things of concern to the surveyors. The surveyor should use such assistance if it is helpful to the survey and makes the process easier. Conversely, *if the* laboratory personnel harass surveyor(s), argue about observed problems, and make the survey more difficult*, t*he surveyor should not tolerate such treatment.

6120 - Completing the Survey Report (Form CMS-1557)

(Rev. 1, 05-21-04)

The Form CMS-1557 (Exhibit 12), is the vehicle for documenting general laboratory information and is designed to facilitate electronic data entry of survey findings.

6120.1 - General

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Form CMS-1557 is completed at the time of the survey, and includes survey data that must be entered into the CLIA data system. It includes information used in preparing *the Statement of Deficiencies and Plan of Correction,* Form CMS-2567.

6120.2 – Specific Items to Consider When Completing the Form CMS-1557

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When completing the Form CMS-1557 during the survey, the surveyor should pay particular attention to the following items:

6120.2.1 - Personnel

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Prior to completing the personnel section of the Form CMS-1557, complete a Laboratory Personnel Report (CLIA), Form CMS-209 (Exhibit 106) that requires more detailed information concerning the qualification of the laboratory's personnel. Only persons listed on a Form CMS-209 are to be included in the classification totals on the Form CMS-1557. The surveyor reviews a sample of testing personnel qualifications to verify the documentation on the Form CMS-209.

6120.2.2 – Specialties/Subspecialties

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The surveyor indicates all categories where at least one test is performed in a specialty or subspecialty, and notes additions, deletions and appropriate effective dates on the form. *The surveyor must verify the estimated test volume(s) for each specialty/subspecialty; for example, the surveyor can review daily or monthly logs or other data.*

6120.2.3 - Deficiencies

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 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.

6120.2.4 - Signature

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

All members of the survey team are required to sign the Form CMS-1557.

6122 - Credentialing of Foreign Trained Laboratory Personnel

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Personnel employed in laboratories subject to CLIA that perform tests of moderate and/or high complexity must meet specific education, training, and experience requirements. Individuals who attended foreign schools must have an evaluation of their credentials determining equivalency of foreign to United States education. The equivalency evaluations may be performed by a nationally recognized organization.

Foreign academic credential evaluation organizations and their affiliates such as the National Association Credential Evaluation Services, Inc. (NACES) and the Association of International Credential Evaluators, Inc. (AICE) may perform the academic credential evaluation. However, there is no limitation to the use of NACES, AICE, or any one organization. There may also be other recognized organizations listed and available via the Internet (See Appendix C).

The laboratory should maintain a copy of the equivalency evaluation/determination in the *laboratory records*.

6124 - Preparation for Exit Conference

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 interfere 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.

6126 - Exit Conference

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Subsequent to the pre-exit meeting held to allow team members to exchange and formulate survey findings, the team conducts an exit conference. Its purpose is to informally communicate the survey team's findings, and to provide an opportunity for the exchange of information with the laboratory. Although it is CMS' general policy to

conduct an exit conference, the surveyor should be aware of situations that would justify a refusal to conduct or continue an exit conference. For example:

- If counsel represents the laboratory (all participants in the exit conference should identify themselves), the surveyor should refuse to continue the conference if the lawyer tries to turn the exit conference into an evidentiary hearing.

- Any time the laboratory creates an environment that is hostile, intimidating, or inconsistent with the informal and preliminary nature of an exit conference, the surveyors should refuse to continue the exit conference.

- If the laboratory wishes to audio tape the conference, it must tape the entire meeting and provide surveyor(s) with a copy of the tape at the conclusion of the conference. Videotaping is also permitted if it does not intimidate the surveyors or disrupt the conference, and a copy is provided at the conclusion of the conference. Use discretion in deciding whether to permit videotaping. (See §2724.)

The survey team should establish and maintain control throughout the exit conference. The survey team presents the findings but should refrain from arguing. The surveyors should be mindful that laboratory staff *may disagree with the survey findings.* The laboratory representatives have a right to disagree with survey findings and to present information to refute them and the team should be receptive to such disagreements. If the laboratory representatives present information to negate any of the survey findings, the surveyor(s) should indicate willingness to reevaluate the findings before leaving the laboratory. If deficiencies are corrected before the completion of the survey, the surveyor should acknowledge the corrections and explain how this situation will be documented. (See §6130.2.) The following guidelines are helpful in performing an exit conference:

6126.1 – Introductory Remarks

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A surveyor should introduce other members of the survey team and restate the purpose of the survey. A surveyor expresses the team's appreciation for anything the staff has done to facilitate the survey and explains that the exit conference is an informal meeting to discuss preliminary survey findings and thereby to assist the laboratory in developing an acceptable PoC or credible allegation of compliance *(AoC)*. A team member should indicate that the official findings are presented in writing on the Form CMS-2567 *(Exhibit 7)* and will be forwarded to the laboratory within 10 calendar days. The laboratory must also be informed they are to return the PoC or credible AoC in 10 calendar days.

6126.2 – Ground Rules

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The surveyor(s) will explain how the exit conference will be conducted and how the team's findings will be presented, i.e., each surveyor will present his/her own findings. *If the laboratory disagrees with the survey findings, allow the laboratory* to submit additional evidence after the conference.

6126.3 – Presentation of Findings

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In presenting findings, the surveyors cite problems that clearly violate regulatory requirements and provide an explanation to the laboratory concerning the deficiency in specific terms (without using data tags or regulation citations) to allow the laboratory to understand why the requirement is not met. Frequently, the explanation will imply the action needed to correct the problem. Because there may be several possible causes for any deficiency, it is not the surveyor's responsibility to sift through various alternatives to suggest an acceptable remedy. For example, if a laboratory was cited for maintaining incomplete patient specimen records, the surveyor specifies what is missing, not why it is missing or what process is best for ensuring that the records are complete in the future. If asked for the regulatory basis, the surveyor provides *the regulatory basis for noncompliance*.

6126.4 - Closure

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When the exit conference is completed, the surveyor explains the certification process to the laboratory and informs them that a formal statement of deficiencies will be provided within 10 days. The surveyor explains the due date for submitting a PoC and how the rest of the certification process works.

If an immediate jeopardy situation has been identified, the surveyor explains the significance of that finding and the need for immediate corrective action to remove the jeopardy. In this or any other instance where adverse action is anticipated, the surveyor explains the implications, making it clear that only compliance will stop the action. The surveyor advises the laboratory that a revisit to verify correction of deficiencies occurs only when the laboratory submits a credible *AoC*. If the laboratory does not provide the RO/SA with a credible *AoC*, no revisit will be made and the adverse action process will continue.

In an initial survey, the surveyor tells the laboratory to expect notification from CMS of their initial approval (issuance of a certificate). For subsequent biennial surveys, the

surveyor explains that CMS issues an updated certificate reflecting any changes in approved services.

6128 - Certification Actions Performed After Survey

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The post-survey certification processes are summarized as follows:

The surveyor completes survey documents. (see Appendix C); and

The Form CMS-2567 *(Exhibit 7)* is sent to the laboratory requesting a PoC or credible *AoC*, if appropriate. A PoC is required for all deficiencies, except in cases of immediate jeopardy where limitations or suspension of the certificate may be imposed prior to an opportunity for a hearing.

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

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The Form CMS-2567 *(Exhibit 7)* serves several important functions, 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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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.

*T*he 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.

6130.2 - Plan of Correction (PoC)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The laboratory enters its planned action to correct the deficiency and the expected completion date opposite the appropriate data tag on Form CMS-2567 *(Exhibit 7)*. Alternatively, the laboratory may enter its disagreement with a finding and may furnish documentation that requirements are met. If a deficiency has been corrected since the survey, the laboratory should indicate this on the form along with the date of correction. The plan must be specific and time frames stated and realistic, stating exactly:

- How the deficient practice will be corrected or how it was corrected;
- What corrective action(s) have been taken for patients found to have been affected by the deficient practice;
- How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;
- What measure has been put into place or what systemic changes have been made to ensure that the deficient practice does not recur; and
- How the corrective action(s) is being monitored to ensure the deficient practice does not recur.

The laboratory director or other authorized official must sign and date the Form CMS-2567 on which the laboratory's PoC is written.

If the laboratory director requests additional time to develop the plan, the SA explains that a preliminary PoC must be submitted within 10 days, as precisely as present information permits, and that it may be followed with a more specific plan as early as possible. Also, the SA advises that a future contact or revisit to verify correction of deficiencies will occur only when the laboratory makes a credible allegation that it has corrected its deficiencies.

After completing the PoC, if the Form CMS-2567 was generated using ASPEN, the SA instructs the laboratory to retain a copy and return the original to RO/SA within 10 days of receipt. If the multi-page *Form* CMS-2567 is used, the SA instructs the laboratory to retain the fifth copy and return the rest to RO/SA within 10 days of receipt. If the response attempts to refute a citation, the SA contacts the laboratory to resolve the disagreement. If not resolved, the laboratory should put its protest in writing in a form suitable for disclosure, but must still provide its plan and time frame for correction.

If the laboratory corrects a cited deficiency before the completion of the survey, the SA documents the deficiency on the Form CMS-2567 and explains to the laboratory director that when the laboratory receives the Form CMS-2567, it is to indicate the correction as of that date.

It is not acceptable, under any circumstances, for a laboratory to allude in any way to another laboratory or to malign an individual on a publicly disclosable Form CMS-2567. The SA *should request* an amended PoC from the laboratory.

6130.3 - Review of Plan of Correction by State Agency

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA reviews the laboratory's PoC for appropriateness, legibility, completeness, and timeliness. If not properly completed or there is a question about the PoC, and the SA contacts the laboratory representative to obtain clarification or appropriate modification of the plan. The SA retains a copy of the Form CMS-2567 in the SA's file and associate additional copies with the certification packet.

6130.4 - Strategy for Repeat Deficiencies

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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

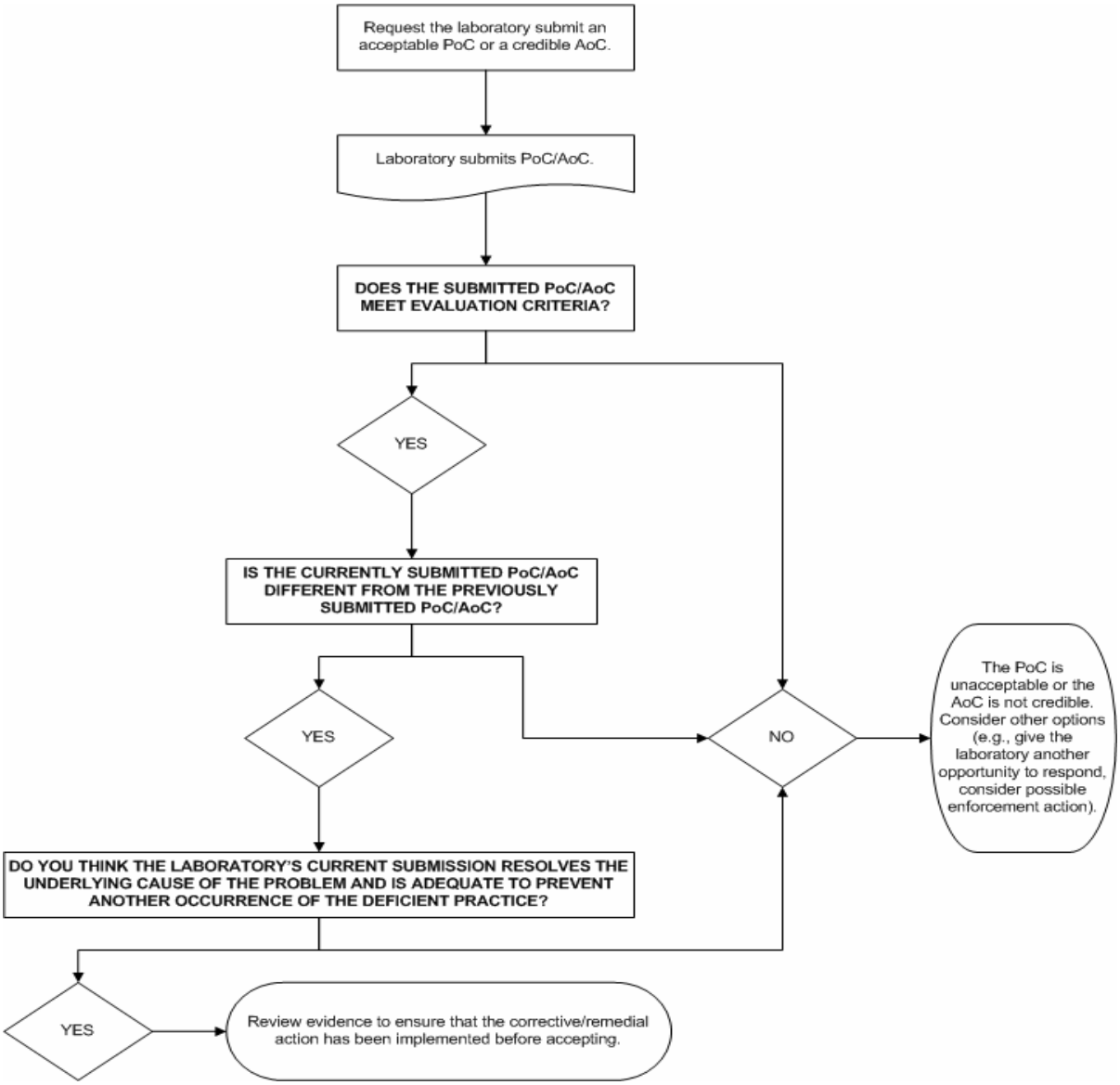
3. *Review the submitted plan of correction or allegation of compliance and determine whether the laboratory's submission meets the criteria for an acceptable plan of correction or a credible allegation of compliance. Based on established criteria, if the plan of correction is not acceptable or the allegation 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:



6132 - Follow-Up on PoCs

(Rev. 1, 05-21-04)

6132.1 - Post-Survey Revisit

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When a laboratory has failed to comply with one or more CLIA conditions, the SA follows up on all citations cited on the Form 2567 only after the laboratory makes a credible AoC and submits acceptable evidence of correction. In some cases, the citations may be of such nature that an electronic transmission, mail or telephone contact may suffice in lieu of an on-site visit, e.g., the laboratory agreed to amend its written policies. An electronic transmission, mail or telephone contact is acceptable, as long as there has been no reason to question the validity of the reported corrections. When conducting a post survey revisit, the SA is verifying that the evidence of correction as documented in the AoC is authentic. If documentary or on-site verification is warranted, the SA obtains appropriate verification before reporting a citation as corrected and completes a post-Certification Revisit Report, Form CMS-2567B (Exhibit 8).

When the deficiencies are below the Condition-level for which the laboratory has submitted a PoC, the SA may certify a laboratory based on an acceptable PoC. The SA is certifying that the laboratory is able to furnish test results without hazard to the health and safety of patients, that the PoC will likely result in compliance within the time frame indicated, and that the time frame is acceptable. No later than 12 months post-survey, the SA conducts a revisit survey. This required post-survey revisit is normally conducted by electronic transmission, mail or telephone contact. When the only deficiencies cited are below the Condition-level, on-site post-survey revisits are not normally conducted. On-site verification of standard-level deficiencies is warranted in rare circumstances where the documentation or correction provided by the laboratory alone does not verify correction of the deficiency and/or the documentation provided is indicative of potential risk to the quality of patient test results. The SA may consult with the RO for a determination regarding cases that are unclear. The SA obtains appropriate documentary verification (or on-site verification if warranted) before reporting a citation as corrected and completes a Form CMS-2567B.

In any event, the SA must record the survey findings in ODIE within 45 days from the date of the survey; post-survey revisit information can be entered into ODIE at any time thereafter.

6132.2 - Post-Survey Revisit Report, Form CMS-2567B

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

At the time of the follow-up visit or when corrections are verifiable by electronic transmission, telephone contact, or mail, the SA completes a Form CMS-2567B for the deficiencies previously reported which have been corrected. On Form CMS-2567B, the SA enters:

1. Laboratory identification information;

2. Date of the revisit or date of verification;

3. Prefix tag;

4. Corresponding regulatory reference cited on the original Form CMS-2567; and

5. Date the correction was completed.

If possible, the review is to be conducted by a member of the survey team that made the findings. The SA has the completed form initialed by the reviewing official, and retains a copy for the SA file. The SA enters Form CMS-2567B into the CLIA data system and if an adverse action is in progress, forwards a copy to the RO.

If, at the time of the revisit, some deficiencies have not been corrected, the SA completes another Form CMS-2567 summarizing the deficiencies not corrected by using the appropriate data prefix tag number. The SA must ask the laboratory to provide a revised PoC with a new completion date. The SA annotates under the heading "Statement of Deficiencies and Plan of Correction," "Summary of Deficiencies Not Corrected on a Follow-Up Visit," and shows the date of the revisit beneath the date of the survey. The SA associates a copy of the revised Form CMS-2567 with the Form CMS-2567B and retains it in the SA's file. The SA sends a copy of the revised Form CMS-2567 and allows the laboratory 10 calendar days to complete and return a PoC for any remaining deficiency(ies). The SA inputs the revised data into the *ODIE* system. If failure to correct deficiencies results in the laboratory no longer being in compliance, the SA documents the case for enforcement action *and forwards the case to the RO*.

6132.3 - Notifying Responsible Parties of Continuing Deficiencies

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA communicates directly with the *laboratory* director on a routine basis. The SA notifies the owner, governing body, or other responsible parties if a director has been ineffective in correcting deficiencies and advises the director of such actions.

6134 - Evaluation of Compliance

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The CLIA requirements establish a single set of *C*onditions and standards for all laboratories. CLIA certification satisfies program eligibility requirements for participation under Medicare and Medicaid programs.

During the laboratory survey, the SA compiles all information required to determine compliance, and completes all official reports of survey findings. Survey findings under CLIA requirements are determinations made by surveyors. When the survey reports and a Medicare/Medicaid Certification and Transmittal, Form CMS-1539 *(Exhibit 9)* are entered into the *OSCAR system*, an official determination of CLIA compliance is made. There are three types of compliance for any laboratory:

6134.1 - Compliance With all CLIA Conditions With No Deficiencies Identified

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

This indicates that there are no deficiencies identified. The laboratory is sent a Form CMS-2567 stating there are no deficiencies on the date(s) of the survey. The laboratory director signs the Form CMS-2567 and returns the form to the SA. The laboratory is issued the appropriate CLIA certificate and is eligible to participate in the Medicare and Medicaid programs.

6134.2 - Compliance Based on an Acceptable PoC

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Compliance based on an acceptable PoC reflects the findings that all applicable Conditions are met, but there are deficiencies below the Condition level for which the laboratory has submitted an acceptable PoC. The surveyor is certifying that the laboratory is able to furnish test results without hazard to the health and safety of patients. Laboratories having deficiencies must correct them within an acceptable time frame (no later than 12 months). Compliance based on an acceptable PoC varies with the level, nature and seriousness of the deficiencies.

In reviewing the PoC, the SA evaluates whether or not the corrective action will result in compliance within the time frame indicated and whether that time frame is acceptable. If the laboratory does not submit an acceptable PoC or if it fails to correct its deficiencies, the SA/RO withdraws the laboratory's approval to receive Medicare and Medicaid payment and revoke*s* its certificate, as appropriate. (See §6284.)

6134.3 - Noncompliance

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In situations where it is determined that a laboratory has failed to comply with one or more CLIA conditions, *the SA requests an AoC and acceptable evidence of correction. If the laboratory fails to submit a credible AoC and acceptable evidence of correction, t*he SA *recommends* to the RO *sanction action* by submitting a Form CMS-1539 (Code Item 4 as 9-Other). (See §6262.) When *determining* noncompliance, the SA enters the survey findings into the *OSCAR system* and sends a hardcopy of the Form CMS-2567 to the RO. After reviewing the Form CMS-2567, the RO makes a final determination of noncompliance and enters the final determination into the *OSCAR* system.

6135 – Data Management

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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

- *Form CMS-116 (Exhibit 125) entered up to 30 days after receipt by the SA. (Before entering the 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.*

6136 - Complaints Involving Laboratories

(Rev. 1, 05-21-04)

This section has been moved to Chapter 5.

6138 - Retention of CLIA Certification Records

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Essential data from all CLIA forms can be captured electronically in CMS' mainframe data system, which will maintain these data for three 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.

6138.1 - No Deficiencies Cited

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Upon completion of a survey in which no deficiencies are cited, the SA enters all applicable CLIA survey forms (see Appendix C) into the *OSCAR* system.

6138.2 - Deficiencies Cited

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Upon completion of a survey where deficiencies are cited, the SA enters all forms into the *ODIE* system *in the time frame specified above, regardless of whether the PoC or AoC are yet verified*. In addition, the SA forwards a hardcopy of the Form CMS-2567 to the RO when certifying noncompliance and retains the above forms in hardcopy form until all corrections specified on a PoC are completed, or if an adverse action is initiated, upon exhaustion of the CLIA/Medicare appeals process.

6138.3 - Exception

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA retains a hard copy of the Form CMS-209 *(Exhibit 106)* until updated or revised at the next survey to prevent evaluation of the same personnel on two consecutive surveys as part of the survey sample of personnel.

6139 - Media Representatives Referred by the CMS Press Office

(Rev. 1, 05-21-04)

The CMS Press office has primary responsibility for media liaison; however, there may be occasional instances when the Press Office refers a media representative to a CLIA program representative. The following policy statement is provided for your reference if the media representative's inquiry is related to individually identifiable health information.

> CLIA program representatives are pleased to discuss the CLIA requirements with media representatives referred by the CMS Press Office. It is the policy of CMS, however, not to comment on the health information of an individual, including laboratory test results, or the impact of a laboratory's services on the treatment or health outcome of a specific individual.

Sample Validation Surveys of Accredited Laboratories

6150 - Background - CMS Approval of Accreditation Organizations

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 six years and must reapply 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 (TJC)* .

6151 - Accredited Laboratories - Deemed Status

(Rev. 1, 05-21-04)

An accredited laboratory is a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization approved by CMS. An accredited laboratory will be deemed to meet CLIA conditions if the laboratory authorizes the accreditation organization to submit to CMS, the SA or other CMS agent records or other information CMS requires, and permits surveys as required by CMS regulations. A laboratory deemed to meet the CLIA requirements by virtue of its accreditation must also successfully participate in a CMS-approved PT program.

6152 - Accreditation Validation Surveys - Citations and General Description

(Rev. 1, 05-21-04)

The statutory basis for validation surveys of accredited laboratories is found in §353(e)(2)(D) of the PHSA. This section requires the Secretary to evaluate and report to Congress annually on the performance of each approved accreditation organization. Further, it requires the Secretary to evaluate the performance of each organization by:

- Surveying a sufficient number of laboratories accredited by the organization to allow a reasonable estimate of performance by the organization, and

- Using such other means as the Secretary determines appropriate.

Regulations authorizing such surveys are found at 42 CFR Part 493, Subpart E, Accreditation by a Private, Nonprofit Accreditation Organization or Exemption under Approved State Laboratory Programs. Section 493.563(a) provides that validation surveys may be conducted on a representative sample basis, (sample validation survey) or in response to a substantial allegation of noncompliance (complaint). The SA performs all validation surveys of accredited laboratories except accredited federal laboratories, which are performed by the RO. The SA and RO conduct the validation surveys according to established procedures for certification surveys of non-accredited laboratories (see Appendix C) in order to assure a fair basis for comparing the effectiveness of the accreditation organizations' programs. Validation surveys cover all CLIA conditions in the specialties and subspecialties for which the organization is approved. Sample validation surveys are performed no later than 90 days after the accreditation organization's inspection. As part of the validation review process, CMS may conduct onsite visits at the accreditation organization's headquarters to verify administrative integrity.

6154 - Objective of Validation Surveys of Accredited Laboratories

(Rev. 1, 05-21-04)

The Validation program is designed to evaluate the premise that a laboratory that receives accreditation is in fact meeting CLIA requirements. By comparing the CLIA findings on each validation survey to the organization's inspection results, calculating the disparity rate as prescribed by the regulations, and reporting the results to Congress annually, CO fulfills the statutory responsibility. The results of the validation surveys provide:

- On a laboratory-specific basis, insight into the effectiveness of the accreditation organization's program, and
- In the aggregate, an indication of the organization's capability to assure laboratory performance equal to or more stringent than that required by CLIA.

6156 - Selection of Sample for Validation Surveys of Accredited Laboratories

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The number *of validation surveys* and criteria for *selection are indicated in the sections below.* . A complaint investigation of an accredited laboratory can also be counted toward the validation target. (See §6156.4 below).

6156.1 - Number of Validation Surveys

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Each fiscal year the number of validation surveys to be performed is specified in the annual budget. Monies are allocated proportionately in the SA budgets for this purpose.

6156.2 - Criteria for Selection - Laboratories Accredited by COLA, CAP, *and TJC*

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CO periodically forwards the COLA, CAP and *TJC* 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 that 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 entire universe of accredited laboratories -- approximately 45-50% COLA, 25-30% CAP and 25% *TJC* .

6156.3 - Selection of Laboratories Accredited by AABB, AOA and ASHI

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Due to the limited number of laboratories using their AABB, AOA, or ASHI accreditation for CLIA purposes, relatively few validation surveys are performed for these organizations. Consequently, not all RO's will oversee validation surveys for these accreditation organizations in a given year. Accordingly, CO provides direction and coordinates the selection of these laboratories for validation survey, rotating them for geographical dispersion as much as possible.

6156.4 - Complaint Investigations Accepted for Validation Survey Target

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A complaint investigation can be counted towards the validation survey target specified in the annual budget call letter if it meets the following criteria:

- Conducted *by the SA* no later than 90 days after the accreditation inspection; and

- Covers the entire laboratory, even if the complaint is limited to particular areas or practices of the laboratory.

Complaint investigations that meet the above criteria are included in the pool for validation review by CO. (See Chapter 5 for additional information *regarding complaint investigation(s) involving an accredited laboratory*).

NOTE: Complaint surveys of laboratories' practices in Cytology, which are performed by outside contractors, are not counted toward the validation survey target or included in the validation review. In the contractor surveys, the time frame is expanded, slides are reviewed and the survey process is much more detailed. Those surveys would not serve as a fair basis for evaluating the effectiveness of the accreditation organization.

6158 - Preparing for Validation Surveys of Accredited Laboratories

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A validation survey is initiated when the RO sends the SA a Request for *Complaint Investigation or* Validation Survey of *Accredited* Laboratory, Form CMS-2802A (Exhibit 242). *(Refer to Chapter 5, "**Complaint Procedures"** for additional instructions regarding conducting complaint investigation(s) in an accredited laboratory.)* When scheduling the survey, the SA verifies the accreditation organization's inspection date to ensure that the validation survey takes place no later than 90 days after the inspection. If the survey cannot be performed, the SA should notify the RO immediately. Validation surveys may be performed simultaneously with accreditation organization inspections. (See §§6226-6228 for pre-survey arrangements and simultaneous survey procedures.)

Validation surveys are typically announced (See §6106). The SA must ascertain the hours when testing is conducted in the laboratory to assure that the survey is conducted at a time when the laboratory is normally functioning.

The SA will assign laboratory surveyors who normally conduct surveys of non-accredited laboratories. In States with more than one laboratory surveyor, the SA rotates the validation survey assignments among all surveyors, whenever possible.

Within budgetary constraints and whenever possible, the SA coordinates validation surveys with other provider/supplier types. The SA also communicates to the appropriate Medicare/Medicaid certifying component in the SA or RO any Condition-level noncompliance or adverse actions resulting from validation surveys.

At its discretion, the RO may plan to accompany the SA on *the* validation survey in order to assist in the survey or to monitor consistency in the validation survey process.

6162 - Accredited Laboratory's Refusal to Permit a Validation Survey

(Rev. 1, 05-21-04)

If a laboratory selected for survey fails to comply with the validation survey procedures, the RO notifies the laboratory, by letter, that it will be subject to full review and survey, and that the laboratory is subject to suspension and revocation of its CLIA certificate of accreditation. The RO will send a copy of the letter to the accreditation organization, SA and CO. An accredited laboratory will be considered deemed to meet the CLIA Conditions when:

- It withdraws any prior refusal to authorize its accreditation organization to release a copy of the laboratory's current accreditation survey, PT results, or notification of any adverse actions resulting from PT failure;

- It withdraws any prior refusal to allow a validation survey; and

- CMS finds that the laboratory meets all the CLIA conditions.

6164 - Conducting Validation Surveys of Accredited Laboratories

(Rev. 1, 05-21-04)

The SA performs validation surveys according to established survey procedures. (See Appendix C.) The surveyor refrains from reviewing any inspection results of the accreditation organization that may be available on site until the validation survey is completed, so that compliance status is independently determined. In that manner, a fair basis will be maintained for evaluating the effectiveness of the accreditation organization. In instances where the survey is conducted by more than one CLIA surveyor, all team members should participate in the entrance and exit conferences, if they individually cannot be on site for the entire survey.

6164.1 - SA Responsibilities

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

- 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 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 the validation survey package to the RO:

    - 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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 *change in* test volume only. The SA enters the corrected data into the CLIA data *system*.

6166 - Results of Validation Surveys of Accredited Laboratories

(Rev. 1, 05-21-04)

6166.1 - Condition-Level Deficiencies With Immediate Jeopardy

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6166.1.1 - The SA

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

- 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 3 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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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.)

6166.2 - Condition-Level Deficiencies With No Immediate Jeopardy

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6166.2.1 - The SA

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

- At the exit conference, informs the laboratory of its Condition-level noncompliance status and its recommendation to the RO that the laboratory no longer meets the applicable CLIA Condition-level requirements by virtue of accreditation. The laboratory is advised that it retains its CLIA certificate of accreditation at this point, however, it becomes subject to the same requirements and same enforcement procedures applied to non-accredited laboratories found out of compliance and the laboratory is monitored until it achieves Condition-level compliance or until its certificate of accreditation is revoked.

- Explains that the Form CMS-2567 *(Exhibit 7)* will be sent by the RO to the laboratory in approximately 10 days. A plan of correction is due within 10 days of receiving the Form CMS-2567. Also explains that the accreditation organization will receive copies of all correspondence to the laboratory and that the laboratory may wish to consult with the organization regarding its efforts to correct the deficiencies.

- Prepares a Form CMS-2567 and forwards the validation survey certification package to the RO within 10 working days from the last day of survey. (See §6164.)

6166.2.2 - The RO

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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

- Routinely copies all correspondence with the laboratory to the SA and the accreditation organization.

- Receives the SA recommendations and determines the appropriate actions to take, according to the policies outlined in §6284.

- Within approximately 10 days of the validation survey date notifies the laboratory that it is out of Condition-level compliance and that it is no longer deemed to meet the CLIA conditions by virtue of its accreditation.

- Requests the laboratory to submit a plan of correction within 10 days of receiving the letter and informs the laboratory that there will be follow-up with the laboratory to determine whether Condition-level compliance has been achieved.

- After consulting with the SA, as appropriate, determines if the laboratory's response constitutes a credible *AoC*. Documents that verify corrective action may include, but are not limited to, the following: verification of proficiency testing enrollment, personnel qualifications, and quality assessment activities.

- If, in 45 days of the laboratory's receipt of the letter, the RO has not received acceptable evidence of correction, or the RO has determined that the laboratory has failed to provide a credible *AoC*, the RO follows the established enforcement actions.(See §6284.)

- If, in 45 days, the RO has received acceptable evidence of correction and the RO has determined the laboratory provided a credible *AoC*, the RO notifies the laboratory that it continues to meet CLIA Condition-level requirements by virtue of its accreditation.

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

6166.3 - No Condition-Level Deficiencies Found at the Time of Survey

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6166.3.1 - The SA

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

- At the exit conference, informs the laboratory that it is in Condition-level compliance.

- If standard-level deficiencies were cited, informs the laboratory that it will receive a Form CMS-2567 *(Exhibit 7)*, which is subject to public disclosure within 90 days of the survey. While not required to complete the plan of correction, the laboratory may wish to submit it for the record.

- Explains to the laboratory that the accreditation organization will receive a copy of the Form CMS-2567 and the correspondence.

- Prepares a Form CMS-2567 and forwards the validation survey certification package to the RO within 10 working days of the last day of survey. (See §6164.)

6166.3.2 - The RO

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

- Notifies the laboratory in writing that the accrediting organization may contact it concerning the correction of deficiencies below the condition level (Exhibit 225);

- Copies all correspondence with the laboratory to the SA and accrediting organization.

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

6170 - Forwarding Completed Validation Survey Information to CO

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When the validation survey of an accredited laboratory and the follow-up activities have been completed, the RO will forward the following forms and other survey information to the CO CLIA component for use in the annual validation review:

- Form CMS-2802A *(Exhibit 242)*;

- Form CMS-1557 *(Exhibit 12)*;

- Form CMS-2567 *(Exhibit 7)* - include PoC *when there are* Condition-level deficiencies;

- Form CMS-2567 *(Exhibit 7)* completed for revisits, if any; and

- Copies of all correspondence to the laboratory related to the validation survey such as compliance determination, follow-up regarding corrections, etc.

6172 - Notification Requirements of Approved Accreditation Organizations

(Rev. 1, 05-21-04)

Responsibilities of each approved accreditation organization include notifying CMS, on an ongoing basis, when certain situations occur. This information must be communicated in writing by the accreditation organizations within a specific time frame as required by the regulations and include the laboratory name, CLIA number, deficiencies identified, if applicable, and dates of identification or of any actions taken. The RO will record the date of receipt of the accreditation organization's notification.

The following describes those situations that should be communicated to the RO:

- Immediate jeopardy situations (within 10 days);
- Newly accredited laboratories using the accreditation organization's program for CLIA compliance, including specialty and subspecialty information (within 30 days);
- Data related to unsuccessful PT performance and actions taken (within 30 days);
- Any adverse actions taken by the organization, i.e., denial, temporary loss, suspension, or withdrawal of accreditation, limitation of specialty/subspecialty, etc. (within 30 days); and
- Revisions in specialty/subspecialty testing (additions or deletions) in existing accredited laboratories (within 30 days).

Information relative to laboratories whose accreditation has been withdrawn or revoked will be helpful when assembling information for the annual laboratory registry. In addition, it may be used as a basis for a complaint or validation survey, as appropriate.

When accreditation has been removed from a facility, it then comes under CMS' jurisdiction for CLIA purposes. The other mechanism by which a laboratory is no longer deemed to meet the CLIA requirements is when the RO removes the certificate of accreditation due to Condition-level noncompliance that has not been corrected.

6174 - Basis for Validation Surveys of Accredited Laboratories in Response to Substantial Allegations of Noncompliance

(Rev. 1, 05-21-04)

The statutory basis for validation surveys of accredited laboratories in response to substantial allegations of noncompliance is found in §353(e)(2)(D) of the PHSA. Regulations authorizing such surveys are found at 42 CFR, Part 493, Subpart E. Title 42 CFR 493.563 provides that validation surveys may be conducted in response to a substantial allegation of noncompliance. Complaints can be received in person, by telephone, through written correspondence, from newspaper or magazine articles or other sources. A substantial allegation of noncompliance, which is defined in 42 CFR 493.2 of the regulations, has two elements:

- Harmful or potentially harmful impact on the health and safety of the general public or the individuals served by the laboratory; and
- Raises doubt as to the laboratory's compliance with one or more CLIA conditions.

For the handling of complaints against accredited laboratories see Chapter 5.

Sample Validation Surveys of CLIA-Exempt Laboratories

6200 - CMS Approval of State Laboratory Licensure Programs Citations and General Description

(Rev. 1, 05-21-04)

Section 353(p) of the PHSA permits the Secretary to exempt from CLIA all laboratories in any State that has demonstrated that its licensure laws or regulations related to laboratory requirements are equal to or more stringent than those requirements imposed by CLIA. The 42 CFR Part 493, Subpart E of the regulations, permits CMS to approve or remove approval from specific State laboratory programs dependent upon specific criteria met. When CMS approves a State laboratory program, a notice is published in the "Federal Register," indicating the State for which an approval was granted, and the rationale for the decision. An approved State laboratory program may be exempt for a maximum of six years; the State must re-apply for each approval period. During the approval period, all laboratories in that State that are subject to the approved licensure program are exempt from the CLIA requirements. A partial CLIA exemption may be granted to an approved laboratory licensure program in a State that does not license all of its facilities performing laboratory testing. If a State does not have a universal, all-inclusive licensure law, laboratories licensed by the State are exempt from the CLIA requirements, and laboratories not licensed by the State remain under CLIA jurisdiction.

6202 - Validation Surveys of CLIA-Exempt Laboratories - Citations and Objectives

(Rev. 1, 05-21-04)

Regulations authorizing validation surveys are found at 42 CFR Part 493, Subpart E, "Accreditation By a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program." Title 42 CFR 493.563(b) and (c), respectively, provide that validation surveys will be conducted on a representative sample basis or in response to a substantial allegation of noncompliance.

The RO conducts CLIA-exempt laboratory validation surveys to ensure that laboratories under the jurisdiction of the approved State laboratory program are continually meeting requirements equal to or more stringent than the CLIA requirements.

The results of the validation surveys are used to validate the appropriateness of the exemption of the State's laboratories from the CLIA program requirements. (See §6214.)

6204 - Number and Criteria for Selection of CLIA-Exempt Laboratories for Validation Surveys

(Rev. 1, 05-21-04)

6204.1 - Number of Validation Surveys

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The number of CLIA-exempt laboratories to be validated is approximately 5 percent of State-licensed laboratories. (Refer to the annual budget call letter.)

6204.2 - Selection of Validation Surveys

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO obtains the laboratory licensure survey schedule from the *approved State* and verifies the date that the approved State completed the inspection, so that the validation survey can *be simultaneous or* be conducted no later than 90 days after the State licensure inspection. The RO selects the sample of laboratories to be validated using the *following* criteria:

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

- Select laboratories that are geographically dispersed.

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

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Validation surveys are typically announced *unless performed simultaneously with CAP or TJC, 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.)*. 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* request*s* the State to take enforcement action under their licensure program.

6208 - Conducting Validation Surveys of CLIA Exempt Laboratories

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO has direct responsibility for the entire validation survey process for CLIA-exempt laboratories, unless CO utilizes a CMS designated contractor, e.g., survey of cytology. The RO surveyor conducts the survey according to established procedures for certification surveys (See Appendix C). *If a surveyor cannot be present at both the entrance and exit conferences, that surveyor shouldn't be assigned to the survey.* At the exit conference the RO surveyor informs the laboratory of any Condition-level findings and the CLIA compliance determination. The validation survey may be conducted simultaneously with the State licensure inspection, however, the RO surveyor makes an independent CLIA compliance determination and completes all necessary documentation and survey forms. *The RO sends to the State Program a notification of determination (letter) with Form CMS-2567 (Exhibit 7), and a copy of both to the laboratory. See, §§6210.2.1 and 6210.3.1 for specifics related to the type of deficiencies.*

NOTE: A State *Program* may recognize a CMS-approved accreditation program in lieu of State licensure. If so, a laboratory accredited by an approved accreditation organization may be subject to validation by *the State Program to validate the accreditation organization* in the same manner as an accredited laboratory (non CLIA-exempt) is subject to a CLIA validation survey. In that case, the State uses State licensure requirements to validate the accredited laboratory. At the RO's discretion, the RO may accompany the State on these surveys *to observe the State Program's validation activities*.

6210 - Results of the CLIA-Exempt Validation Survey - RO and SA Responsibilities

(Rev. 1, 05-21-04)

6210.1 - Condition-Level Deficiencies With Immediate Jeopardy

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If the deficiencies identified are Condition-level and pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public:

6210.1.1 - The RO

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

- At the exit conference, informs the laboratory of its Condition-level noncompliance status, explains to the laboratory that it does not meet the CLIA Condition-level requirements and is subject to sanctions imposed by the State program.

  NOTE: If onsite simultaneously with the State inspection, assures that the laboratory is fully aware of the deficiencies that pose immediate jeopardy and is subject to State sanctions;

- Within 2 days of the survey, sends to the State program a notification of determination (letter) that clearly explains the nature of the jeopardy, and directs the State to take appropriate action under its approved licensure program. A Form CMS-2567 *(Exhibit 7)* with summary of the findings is an enclosure with the notification of determination. Sends to the **laboratory** a copy of the letter, including the Form CMS-2567 enclosure.

6210.1.2 - The State Program

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

- Takes the appropriate enforcement actions based on the enforcement policies of it's approved licensure program. Within 10 days of the survey, notifies the RO of the action taken.

6210.1.3 - The RO

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Follows up with the State within 15 days if not notified of the action taken or notified that the jeopardy situation has been corrected. If the State program is unwilling or unable to take enforcement action appropriate (as determined by the RO) to the jeopardy situation, the RO may request CO to either contact the State or attempt other resolution to eliminate the jeopardy. (See 42 CFR 493.557(b)(13).)

6210.2 - Condition-Level Deficiencies With No Immediate Jeopardy

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6210.2.1 - The RO

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

- At the exit conference informs the laboratory of its Condition-level noncompliance and explains to the laboratory that it does not meet the CLIA Condition-level requirements and is subject to sanctions and follow-up by the State program;

  NOTE: If onsite simultaneously with the State licensure inspection, assures that the laboratory is fully aware of the Condition-level deficiencies and follow-up by the State.

- Within 10 days of completing the survey, sends to the State a notification of determination (letter) that explains the Condition-level deficiencies and directs the State to take appropriate action under its approved licensure program. A Form CMS-2567 *(Exhibit 7)* with summary of the findings is an enclosure with the notification letter. Sends to the **laboratory** a copy of the letter, including the Form CMS-2567 enclosure (See Exhibit 232.)

6210.2.2 - The State Program

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Takes the appropriate enforcement actions based on the policies of its licensure program. Within 30 days, the State program notifies the RO of the action taken.

6210.2.3 - The RO

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Follows up with the State Program within 45 days if not notified of the action taken. If the State Program has not taken appropriate enforcement action, (as determined by the RO) and/or the Condition-level noncompliance remains, the RO contacts the State Program to seek resolution/take action so that the laboratory comes into Condition-level compliance.

6210.3 - Deficiencies Found Below the Condition-Level

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6210.3.1 - The RO

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

- At the exit conference, informs the laboratory that it is in Condition-level compliance with the CLIA requirements, but that standard level deficiencies are identified.

- Prepares a Form CMS-2567 *(Exhibit 7)* and *sends it to the State Program as an attachment to a notification of determination (letter), within 10 working days of the survey. Sends to the* ***laboratory*** *a copy of the letter, including the attachment (Form CMS-2567).*

6210.3.2 - The State Program

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Monitors the correction of the cited deficiencies based on the policies of its licensure program.

6212 - Processing Validation Survey Records

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO inputs the survey information into the *ODIE* system within 45 days of completing the survey. The applicable documents should be completed and processed (see Appendix C).

6214 - Evaluation of Approved State Licensure Program

(Rev. 1, 05-21-04)

The RO not only performs the validation surveys as described above, but also prepares and forwards to CO an annual evaluation of the State's licensure program operations. The report includes a comparison of the State program's findings with validation survey findings at the Condition-level. It also includes summary information about the State's laboratory universe, adverse actions, complaints, surveyor staffing, proficiency testing review, financial resources and any other information pertinent to the ongoing acceptability of the program exemption as an alternative to CLIA survey and certification activities.

6216 - Onsite Visit to State Laboratory Program

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Title 42 CFR 493.563 (d)(2) allows CMS to conduct visits to the State's laboratory program offices and operations. The purpose of the visits is to gather information about the State laboratory licensure program operations, including any verifications needed about the representations made by the State in their application for CLIA exemption. Additionally, the RO may assess the State's compliance with its own policies and procedures as approved by CMS.

An onsite visit may include, but is not limited to, an evaluation of the following:

- Survey workload;
- Enforcement activities;
- Complaint management;
- Validation surveys of accredited facilities *(if accredited facilities are deemed to meet the State Licensure requirements)*;
- Surveyor competency;
- Surveyor training and continuing education;
- Proficiency testing monitoring;
- Internal quality improvement activities; and
- Financial management.

Data may be gathered through employee interviews, documentation review, meeting attendance, or other means. Refusal by the State to allow an onsite visit or poor performance in the management of the above activities may jeopardize the renewal of a State's CLIA exemption.

6218 - Notification Responsibilities of Approved State Licensure Program

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Responsibilities of each approved State laboratory licensure program include notifying CMS, on an ongoing basis, when certain situations occur*, as listed below*. This information must be communicated in writing by the State program within a specific time frame (specified below). Include the laboratory name, CLIA number, deficiencies identified, if applicable, and dates of identification or of any actions taken. The RO records the date of the State's notification of the information.

The following describes those situations that the approved State program communicates to the RO:

1. Immediate jeopardy situations (within 10 days);

2. Newly licensed laboratories, including specialty and subspecialty information (within 30 days);

3. Data related to unsuccessful PT performance and actions taken (within 30 days);

4. Any sanctions taken by the State i.e., denial, withdrawal, or revocation of State licensure, limitation of specialty/subspecialty, etc. (within 30 days); and

5. Revision in specialty/subspecialty testing (additions, deletions) in existing CLIA-exempt laboratories (within 30 days).

Information relative to laboratories whose licensure has been withdrawn or revoked will be helpful when the RO assembles information for the annual laboratory registry and for use in the evaluation report of the State's operations.

Validation Surveys Performed Simultaneously With Accreditation Organization Inspections or Approved State Program Inspections

6226 - Simultaneous Validation Surveys - General

(Rev. 1, 05-21-04)

6226.1 - Simultaneous Validation Survey - Definition

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A validation survey of an accredited or CLIA-exempt laboratory in which the CLIA surveyor accompanies the accreditation organization or approved State program inspector during the inspector's fact-gathering, and uses the outcome-oriented survey principles (see Appendix C) to determine whether the laboratory meets the CLIA Condition-level requirements.

6226.2 - Purpose

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The main purpose of the simultaneous validation survey is the same as any CLIA validation survey: to verify that the laboratory meets all applicable CLIA conditions. While determining the laboratory's Condition-level compliance status, the CLIA surveyor gains insight into accreditation or State program processes. It is also an opportunity to partner in the efforts to improve quality of laboratory practices and testing outcomes in clinical laboratories.

6226.3 - Relationship to Look-Behind Validation Surveys

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The simultaneous protocol offers an additional approach for conducting validation surveys. Like the look-behind protocol, the simultaneous focuses on the laboratory's compliance status, however, the timing is different. Instead of performing the validation survey up to 90 days after the accreditation organization or approved State program inspection, the surveyor performs it while accompanying the inspector.

6226.4 - Relationship to Annual Validation Survey Target

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

One or more of a SA's or RO's validation survey target, as specified in the annual budget, is performed simultaneously. Performing all surveys simultaneously, however, is not recommended. A combination of look-behind and simultaneous validation surveys provides a more balanced view.

6226.5 - Team Size

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

With RO approval, the SA may increase the number of CLIA surveyors when the accreditation inspection is performed by a team. Additional surveyors may be from the SA or RO, as available.

6227 - Scheduling Simultaneous Validation Surveys and Coordinating Pre-Survey Arrangements

(Rev. 1, 05-21-04)

6227.1 - Importance of Coordinating Pre-Survey Arrangements

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Well-coordinated pre-survey arrangements, open communication and flexibility are key to promoting a successful survey experience by all parties - the accreditation organization or State program inspector, the CLIA surveyor, and the laboratory. With this foundation:

- Both teams can conduct their activities in the usual professional manner;
- Both teams can focus on the quality of the laboratory practices and testing outcomes; and
- The laboratory operations can continue, minimally impacted by the survey.

6227.2 - Surveyor Responsibilities

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The *CLIA* surveyor sets the tone for open communication and flexibility in pre-survey and onsite activities, therefore the surveyor (rather than other SA personnel) makes the pre-survey arrangements whenever possible. Direct contact by the surveyor with the accreditation organization or State program representatives is strongly encouraged in

order to enhance *CLIA* surveyor/*AO* inspector coordination, an essential element in a smooth-flowing survey.

6227.3 - Pre-Survey Arrangements for Accredited Laboratories

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 CAP and TJC and some simultaneous validation surveys performed with COLA.*

6227.3.1 - Coordinating With Accreditation Organization (AO) Contact Person

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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, r*equests 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 CAP's and TJC's policies of unannounced surveys; therefore, request the CAP or TJC 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 TJC's policy of unannounced inspections when performing inspections of laboratories deemed to meet TJC 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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 CAP or TJC, 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.

6227.3.3 - Coordinating With RO

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The surveyor ensures that the RO is apprised of the survey shortly after it is scheduled, so that the RO is current on all simultaneous survey activity in the region.

6227.3.4 - Coordinating With Accreditation Organization Inspector

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Every effort should be made to perform these pre-entrance activities *with the AO inspector* in all simultaneous validation surveys, *irrespective of the AO's policy of announcing/not announcing inspections to the laboratory*.

- The CLIA surveyor telephones the *AO* inspector. In addition to verifying the time and date of inspection, the surveyor arranges to meet with the inspector briefly before entering the laboratory.

- The CLIA surveyor and the *AO* inspector have a pre-entrance meeting to coordinate for a smooth-flowing survey.

The following activities are performed at the pre-entrance meeting:

- Mutual agreement on the content of the opening conference (see §6228), as well as the inspector and surveyor roles, recognizing that the accreditation inspector has the lead;

- Orientation of the CLIA surveyor on the inspector's planned flow through the laboratory, so that CLIA survey fact-gathering can be coordinated accordingly, thereby minimizing interruption to laboratory operations and duplication of inquiry;

- Orientation of the accreditation inspector, as appropriate, to the basics of the CLIA outcome-oriented survey *protocol*, and assurance that the CLIA surveyor's role is to conduct an evaluation of the laboratory's compliance with CLIA, not a performance evaluation of the inspector or a comparison of the accreditation standards with the CLIA requirements.

6227.4 - Pre-Survey Arrangements for CLIA-Exempt Laboratories

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO CLIA surveyor coordinates pre-survey arrangements for simultaneous validation surveys in CLIA-exempt laboratories. The surveyor adapts the procedures *for pre-survey arrangements with the laboratory, the RO and the AO inspector, (see preceding sections) as appropriate, to coordinate pre-survey arrangements with the laboratory, State program official, and the State program inspector.*

6228 - Onsite Activities - Simultaneous Validation Surveys

(Rev. 1, 05-21-04)

6228.1 - Entrance Conference

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The CLIA surveyor ensures that the laboratory officials are presented the following information:

- The purpose of the validation survey;

- The planned flow through the laboratory; and

- The *CLIA* surveyor/*AO* inspector joint intent to coordinate fact-gathering as much as possible in order to minimize disruption to laboratory operations and avoid duplication of inquiry.

6228.2 - Fact-Gathering

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The accreditation/State program inspector sets the flow of the fact-gathering. The surveyor accompanies the inspector, and at the same time determines if sufficient information is obtained to evaluate compliance with CLIA Conditions, using the outcome-oriented survey principles. (See Appendix C.) The surveyor's approach may be tailored to the facility and circumstances, based on professional judgment and survey experience. If the fact-gathering and discussions with the inspector do not result in sufficient information to make a CLIA compliance determination, the CLIA surveyor and the inspector mutually agree on the next course of action. The CLIA survey need not end at the same time as the accreditation/State program inspection, however, there may be blocks of time, such as the inspector's period for administrative tasks, when the surveyor can gather sufficient additional information to make the compliance determination.

6228.3 - Pre-Exit Discussion

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The CLIA surveyor should plan to have a pre-exit meeting with the inspector (away from laboratory personnel) to discuss each other's findings, share the CLIA compliance determination, and to coordinate the exit presentations to the laboratory. There may be instances where the surveyor's conclusions differ from the inspector's. Acknowledge this as you coordinate on the exit conference agenda. Should the inspector be concerned about the discrepancies in findings, refrain from debating the merits of each one, and draw attention to the mutual interest in quality of laboratory practices and outcomes. Explain, as appropriate, that a laboratory holding a CLIA Certificate of Accreditation has an ongoing responsibility to meet the applicable CLIA Conditions, irrespective of the accreditation inspection findings or the laboratory's agreement with the accreditation organization.

NOTE: The CLIA surveyor should be mindful that each set of accreditation and State program requirements was approved by CMS as being equivalent (not necessarily identical) to the CLIA Conditions, taken as a whole. Clarify, accordingly, for concerns about apparent dissimilarities in the requirements or discrepancies in findings that may be raised at the pre-exit discussion or the exit conference. Also clarify, as appropriate, that the surveyor's role is to evaluate the laboratory under CLIA, not compare the two sets of requirements, or comment on the merits of the accreditation inspection findings.

6228.4 - Exit Conference

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

As coordinated with the accreditation/State program inspector, the surveyor presents the CLIA findings. The surveyor also explains that the laboratory will be informed in writing of the CLIA compliance determination, the laboratory's responsibility for responding, if necessary, and the time frames involved. If the information gathered was insufficient to make a CLIA compliance determination, the surveyor advises the laboratory accordingly and after the exit conference arranges to complete the remainder of the survey. In instances where the laboratory raises questions about discrepancies in the accreditation inspection and CLIA survey results, or apparent dissimilarities in requirements, refer to the guidance in *the* section above (Pre-Exit Discussion), as appropriate.

After the survey is completed, follow the procedures in §6166.

Other Activities

6230 - CLIA State Agency Performance Review (SAPR)

(Rev. 1, 05-21-04)

The CLIA SAPR is an evaluation by the RO each fiscal year of each SA's performance of its survey and certification responsibilities under the CLIA Program, as specified in the Section 1864 Agreement. The goal of the SAPR is to promote optimal performance by State Agencies. Sustained proficiency is recognized and areas of improvement are identified for corrective action by the SA. The RO retains its overarching responsibility for program oversight; however, its primary role in the SAPR is education and support for SA improvement, with flexibility to address the variation in SA sizes and operations.

The CLIA SAPR is distinguished from the CLIA Federal Monitoring Survey (FMS) (see §6232) by its scope. The SAPR is more comprehensive than the FMS. While the FMS pertains to individual CLIA surveys, the SAPR focuses on the SA's surveys in the aggregate and the SA's response to the FMS feedback, as well as other survey and certification responsibilities, such as financial management, workload completion and enforcement.

The CLIA SAPR is structured to measure performance in an objective and consistent manner. Modifications to the structure or content may be made by CO based on operational experience. CO will utilize the aggregate findings to update and clarify policy and to determine national training needs.

6232 – *CLIA* Federal Monitoring Survey (FMS) Selection

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The primary purpose of the FMS system is to monitor each SA surveyor's use and performance of the CLIA Outcome-oriented Survey Process (OSP) to: determine training needs, provide timely feedback for surveyor education and improve survey process performance. The Comparative CLIA-FMS is done preferably no later than 60 days from when the SA perform*s* its respective surveys. Monitoring of problem providers is a secondary goal of the system. The RO's FMS strategy should be consistent with this approach. Actual monitoring survey targets and allocation requirements will be established at the beginning of each fiscal year through a CO component negotiation process. As a basic rule, however, the RO does not include in the FMS sample selection any facility against which adverse action has been initiated by the State survey agency.

6234 - FMS of Laboratories - Definitions and Purpose

(Rev. 1, 05-21-04)

6234.1 - Definition

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

An FMS is any survey in which an RO laboratory specialist accompanies or follows the SA survey to monitor the surveyor's use and performance of the CLIA OSP. Laboratories under direct Federal jurisdiction are exempt from the *CLIA* FMS process (*see* §6022).

6234.2 - Purpose

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO *performs* the survey *for the following reasons*:

- *Monitoring and improving* SA performance in interpreting and applying CLIA requirement(s), *applying survey policies and procedures*;
- Identify*ing* training/or technical assistance needs of surveyors *such as issues pertaining to test results and patient outcome;*
- Identify*ing* problems that surveyors and/or laboratories encounter in implementing Federal regulations and survey procedures; and
- *To u*ncover and correct problem*s* that exist in individual States, laboratories, or on individual surveys*; and*
- Providing documented feedback to the *RO,* SA and Central Office (CO).

NOTE: *New surveyors' work products (e.g., survey packages) are reviewed and/or verified, and signed off with supervisory review prior to the new surveyor being released to independently perform surveys. Upon completion of the new SA surveyor's training program, the RO can use the CLIA FMS in lieu of basic training until the surveyor has completed the formal Basic Surveyor Training Module. This only pertains to CLIA surveys and would not be applicable for performing health facility or Life Safety Code surveys.*

6234.3 - Scope of FMS Surveys

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

1. **Full Survey -** This is a survey of all applicable CLIA Conditions and/or standards for laboratories.

2. **Partial Surveys -** This is a survey of selected CLIA Conditions and/or standards for laboratories.

6234.4 - CLIA-FMS Survey Types

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A description of the three types of CLIA-FMS is as follows:

- The **Observational** CLIA-FMS is a survey in which the RO surveyor accompanies the SA surveyor and interacts as necessary during the survey process. The interaction is also intended to provide guidance at the appropriate times during the survey process. The RO surveyor serves as a resource to enable the SA surveyor to strengthen skills, knowledge base, and adherence to the CLIA regulations, policies, and the OSP. It is important that the RO surveyor communicates and interacts in a neutral non-judgmental manner, providing objective and constructive feedback about the SA surveyor's strengths and weaknesses. The SA surveyor prepares the Form CMS-2567 after discussing the deficiencies with the RO surveyor.

- The **Participatory** CLIA-FMS is a survey in which the RO surveyor observes the SA surveyor and participates in the survey. The Participatory survey facilitates a collaborative relationship between the RO and SA. As in the Observational FMS, the RO surveyor serves as a resource to enable the SA surveyor to strengthen skills, knowledge base, and adherence to the CLIA OSP, regulations, and policies. The goal is to jointly identify deficiencies by the RO and the SA surveyor. Both the SA and RO surveyor collaborate on a final compliance determination when there are different conclusions.

- The **Comparative** CLIA-FMS is a survey in which the RO surveyor surveys the laboratory after the SA surveyor, preferably within 30 days but no later than 60 days *from when the SA performs its survey. The deficiency citations of the RO surveyor are compared* to those of the SA surveyor. When assessing comparability, the RO surveyor must keep in mind the possibility that deficiencies may not have been present in the laboratory at the time of separate surveys. If an issue arises, then the RO surveyor must contact the SA surveyor for clarification.

6236 - CLIA-FMS Procedures

(Rev. 1, 05-21-04)

The modification to CLIA-FMS National Guidance package under its Section E heading titled, "Considerations for Selecting and Planning the CLIA-FMS," incorporates the following clarification: The Comparative "CLIA-FMS" is a survey in which the RO surveyor surveys the laboratory after the SA surveyor, preferably within 30 days but no later than 60 days. The following is an abbreviated RO guide for the scheduling and performing CLIA FMS.

6236.1 - Scheduling of Surveys

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Scheduling of surveys can occur as far in advance as the RO needs to organize its workload in consideration of survey priorities. Public Law 100-578(g) permits inspections of laboratories on an announced or unannounced basis during regular hours of operation. The RO conducts FMS surveys on an announced or unannounced basis. In the case of an announced Participatory or Observational FMS survey, the SA notifies the *laboratory* of the upcoming survey *with a maximum of 2 weeks advanced notice of the CLIA survey* and that the RO surveyor will accompany the SA surveyor. In the case of an announced Comparative FMS survey, the RO notifies the facility of the upcoming CLIA survey. *Complaint surveys/investigations are always unannounced regardless of the type of laboratory circumstances. Refer to Chapter 5, "Compliant Procedures," for additional information about complaint investigations in a laboratory.*

6236.2 - Survey Findings

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA and RO end each Federal survey with a standard exit conference with appropriate facility staff and discuss findings in general terms as well as specify any deficiencies that could significantly affect the health and safety of individuals or result in adverse action.

If the RO determines that CLIA Conditions are out of compliance, see §§6250-6299 for enforcement process. The RO is responsible for subsequent enforcement actions under these circumstances. However, the RO may request that the SA do any necessary follow-up visits except for Federal jurisdictional surveys. The RO forwards to the SA the survey findings and copies of all correspondence with the entity.

The RO requests that the SA obtain a P*o*C from the facility, and monitors the SA's follow-up activities. The RO may wish to work with the institution and the SA directly if the seriousness of the findings warrants it.

6238 – Completion of FMS Workload and Time Expenditures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

To provide accurate information on both the number and types of monitoring surveys the RO completes the Form CMS-670 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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

- **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, "Compliant 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.

Adverse Actions

6250 - Purpose of and Basis for Enforcement Action

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Laboratories holding any type of CLIA certificate are subject to enforcement actions under the authority of §353 of the Public Health Service Act (PHSA) and §1846 of the Social Security Act (the Act). Title 42 CFR Part 493, Subpart R, sets forth the enforcement procedures for laboratories.

6250.1 - Purpose

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The enforcement process serves the following purposes:

- To protect all individuals served by a laboratory against substandard testing of specimens;
- To safeguard the general public against health and safety hazards that might result from laboratory activities; and
- To motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

6250.2 - Basis for Enforcement

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

- ***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.

6254 - Denial of Form CMS-116 from Prospective Laboratory or Denial of *Request* to Test in New Specialties or Subspecialties

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If *the* Form CMS-116 *(Exhibit 125)* for any CLIA certificate is denied, the RO prepares a notice to the laboratory outlining:

- The decision and the reason for the denial, citing provisions of the law or implementing regulations not met;
- The laboratory's appeal rights;
- The fact that the laboratory cannot operate or receive payment under Medicare or Medicaid unless the denial is overturned at the conclusion of the administrative appeals process and a CLIA certificate is issued; and
- The procedures to follow for a reconsideration.

The denial notice must be signed by the RO *in accordance with the Delegations of Authority*.

6256 - Voluntary Withdrawal from CLIA Program *or from Specialty/Subspecialty*

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6256.1 - Laboratory Gives Notification of Going Out of Business

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A laboratory ***not facing enforcement action*** may voluntarily withdraw from all testing, and, therefore, relinquish its CLIA certificate and go out of business by notifying the RO or SA of its intent, in writing. *The SA completes the necessary actions.* If the SA learns that a laboratory ***facing enforcement action*** intends to close, the SA notifies the RO by letter, including the projected date of closure. Any correspondence received from the laboratory and any other pertinent document(s) are submitted to the RO.

6256.2 - Laboratory Gives No Notification of Going Out of Business

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If a laboratory ***not facing enforcement action*** voluntarily withdraws from all testing, and refuses new requests for testing, it voluntarily relinquishes its CLIA certificate. If the SA learns that a laboratory may be going out of business, it verifies the situation and

completes the necessary actions. *If the SA learns that a laboratory* ***facing enforcement action*** *has closed, the SA notifies the RO in writing.*

6256.3 - Voluntary Withdrawal When Enforcement Action Is Pending

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO *should* proceed with the *enforcement action* despite the laboratory's withdrawal, *particularly* if the RO decides that the laboratory's *performance warrants inclusion on the annual Laboratory Registry and public notification, actions that are triggered by imposition of the adverse action*.

If the RO decides to proceed with the *enforcement action*, it prepares a notice to the laboratory explaining that, although it has withdrawn from the CLIA program, its CLIA certificate will remain active until the *enforcement action* takes effect so that CMS may exercise its right to take its enforcement action to conclusion. The RO will restate in the notice the laboratory's appeal rights mentioned in the notice of sanction.

If the RO decides to discontinue the revocation, it processes the withdrawal.

6260 - Requests to Change Certificate Type *When Enforcement Action is Pending*

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO proceeds with the enforcement action proposed against a laboratory's existing certificate if the laboratory's deficiencies warrant it.

If the RO proceeds with the enforcement action, the RO notifies the laboratory that its certificate will remain active until the enforcement action becomes effective, at which time the request will be acted upon.

If the enforcement action is discontinued, the RO proceeds as if the enforcement action was not pending.

6262 *- CLIA Conditions Not Met - Enforcement Options for All Laboratories*

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CMS may impose one or more of the *sanctions specified in this section on any laboratory that is out of compliance with one or more CLIA requirements.*

6262.1 - Principal Sanctions

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CMS may impose any of the three principal CLIA sanctions, which are:

- *Limitation of the CLIA certificate;*
- *Suspension of the CLIA certificate; or*
- *Revocation of the CLIA certificate.*

6262.2 - Alternative Sanctions

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CMS may impose one or more of the following alternative sanctions on any laboratory in lieu of or in addition to imposing a principal sanction:

- Directed PoC and directed portion of a PoC;
- State onsite monitoring; and/or
- Civil money penalty *(CMP).*

EXCEPTION: Alternative sanctions may not be imposed on a laboratory that has a certificate of waiver because there are no Condition-level requirements for the waived tests. These laboratories are not inspected for compliance with Condition-level requirements.

6262.3 – Additional Sanctions

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

For laboratories approved to receive Medicare payment, sanctions also include:

- Suspension of part of Medicare payment;
- Suspension of all of Medicare payment; or
- Cancellation of Medicare payment.

6262.4 - Civil Suit

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CMS may bring suit in the appropriate U.S. District Court to enjoin continuation of any specific activity that is causing a significant hazard, or to enjoin the continued operation of the laboratory itself (including a CLIA-exempt laboratory that has been found to have deficiencies during a validation survey), if CMS believes that continuation of the specific activity or laboratory operations would constitute a significant hazard to the public health. Upon proper showing, the court issues a temporary injunction or restraining order without bond against continuation of the activity or operations.

6262.5 - Criminal Sanctions

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

An individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined. An intentional violation is knowing and willful noncompliance with any CLIA requirement. The RO refers suspected instances of intentional violations to *the Office of Inspector General (*OIG*)*.

6262.6 - Unsuccessful Participation in PT: Training and Technical Assistance Option

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If a laboratory's participation in PT is unsuccessful, the RO may require the laboratory to undertake special training of its personnel, or to obtain necessary technical assistance, or both. This enforcement action is separate from all other principal and alternative sanctions available for all laboratories. The authority to impose this remedy in lieu of or in addition to other sanctions is discretionary with the RO, and it continues after the CLIA phase-in period has expired. An educational focus is recommended for initial unsuccessful PT performance that does not cause immediate jeopardy.

6262.7 - Reissuance of Certificates to Laboratories Found Out of Compliance

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A laboratory that has been found out of compliance with one or more CLIA Condition(s) may be reissued a CLIA certificate before the expiration date when:

- Alternative sanctions, or training and technical assistance, or both are imposed; or

- There is no immediate jeopardy to individuals served by the laboratory or to the general public health and a principal sanction or civil money penalty has been imposed and the laboratory's appeal of that sanction, including revocation, is pending when its current certificate expires.

A *C*ertificate *of Compliance* or *C*ertificate of *A*ccreditation may also be reissued to a laboratory that has been found out of compliance if the laboratory holds a *C*ertificate *of Compliance* or *C*ertificate of *A*ccreditation that has been subject to a principal sanction or civil money penalty and the laboratory's appeal of that sanction is pending when its current certificate expires.

Any certificate issued under any or these circumstances is subject to all principal and alternative sanctions.

6264 - CLIA Conditions Not Met - Principal and Alternative Sanctions for Laboratories *t*hat Participate in Medicare

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CLIA certification is mandatory for all laboratories, regardless of payment, while enrollment in Medicare and Medicaid is voluntary.

The Medicare program has for many years required that noncompliant suppliers, including laboratories, be subject to enforcement actions under the Medicare statute*, in most cases,* before there is an opportunity for a hearing. CLIA permits imposition of alternative sanctions other than a civil money penalty prior to a hearing and also permits the suspension or limitation of the CLIA certificate prior to a hearing if:

- Immediate jeopardy exists;

- The laboratory has refused a reasonable request for information, materials, or work (e.g., failure to conduct PT) on materials necessary to determine compliance with CLIA; or

- The laboratory has refused CMS or its agent(s) permission to conduct a survey.

Although the Federal health and safety requirements are now the same for Medicare and CLIA, failure to meet CLIA requirements may result in additional enforcement actions under Medicare, since both the Public Health Service Act and the Social Security Act apply to these facilities. These Medicare sanctions are described below.

6264.1 - Principal Sanction

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CMS may cancel the laboratory's approval to receive Medicare payment for its services.

6264.1.1 - Basis for Cancellation

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 timeframe; or

- The laboratory fails to correct lower level deficiencies within the timeframes 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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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

6264.1.4 - Effect of Cancellation of Medicare on Laboratory's Eligibility to Receive Medicaid Payments

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

As provided in §1902(a)(9)(C) of the Act, payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that meet CLIA requirements or is licensed by a State whose licensure program has been approved for CLIA exemption by CMS.

6264.2 - Alternative Sanctions

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6264.2.1 - Suspension of Part of Medicare Payments

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 timeframes specified in the PoC, which cannot exceed 12 months, the RO cancels the laboratory's approval to receive Medicare payment for its services.

6264.2.2 - Suspension of All Medicare Payments

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CMS suspends Medicare payment for all tests in all specialties and subspecialties that are performed on or after the effective date of the sanction in any of the following situations:

- The laboratory has not corrected its Condition-level deficiencies included in the PoC within three months from the last date of survey; or

- The laboratory has had the same Condition-level deficiency(ies) during three consecutive biennial cycles, and the laboratory agrees not to charge Medicare beneficiaries, their private insurance carrier, the FI, carrier, *or MAC* for those services for which payment is suspended. The laboratory also agrees to waive any rights to appeal Medicare claims that are denied during the period of suspension. The laboratory may 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 MAC 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. CMS suspends Medicare payment for all tests performed on or after the effective date of the sanction. This 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, the RO resumes Medicare payment and eligibility to receive Medicaid 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.

6264.2.3 - Exception for Laboratories With Certificates of Waiver

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Alternative sanctions are not imposed on laboratories with certificates of waiver that receive Medicare payments for their services, because there are no Condition-level requirements for these tests. However, the fact that a deficiency is not at the Condition-level does not preclude taking adverse action based on the provisions contained in 42 CFR Part 493.1840. For example, if a laboratory is not following a manufacturer's

instructions it is not considered to be meeting the requirements in subpart B and the certificate can be suspended, revoked, or limited. If a laboratory is found to be performing nonwaived tests under its certificate of waiver, its certificate may be suspended or revoked. When a laboratory's certificate of waiver is revoked or suspended, its approval to receive Medicare payment for its services is concurrently canceled.

6264.2.4 - Effect on Medicaid Participation

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Payment for laboratory services may be made under the State plan only if a laboratory that meets CLIA conditions or is operating under a CLIA certificate furnishes those services.

6266 - Failure to Furnish Notification of Changes

(Rev. 1, 05-21-04)

If a laboratory fails to meet the notification of change requirements, RO may impose a sanction.

6266.1 - Notification Required Within 30 Days

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A laboratory *with a CLIA certificate* must notify CMS or the *SA* within 30 days of any changes in its:

- Ownership;
- Name;
- Location;
- Director; or
- Technical Supervisor.

6266.2 - Notification Required Within Six Months

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A laboratory with a CLIA certificate must notify the SA (or the RO for Federal jurisdictional surveys) within six months of any changes in specialty or subspecialty

testing that is not included in the laboratory's certification. However, no Medicare payment may be made to the laboratory until proper notification has occurred.

For a laboratory with a *C*ertificate of *A*ccreditation, the notification of these changes must be made to its accreditation organization.

NOTE: A laboratory with a *Certificate of R*egistration is not required to report such changes, since *Certificates of R*egistration do not specify the specialties/subspecialties of services offered.

6266.3 - Notification Requirements for Laboratories With Certificate of Waiver

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6266.3.1 - Expansion to Include Tests Other Than Waived Tests or Examinations

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A laboratory with a *C*ertificate of *W*aiver may not perform any examination or procedure not listed in the waived test category until it has reapplied and has been issued the appropriate certificate (i.e., *C*ertificate for PPM procedures or *Certificate of R*egistration) that covers the additional examinations or procedures requested by the laboratory.

6266.3.2 - Changes in Waived Tests or Examinations

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

For a laboratory with a *C*ertificate of *W*aiver, no notification is required if the only change is an addition or deletion within the list of waived tests, since these laboratories are authorized to perform any or all waived tests.

6266.4 - Notification Requirements for Laboratories With Certificate for Provider- Performed Microscopy (PPM) Procedures

(Rev.)

6266.4.1 - Expansion to Include Tests Other Than Waived Tests or Examinations

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A laboratory with a *C*ertificate for PPM procedures may not perform any examination or procedure not specified as PPM procedures or approved as waived tests, until it has reapplied and CMS has issued a *Certificate of R*egistration that covers the additional examinations or procedures requested by the laboratory.

6266.4.2 - Changes in PPM Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

For a laboratory with a *C*ertificate for PPM procedures, no notification is required if the only change is an addition or deletion within the procedures specified as PPM procedures or approved as waived tests, since these laboratories are authorized to perform any or all PPM procedures and waived tests.

6270 - Enforcement Based on Actions of Laboratory's Owner, Operator, or Employees

(Rev. 1, 05-21-04)

6270.1 - Enforcement

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6270.1.1 - Basis for Action

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO may initiate an enforcement action when it finds that a laboratory's owner, operator(s), or one of its employees has:

- Been found guilty of misrepresentation in obtaining a CLIA certificate;

- Performed, or represented 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;

- Failed to comply with CLIA certificate requirements and performance standards;

- Failed to comply with notification of change requirements;

- Failed to comply with reasonable requests by the RO or CMS' agent for any information or work on materials that the RO or CMS' agent conclude is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by CMS (no hearing necessary before the action);

- Refused a reasonable request by the RO or CMS' agent for permission to inspect the laboratory and its operation and pertinent records during the hours that the laboratory is in operation (no hearing necessary before the action);

- Violated or aided and abetted in the violation of any provisions of CLIA and its implementing regulations;

- Failed to comply with an alternative sanction previously imposed; or

- Within the proceeding 2-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all other laboratory's employees.)

6270.1.2 - Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If the RO determines that any of the above CLIA violations have occurred, the RO imposes a principal sanction. Also, the RO determines whether referral to OIG is necessary.

6270.1.3 - Referral to OIG

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In addition to imposing sanctions, the RO refers to OIG, within 30 days, for action any situation in which the RO determines:

- The owner, operator, or one of the laboratory's employee is guilty of misrepresentation in obtaining a CLIA certificate;

- The owner, operator, or one of the laboratory's employees performed or represented the laboratory as entitled to perform a laboratory examination or other testing not included in the laboratory's CLIA certificate;

- The owner, operator, or one of the laboratory's employees violated or aided and abetted in the violation of CLIA provisions; or

- The laboratory intentionally referred PT samples to another laboratory for analysis.

6272 - Sanctions(s) - Factors Considered

(Rev. 1, 05-21-04)

6272.1 - Choice of Sanction

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CMS is required to impose those sanctions that are most likely to bring laboratories into compliance in the shortest possible time from the date of determination of deficiencies. The RO considers a number of factors when choosing a sanction. These factors include, but are not limited to:

- Whether the deficiencies pose immediate jeopardy;

- The nature, incidence, severity, and duration of the deficiencies or noncompliance;

- Whether the same Condition-level deficiencies have been identified repeatedly;

- The accuracy and extent of the laboratory's records (e.g., remedial action) in regards to the noncompliance and their availability to the SA/RO;

- The relationship of one deficiency or group of deficiencies to other deficiencies;

- The overall compliance history of the laboratory, including but not limited to any period of noncompliance that occurred between certifications of compliance;

- The corrective and long term compliance outcomes that would be achieved through application of the chosen sanction or sanctions;

- Whether the laboratory has made any progress toward improvement following a reasonable opportunity to correct deficiencies;

- The size and test volume of the laboratory;

- Any recommendation by the SA as to which sanction would be appropriate; and

- Whether the laboratory participates in the Medicare program, since additional sanctions might apply in these situations.

6272.2 - Number of Alternative Sanctions

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A separate sanction may be imposed for each Condition-level deficiency or a single sanction may be imposed for all Condition-level deficiencies that are interrelated and subject to correction by a single course of action.

6272.3 - Training and Technical Assistance

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

This sanction option may be applied alone or with other sanctions when a laboratory is not in compliance with the CLIA PT requirements for successful participation.

6274 - Principal Sanctions

(Rev. 1, 05-21-04)

6274.1 - Suspension or Limitation of CLIA Certificate

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6274.1.1 - Basic Rule

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO will not suspend or limit a CLIA certificate until after an ALJ hearing has upheld the suspension or limitation.

6274.1.2 - Exceptions

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO may suspend or limit a CLIA certificate before the ALJ hearing in any of the following circumstances:

- The laboratory's deficiencies pose immediate jeopardy;

- The laboratory has refused a reasonable request for information or work on materials that RO or CMS' agent has concluded are necessary in determining compliance; or

- The laboratory has refused to allow a survey of the laboratory or its operation.

6274.2 - Revocation of CLIA Certificate

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO will not revoke any type of CLIA certificate *for a laboratory that has filed an appeal* until after an ALJ hearing decision upholds the revocation. If the hearing decision upholds the revocation, it may be imposed even if CMS had not previously limited or suspended the certificate.

6276 - Alternative Sanction: Directed PoC and Directed Portion of a PoC

(Rev. 1, 05-21-04)

6276.1 - Basis for Action

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 timeframes 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 – Notice Requirements

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6276.2.1 – Notice of Proposed Sanction(s)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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

6276.2.2 – Notice of Imposition of Sanction(s)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO provides written notice of the imposed sanction(s) at least five days before the effective date in immediate jeopardy situations, and at least 15 days before the effective date in situations that do not pose immediate jeopardy. [See updated sample letter at http://www.cms.hhs.gov.clia.

6276.3 - Processing Directed PoC

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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

- **Specific Corrective Action and Timeframes** - Directs the laboratory to take specific corrective action within specified timeframes.

- **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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 timeframe 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.

6278 - Alternative Sanction: State Onsite Monitoring

(Rev. 1, 05-21-04)

6278.1 - Basis for Action

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Continuous or intermittent monitoring by the SA may be required to ensure the laboratory implements its PoC and complies with the Condition-level requirements. The monitor's responsibility is to oversee whether deficiencies are being corrected. The monitor has no management authority, i.e.; the monitor cannot hire or fire staff, obligate funds, or otherwise dictate how the laboratory operates.

The laboratory must pay for the costs of onsite monitoring by the SA. The costs of onsite monitoring are computed by multiplying the number of hours of onsite monitoring in the laboratory by the hourly rate negotiated by the RO and each State. The hourly survey rate as negotiated during the budget process includes salary, fringe benefits, travel, and other direct and indirect costs negotiated by the RO and the State. Form CMS-670 *(Exhibit 74)* is used to collect this data.

6278.2 - Notice Requirements

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6278.2.1 – Notice of Proposed Sanction(s)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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].

6278.2.2 – Notice of Imposition of Sanction(s)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO provides written notice of the imposed sanction(s) at least five days before the effective date in immediate jeopardy situations, and at least 15 days before the effective date in situations that do not pose immediate jeopardy. [See updated sample letters at http://www.cms.hhs.gov/clia].

6278.3 - Duration of Sanction

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Once imposed, onsite monitoring continues until the laboratory demonstrates that it is capable of ensuring compliance with all Condition-level requirements.

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 the RO notifies the laboratory of its intent to impose a principal sanction against the laboratory's CLIA certificate. If the laboratory still does not correct its deficiencies, the Medicare sanction will continue until the principal sanction against the laboratory's CLIA certificate is effective.

6280 - Alternative Sanction: Civil Money Penalty

(Rev. 1, 05-21-04)

6280.1 - Scope and Basis

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Section 1846 of the Act and §353(h)(2)(B) of the PHSA authorizes the Secretary to impose civil money penalties on laboratories. Section 1846(b)(3) of the Act specifically provides that incrementally more severe fines may be imposed for repeated or uncorrected deficiencies.

When a laboratory has Condition-level deficiencies, the RO may impose a civil money penalty in lieu of, or in addition to, imposing a principal sanction against the laboratory's CLIA certificate, regardless of whether the deficiencies pose immediate jeopardy. According to the law, civil money penalties may only accrue and not be collected prior to a hearing (if one is requested). The penalty is collected according to the procedures outlined below.

6280.2 - Amount of Penalty

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The following factors are considered in determining the amount of penalty:

- The nature, scope, severity, and duration of the noncompliance;
- Whether the same Condition-level deficiencies have been identified during three consecutive surveys;
- The laboratory's overall compliance history, including, but not limited to, any period of noncompliance that occurred between certifications of compliance;
- The laboratory's intent or reason for noncompliance; and
- The accuracy and extent of laboratory records and their availability to RO or CMS' agent.

6280.3 - Range of Penalty Amount

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

1. **Immediate Jeopardy (Higher Range) -** The penalty will range from $3,050 to $10,000 per day of noncompliance or per violation.

2. **No Immediate Jeopardy (Lower Range) -** The penalty will range from $50 to $3,000 per day of noncompliance or per violation.

3. **Changes in Penalty Amount** -If a civil money penalty is proposed for immediate jeopardy and the immediate jeopardy is subsequently removed, but the Condition-level deficiency continues, the penalty amount may be shifted to the lower range.

In turn, if deficiencies cited during the survey did not pose immediate jeopardy and the RO proposed a penalty in the lower range, the RO may propose an increase in the penalty amount to the higher range when deficiencies become sufficiently serious to pose immediate jeopardy. In this case, propose the increase in penalty amount before the hearing.

6280.4 - Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6280.4.1 - Notice of Intent

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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.

6280.4.2 - Accrual of Penalty

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The civil money penalty begins accruing five days after the date of the notice of intent if immediate jeopardy is cited. In no immediate jeopardy cases, the penalty begins accruing 15 days after the notice of intent.

6280.4.3 - Duration of Penalty

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The penalty continues to accrue until the earliest of the following occurs:

- Condition-level compliance is verified, based on a revisit or evidence presented by the laboratory in its credible allegation of compliance. If a revisit finds compliance and the laboratory presents no credible evidence that compliance was achieved before the revisit, the civil money penalty stops accruing as of the last day of the revisit;

- The laboratory presents credible evidence at the time of the revisit that establishes that the laboratory achieved compliance with all Conditions before the revisit. In this instance, the civil money penalty stops accruing as of the date of compliance; or

- The laboratory's CLIA certificate is suspended, limited, or revoked.

6280.5 - Computation and Notice of Total Penalty Amount

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

After the laboratory's compliance is verified or its CLIA certificate has been suspended, limited, or revoked, the RO computes the total penalty amount due. This is **after** the 60-day period for requesting a hearing has expired without a request, the laboratory has waived its right to hearing, or the ALJ issues a hearing decision that upholds imposition of the penalty.
The RO sends a written notice to the laboratory informing it of the daily or per- violation penalty amount, the number of days or violations for which the penalty is imposed, the total amount due, and the due date for payment of the penalty. Payment is due 15 days from the date of the notice. At the RO's option, it may choose to approve a plan allowing the laboratory to pay the penalty, plus interest, over a period of up to one year from the original due date. The RO computes interest in accordance with 42 CFR Part 405.378(d). *[See updated sample letters at http://www.cms.hhs.gov/clia].*

6280.6 - Collection of Penalty Amounts

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The penalty amount due may be deducted from any monies then or later owed the laboratory by the Federal Government. Interest accrues on the unpaid balance of the penalty beginning on the due date, and is based on the rate specified in 42 CFR Part 405.378(d).

6280.7 - Settlement

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO has the authority to settle any case at any time before the ALJ issues a hearing decision.

6282 - Noncompliance With One or More Conditions - Immediate Jeopardy Exists

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When a laboratory's deficiencies pose immediate jeopardy, the RO requires the laboratory to take immediate action to remove the jeopardy and it may also impose one or more *principal and/or* alternative sanctions as necessary to encourage compliance. If the RO has reason to believe that continuation of any activity by the laboratory (either by the entire laboratory operation or in any specialty or subspecialty of testing) would constitute a significant hazard to the public health, it may bring suit and seek a temporary injunction or restraining order against the continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has or whether it is a CLIA-exempt laboratory.

If the laboratory has not *removed* the immediate jeopardy, *the RO notifies* the laboratory that *CMS* will suspend or limit its CLIA certificate. In instances of immediate jeopardy, a suspension or limitation of the laboratory's CLIA certificate is not delayed because the laboratory has appealed and the hearing or hearing decision is pending. The laboratory's *suspended* CLIA certificate may be revoked following a hearing, when one is requested, if the ruling is in CMS' favor.

6282.1 - Processing Immediate Jeopardy Enforcement Actions

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 two 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.

- *The* SA forward*s* all supporting documentation to the RO by overnight mail.

4. **Eighteenth Calendar Day -** At least five days before the effective date of the sanction(s), the RO notifies the laboratory *of* the proposed sanction(s) and of its right to due process. In the notice, the RO acknowledges any evidence or information received from the laboratory. (See *updated sample letters at http://www.cms.hhs.gov/clia*.)

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. (However, in situations of immediate jeopardy, an onsite revisit is usually necessary to determine first hand whether the jeopardy has been removed.) If the RO determines a revisit is needed, it instructs the SA to conduct it prior to the effective date of the sanction*s*. The RO further instructs the SA to notify it of the outcome immediately upon completion of the revisit. The SA is not permitted to perform another revisit without permission from the RO.

If the RO concurs on the basis of evidence presented or the outcome of a revisit that the immediate jeopardy has been removed and there are no remaining Condition-level deficiencies, the RO certifies compliance and ensure that a CLIA certificate is issued or reissued to the laboratory, if appropriate. The RO advises the laboratory in writing that compliance has been achieved. If the immediate jeopardy has been removed, but Condition-level deficiencies **remain**, the RO uses the appropriate enforcement procedures.

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

5. **Twenty-Third Calendar Day -** If the laboratory is still out of compliance at the Condition-level and immediate jeopardy still exists, *the RO imposes* suspension or limitation of the laboratory's CLIA certificate *and notifies the laboratory*. In addition, if the RO has reason to believe that the continuation of any activity by the laboratory (either the entire laboratory operation or any specialty or subspecialty of testing) would constitute a significant hazard to the public health, it may bring suit and seek a temporary injunction or restraining order against continuation of that activity by the laboratory, regardless of the type of CLIA certificate the laboratory has and whether it is CLIA-exempt. If a principal sanction is imposed, the RO arranges to publish a public notice. 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 that are no longer covered under Medicare.

If the immediate jeopardy is subsequently removed, but Condition-level deficiencies still exist, the RO may continue to impose the principal sanction or any other alternative sanction until the laboratory achieves compliance.

6284 - Noncompliance With One or More Conditions - No Immediate Jeopardy

(Rev. 1, 05-21-04)

6284.1 - Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 ensure 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.

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 - Ensuring Timely Correction of Condition-level Deficiencies

(Rev. 1, 05-21-04)

6286.1 - Monitoring of Corrective Action(s)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO may direct the SA to revisit the laboratory or conduct a follow-up at any time to evaluate progress and at the end of the enforcement period to determine whether all corrections have been made.

6286.2 - Deficiencies Corrected before Revisit

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If a laboratory produces credible evidence that it achieved compliance before the revisit, the RO lifts the sanctions as of that earlier date.

6286.3 - Alternative Sanction Imposed - Failure to Correct Condition-level Deficiencies

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If a revisit verifies that the laboratory has not corrected its Condition-level deficiencies within the period specified in the approved PoC, the RO initiates action to impose a principal sanction against the laboratory's CLIA certificate.

Alternative sanctions may continue for more than 12 months from the date of the survey while a hearing on the proposed principal sanction against the CLIA certificate is pending. If a hearing decision upholds the proposed principal sanction against the laboratory's CLIA certificate, the RO lifts the alternative sanction as of the day the principal sanction is effective.

6286.4 - Condition-level Deficiencies Corrected but Other Deficiencies Remain - 12-Month Maximum for Correction

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

At the end of the PoC period, if all Condition-level deficiencies have been corrected, but there are *standard* level deficiencies that remain uncorrected, the SA will request a revised PoC from the laboratory that addresses these remaining deficiencies. The SA will not accept a revised PoC that extends beyond 12 months from the date of the survey that originally identified the deficiencies.

If a revisit at the end of the 12-month period verifies that the laboratory has not corrected its deficiencies, the RO imposes a principal sanction against the laboratory's CLIA certificate and cancels the laboratory's Medicare approval.

Alternative sanctions may continue for more than 12 months from the date of the survey while a hearing on the proposed principal sanction against the CLIA certificate is pending and while Condition-level as well as lower-level deficiencies remain uncorrected. If a hearing decision upholds the proposed principal sanction against the laboratory's CLIA certificate, the RO lifts the alternative sanction as of the day the principal sanction is effective.

6286.5 - Revocation of CLIA Certificate

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If the RO decides to revoke a noncompliant laboratory's CLIA certificate, it may do so within the timeframes 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.

6286.6 - Acceleration of Timetable

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO switches from the no immediate jeopardy procedures to the accelerated procedures of §6282 at any point that it determines immediate jeopardy to patient health or safety exists.

6288 - Procedures for Noncompliant Federal and State Operated Laboratories

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If the RO surveys a Federal or State operated laboratory and finds Condition-level noncompliance, one or more letters are sent to the laboratory including a warning and informing the laboratory of its opportunity to respond, its appeal rights, and the projected effective date of the sanction(s). *[See updated sample letters at http://www.cms.hhs.gov/clia.]*

6289 – Withdrawal or Denial of Laboratory Accreditation

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When an accreditation organization withdraws or denies a laboratory's accreditation, the RO will authorize the SA to conduct a complaint investigation to determine compliance with all CLIA requirements. (See Chapter 5, Compliant Procedures.) The RO takes appropriate enforcement action if deficiencies are found. If the laboratory is found to be in compliance with all CLIA requirements, the SA obtains an updated Form CMS-116 (Exhibit 125) and processes the change in certification type. [See updated sample letters at http://www.cms.hhs.gov/clia.]

6290 - Procedures for Laboratories Found Out of Compliance during a Survey of an Accredited Laboratory

(Rev. 1, 05-21-04)

6290.1 - General

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 determine whether a complaint investigation is warranted.

6290.2 - Laboratory Found Not in Compliance Following Validation Survey or Complaint Survey

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

NOTE: Refer to SOM *C*hapter 5, *Compliant Procedures* regarding additional information about complaint investigations/surveys.

If deficiencies identified are Condition-level and pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public, the RO follows the adverse action procedures described in §6282 and notifies the laboratory by overnight mail or facsimile of the action being taken. (See *updated sample letters at http://www.cms.hhs.gov/clia*.)

If it is documented that the laboratory is out of compliance with one or more CLIA conditions, but the deficiencies **do not** pose immediate jeopardy to the health and safety of individuals served by a laboratory or that of the general public, the RO follows the adverse action procedures described in §6284. The RO processes the certification as any certification of a nonaccredited laboratory including the disclosure of survey findings and notifies the laboratory that it has been found out of compliance with a *C*ondition(s) and is, therefore, placed under *CMS* jurisdiction. (See *updated sample letters at http://www.cms.hhs.gov/clia*.)

The laboratory is placed under *CMS* jurisdiction until it reaches Condition-level compliance or when it loses its *C*ertificate of *A*ccreditation. For all cited Condition-level

deficiencies, the RO informs the laboratory that a PoC must be obtained within 10 days of notification if participation in the CLIA program is to continue. (See *updated sample letters at http://www.cms.hhs.gov/clia*.)

If only standard-level deficiencies are identified, the RO refers the Form CMS-2567 (Exhibit 7) to the applicable accreditation organization for follow-up. A PoC is encouraged for below Condition-level deficiencies, since the Form CMS-2567 is a public record, but is not required.

6290.2.1 - Plan of Correction

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If the RO concurs with the SA's recommendation of an acceptable PoC, the RO sends written notification to the laboratory and to the accreditation organization. (See *updated sample letters at http://www.cms.hhs.gov/clia*.) Where the SA has found the PoC unacceptable and the RO concurs with the SA's recommendation, the RO notifies the laboratory accordingly and requests an amended acceptable PoC.

6290.2.2 - Compliance With All CLIA Conditions After Correction of Deficiencies

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When an accredited laboratory is determined to be in compliance with all CLIA conditions, the RO notifies the laboratory and the accrediting organization accordingly. (See *updated sample letters at http://www.cms.hhs.gov/clia*.) The RO informs the SA in writing to cease monitoring activities. Revisits are never authorized after an accredited laboratory has been notified that it is in Condition-level compliance with all CLIA conditions.

6290.2.3 - Notification of Accreditation Organization

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 communication 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 - Deficiencies That Are Not at Condition Level

(Rev. 1, 05-21-04)

If a laboratory has deficiencies that are not at the Condition level, the following rules apply.

6292.1 - Initial Action

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The laboratory must submit a PoC that is acceptable in terms of both its contents and the timeframes 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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 impose a principal sanction against the laboratory's CLIA certificate.

6293 - Intervening Actions That Do Not Postpone or Delay Enforcement Timetable

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Only correction of noncompliance can stop an enforcement action.

(S&C-01-22)

A change of ownership does not affect completion of an enforcement action. However the RO or SA does not solicit a PoC from the new owner. Court-appointed receivership is not a basis for cessation of the sanction process.

6294 - Duration of Alternative Sanctions

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

An alternative sanction continues until the earlier of the following occurs:

- The laboratory corrects all Condition-level deficiencies; or
- A principal sanction against the laboratory's CLIA certificate becomes effective.

If an alternative sanction is imposed for Condition-level noncompliance *that* does not pose immediate jeopardy, and a revisit verifies that the laboratory has not corrected all deficiencies within 12 months from the survey date, the RO takes the following action:

- Cancels the laboratory's approval to receive Medicare payment for its services, and discontinues any Medicare alternative sanctions as of the date the cancellation is effective;
- Notifies the laboratory of its intent to impose a principal sanction against the laboratory's CLIA certificate and of its right to a hearing; and
- Imposes (or continue to impose) any alternative sanctions that do not pertain to Medicare payments. Sanctions imposed against the CLIA certificate may continue for more than 12 months from the date of survey while a hearing on the proposed limitation, suspension, or revocation of the laboratory's CLIA certificate is pending.

6295 - Lifting of Alternative Sanctions

(Rev. 1, 05-21-04)

6295.1 - General Rule

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Alternative sanctions are not lifted until compliance with all Condition-level requirements is verified.

6295.2 - Credible Allegation of Compliance

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When a sanctioned laboratory submits a credible allegation of compliance, the RO determines whether:

- Compliance can be verified on the basis of evidence submitted by the laboratory in its allegation or other written documentation; or
- A revisit is necessary to verify whether compliance has been achieved.

If compliance can be verified on the basis of evidence submitted, the RO lifts the sanction as of the date of compliance supported by the evidence.

6295.3 - Compliance Achieved Before or During Date of Revisit

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If a laboratory is in compliance at the time of the revisit and it produces credible evidence that it achieved compliance before the revisit, the RO lifts the sanction as of that earlier date. If the revisit finds compliance and there is no credible evidence presented by the laboratory that compliance was achieved before the revisit, the RO lifts the sanction as of the last day of the revisit.

6296 - Sanction Imposed on Any Type of CLIA Certificate - Effect on Medicare Approval

(Rev. 1, 05-21-04)

6296.1 - Suspension or Revocation of Any Type of CLIA Certificate

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When the RO suspend*s* or revoke*s* any type of CLIA certificate, the laboratory's approval to receive Medicare payment for its services is canceled concurrently.

6296.2 - Limitation of Any Type of CLIA Certificate

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When the RO limits any type of CLIA certificate, it concurrently cancels the laboratory's approval to receive Medicare payment to only those specialties or subspecialties that are authorized by the laboratory's limited certificate.

6297 - Summary of RO Responsibilities during CLIA Adverse Action Process

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 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.*

6298 - Limitation on Medicaid Payment

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

As provided in §1902(a)(9)(C) of the Act, payment for laboratory services may be made under the State plan only if a laboratory that meets CLIA requirements furnishes those services.

6299 - CLIA Violations - OIG Excludes Laboratory From Medicare Participation - Effect on CLIA Certificate

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If *the* OIG excludes a laboratory from participation in the Medicare program, the RO suspends the laboratory's CLIA certificate for the period during which the laboratory is excluded.

The notice of suspension should be sent immediately after the RO learns that the exclusion takes effect. The laboratory is entitled to a hearing before the suspension is imposed, but may only appeal whether the OIG exclusion did take effect. A change of

laboratory ownership may not release a laboratory from its exclusion from Medicare and the suspension.

6300 - Application of Appeals Procedures

(Rev. 1, 05-21-04)

The procedures under the CLIA program for reconsiderations, hearings and appeals, and civil actions outlined in this section apply to all laboratories that meet the definition for a laboratory under CLIA and, where indicated, prospective laboratories. These procedures are set forth in 42 CFR Part 493.1844 and are explained in the following sections.

6302 - Reconsideration

(Rev. 1, 05-21-04)

6302.1 - Definition of Reconsideration

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A reconsideration is a thorough, independent review by CMS of a prior decision by CMS. The entire body of evidence, including any new information presented is reviewed.

6302.2 - Right to Reconsideration

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A reconsideration may be given only to a prospective laboratory (i.e., a laboratory that is applying for a CLIA certificate or for both a CLIA certificate and approval to receive Medicare/Medicaid payment for its services) or to a laboratory that applies to test in new specialties or subspecialties. The RO reconsiders only initial determinations as outlined below and in 42 CFR Part 493.1844(b). Appeals of initial determinations of laboratories that already hold a CLIA certificate and/or have previously been approved to participate in Medicare/Medicaid are submitted directly to an ALJ. There is no reconsideration given at RO level for these types of cases.

The following are the initial determinations applicable to prospective laboratories, and, therefore, are valid reasons for which prospective laboratories may provide the SA (or the RO directly) with a written request for a reconsideration:

- The denial of a laboratory's request for a CLIA certificate;
- The denial of a laboratory's request for additional specialties or subspecialties; and

- The denial of a laboratory's request for approval to receive Medicare payment for its services.

In 42 CFR Part 493.1844(c), there is a list of administrative actions that are not initial determinations and are, therefore, not appealable and not subject to a reconsideration.

6302.3 - Request for Reconsideration: Manner and Timing

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

A request for reconsideration is any written expression of dissatisfaction with the RO's initial determination with regard to a CLIA certificate. The request may be in the form of a letter, statement, or submittal of a new request for Medicare approval or a CLIA certificate, must be submitted within 60 days of the initial determination, and must include a statement of the issues with which the prospective laboratory disagrees, with the reasons for the disagreement.

6302.4 - Actions upon Receipt of Request for Reconsideration

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The RO or the SA will date-stamp the request when it is received, and promptly acknowledge the request. A copy of the request and the letter of acknowledgment will be forwarded immediately to the RO from the SA. Any additional information the SA subsequently receives from the prospective laboratory that may affect the reconsideration or hearing will be forwarded to the RO. All reports of onsite visits and telephone contact with the prospective laboratory will also be sent to the RO from the SA.

6302.5 - Withdrawal Requests and Extensions

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If the affected party files a written notice to withdraw its request for reconsideration, the RO will approve the withdrawal request if it is received prior to its mailing the notice of reconsidered determination.

If the prospective laboratory is unable to file a request for reconsideration within 60 days, it may file a written request for an extension to the RO, stating the reasons why the request was not filed timely. The RO is responsible for deciding whether good cause for missing the filing deadline existed. If the affected party has not shown good cause for the late filing, the RO should dismiss the reconsideration request. It may also dismiss a request for reconsideration from a prospective laboratory if it does not involve an initial determination, as defined in 42 CFR Part 498.3.

6304 - RO Notice of Reconsidered Determination

(Rev. 1, 05-21-04)

6304.1 - Determination Reversal (Approval)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If a reconsideration is requested and a laboratory's application is subsequently approved, the RO *notifies the laboratory* within 20 days of approving the prospective laboratory's application to participate in the CLIA program. After confirming that the Form CMS-116 *(Exhibit 125)* is correct, the RO has a CLIA ID number assigned and completes the applicable portions of the Form CMS-1539 *(Exhibit 9)*. The RO marks on the Form CMS-1539 and Form CMS-116 "Determination Reversed." The *laboratory is then billed, and issued*, a *Certificate of R*egistration, *C*ertificate of *W*aiver, or *C*ertificate for PPM testing, whichever is applicable.

6304.2 - Denial Affirmed

(Rev. 1, 05-21-04)

The RO includes with the notice of this decision a listing of each statutory and regulatory requirement with which the prospective laboratory is not in compliance and why.

If the ARA did not sign the initial denial notice, he or she should sign the reconsidered denial notice.

The notice of reconsideration and denial of the initial determination will be released via the signature of the RA. The RO mails the action, notifies all affected components, and transmits the Form CMS-1539 and Form CMS-116.

6304.3 - Administrative Evidentiary Hearing

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Any prospective laboratory dissatisfied with a reconsidered determination under 42 CFR 493.1844(e)(1) or a revised reconsidered determination under 42 CFR 498.30 may submit a written request for an administrative evidentiary hearing by the Departmental Appeals Board (DAB).

6306 - Administrative Hearing

(Rev. 1, 05-21-04)

6306.1 - Actions Which Are Appealable

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The following actions are initial determinations and are, therefore, subject to appeal in accordance with 42 CFR 493.1844:

- The suspension, limitation, or revocation of the laboratory's CLIA certificate because of noncompliance with CLIA requirements;
- Denial of a CLIA certificate;
- The imposition of alternative sanctions under 42 CFR 493.1806 - 1807 (but not the determination as to which alternative sanction(s) to impose); and
- Denial or the cancellation of the laboratory's approval to receive Medicare payment for its services.

6306.2 - Procedure for Requesting a Hearing

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Any laboratory or prospective laboratory dissatisfied with a request of reconsideration of an initial determination is entitled to an administrative hearing before an ALJ of the DAB. If the affected laboratory shows good cause why the request for a formal hearing was not filed timely, the ALJ is responsible for granting the filing extension. However, a prospective laboratory must go through the reconsideration process first before filing a formal appeal.

Any laboratory which already holds a CLIA certificate and/or participates in Medicare/Medicaid that is dissatisfied with any of the initial determinations listed above would file its appeal directly with an ALJ of the DAB. Previously approved laboratories are not given reconsideration determinations. Hearings are conducted in accordance with Subpart D of 42 CFR Part 498. In order to request a hearing, the laboratory, prospective laboratory or its legal representative must file a written request for an appeal with the SA or the RO within 60 days of its receipt of the notice of initial, reconsidered, or revised determination.

6306.3 - Content of the Request for Hearing

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The request for a hearing must contain the following information:

- Specific issues or findings with which the laboratory disagrees; and
- Specification of the basis for contending that *the* findings are incorrect.

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

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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*.

6308 - Processing of Hearing Requests

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Any laboratory or prospective laboratory dissatisfied with an initial, reconsidered or revised determination may file a written request for an administrative hearing before an ALJ. This request must be filed within 60 days of the laboratory's receipt of the notice of the sanction. The RO sends all hearing requests that are sent to it (or which are sent to the State and forwarded to the RO) to:

Departmental Appeals Board
Civil Remedies Division
Cohen Bldg., Room G-644
300 Independence Avenue, SW
Washington, D.C. 20201.

If the laboratory requests a hearing prior to receiving a notice of sanction or a notice of a reconsidered determination, the RO explains in writing to the laboratory why the request for an appeal is premature and provides instructions to the laboratory or prospective laboratory explaining the procedures for correctly filing the appeal.

6310 - Scheduling of the Hearing

(Rev. 1, 05-21-04)

6310.1 - Timing of the Hearing

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Any laboratory, regardless of whether it is approved under Medicare, will receive **one** administrative evidentiary hearing by the DAB. The Medicare principal sanction (cancellation of Medicare approval) may take place **prior** to the hearing, while the principal sanctions authorized under CLIA are imposed **after** the hearing, unless: immediate jeopardy exists; the laboratory has refused a reasonable request for information; or has refused permission to inspect the laboratory.

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

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 with in the appropriate timeframe) is held.

6310.3 - Relationship of Action on a Laboratory's CLIA Certificate to the Timing of the Hearing

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In cases where a laboratory's deficiencies do not constitute immediate jeopardy, action against a laboratory's CLIA certificate occurs after the hearing. Civil money penalties, which accrue during periods of noncompliance prior to the hearing, are collected following the hearing decision.

6312 - Adverse Hearings Decisions by ALJ

(Rev. 1, 05-21-04)

Any laboratory or prospective laboratory dissatisfied with the ALJ's decision may, within 60 days from the receipt of the notice of the ALJ's decision, file a written request for review in accordance with Subpart E of 42 CFR Part 498. The authority to change a decision rests solely with the DAB. If the SA receives the request, it transmits the request immediately to the RO. The RO will keep the SA apprised of action on such cases.

NOTE: After the CLIA administrative appeal process is exhausted, a laboratory dissatisfied with the final decision to impose a CMP or principal sanctions may file a petition for judicial review with the U.S. Court of Appeals of the circuit in which the laboratory has its principal place of business. (See 42 CFR 493.1846(f)(3).)

6314 - Readmission to CLIA Program

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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 two years, as outlined in 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 in 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. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

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, 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.

NOTE: Actions under appeal are noted as such.

A laboratory should only be listed in the registry **when an action has been completed** that meets one of the above designated categories.

Budget and Administration

6400 - The CLIA Federal/State Relationship

(Rev. 1, 05-21-04)

The Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578) continue to foster a close and integrated relationship between the Federal government and SAs charged with the implementation, maintenance and enforcement of Federal requirements. Regulations and guidelines developed are the interpretative documentation that both State and Federal agencies will follow as we jointly seek to assure that the clinical laboratory improvements mandated by Congress are initiated properly and fulfilled in the most effective manner possible.

The SA is the key local interface and representative of CMS with the clinical laboratories that are not State or Federally owned. Although CLIA has expanded the Federal government's oversight role to virtually all laboratories in the country that do testing for diagnostic purposes, it is through the SAs or their agents that virtually all non-Federal CLIA oversight of laboratories occurs. SAs or their agents are responsible for hiring, training and managing personnel needed to fully implement and assure the ongoing effective conduct of regulations promulgated for CLIA in accordance with contractual provisions in the 1864 Agreement.

The law further mandates that CLIA be a self-funded program. Fees for compliance determination and oversight covering all CLIA-related expenses must be established and collected. There are no other funds available from any source other than from those laboratories subject to CLIA requirements. Therefore, for CLIA laboratories, workload planning and budgeting are key features in the CLIA Federal/State administrative partnership. This is a negotiated process that closely involves the SA, each State's budget process, the laboratory surveys and related workloads and the cost to accomplish the required workload. The SA is the responsible State organization in this process. The RO is the Federal government's representative for helping the States develop acceptable work plans and appropriate budgets to accomplish the required workload targets. For CLIA-exempt and accredited laboratories, payment of the initial fees and fees covering the Federal oversight activities constitutes the main exchange between the State and CMS in the budget process. The CLIA Exempt State or accrediting body may make additional charges to individual laboratories.

The budget process begins with the State preparation of the Planned Workload Report (with its narrative activity work plan) and a Budget Request that is forwarded to CMS. Next comes budget approval and the advancement of CLIA funds. Survey Team Composition and Workload Reports are prepared and submitted for each completed

survey and related support activity, and quarterly reports of work completed are filed for Federal payment for SA completed work on the CLIA workload.

6402 - Federal Administrative Responsibilities

(Rev. 1, 05-21-04)

Among the responsibilities of the parties are obligations imposed upon the Federal government. The following are delegated to the Regional Offices:

- Setting policy and policy interpretations;
- Providing consultation to necessary agencies involved in administering the Federal requirements;
- Paying the appropriate and allowable costs of the SA functions relating to the administration of regulations and guidelines for CLIA;
- Making determinations of allowable State costs submitted for Federal payment; and
- Controlling payment of funds to appropriate State agencies for costs incurred in administering CLIA.

6404 - Nature and Source of Payments to States

(Rev. 1, 05-21-04)

6404.1 - Funds for Clinical Laboratory Improvement Act Related Activities

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The Clinical Laboratory Improvement Amendments of 1988 *(CLIA)* mandates that the CLIA program be self-funded. Program participants (laboratories that do clinical testing of human specimens for diagnostic purposes) bear all financial burden for implementation, day-to-day operations, enforcement and other Federal/State oversight expenses of the program. The funds needed to run the program come from the variety of mechanisms put in place to administer the program. The sources include:

- *Certificate of Registration* fees, from the start-up period, that are to accompany the initial registration;
- Certificate fees for Federal administration of the program; and

- Compliance determination and enforcement fees to cover the costs incurred by the State and Federal government to ensure program requirements are met.

6404.2 - Laboratory Remitted Funds

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When a lock-box contractor receives these laboratory-remitted funds, they are deposited into a CMS CLIA account where they are available for State advances and payments for CLIA work. The States bill CMS for payment for surveys, visits or re-contacts, complaint visits, follow-ups and other CLIA work, by preparing a Form CMS-670 , "Survey Team Composition and Workload Report," (Exhibit 74) and a Form CMS-102, "Budget Requests, Clinical Laboratory Improvement Amendments Program," (Exhibit 116). The Form CMS-670 for CLIA is intended to capture the total time expended on a laboratory survey, or other CLIA-related workload from beginning to end. All work performed, including all discussions, report preparation and similarly related work expenditures for all employees involved in the process are to be reported. Payments to States under §1864 of the Act are made from user fees collected from the laboratories at registration. These fees pay for administrative expenses (including advances or payment to States under §1864) as authorized for expenditure from the CLIA user fee account.

As surveys and related CLIA work are performed, actual expenditures are determined and forwarded to the RO for review and action. They are then forwarded to CMS' CO or their representative for approval. An end of year reconciliation and balancing of accounts will occur between CMS and each State. Actual expenses data will then be used by CMS as a basis for determining and setting future fee schedules for the participating laboratories.

6406 - State Agency Administrative Responsibilities

(Rev. 1, 05-21-04)

The SA is responsible for:

- Establishing and maintaining organizational relationships with other State and local governmental groups, as necessary, for attaining program or related program goals;

- Knowing the needs of laboratories in the State which affect their ability to comply with program standards, and devising and executing plans to address those needs;

- Advising the RO of program needs and trends, and of responsive actions which have been taken;

- Providing the material, equipment, and the training and support of personnel to perform the above functions; and

- Furnishing necessary records and accounting to justify costs claimed for payment by CMS.

6408 - State Agency Responsibility for Records and Reports

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

SAs are to establish and maintain basic records and prepare operating reports in the form of the Form CMS-670, (Exhibit 74), and the Form CMS-102, (Exhibit 117). These report the essential administrative and fiscal information, records and reports which will help to provide an:

- Evaluation of the effectiveness of program operations;

- Analysis of workloads and degree of accomplishment;

- Identification of administrative or technical problem areas;

- Development and justification of payments; and

- Documentation to support the expenditure of CLIA funds for compliance determination surveys and oversight activities.

SAs are responsible for maintaining records and reports, on a continuing or special request basis, which are pertinent to the managing of agency operations and reflect the agency's workload. Records and reports are to be designed to fit within the framework of the SA operations. The design of those records and report mechanisms need not be limited to paper applications; it is acceptable for all parties to strive to use good modern management practices and tools to support the CLIA effort. Computer formats of CMS forms and reports have been developed for State use. The CMS requirement for a minimum of specific records and reports is not intended to limit in any way SAs fiscal and administrative practices. Reasonable costs to facilitate the implementation of quality modern databases and information systems are to be available for CLIA funding. However, if a State's fiscal and administrative requirements are in excess of the CLIA-mandated requirements, then expenses for work done above and beyond that prescribed by CLIA is not normally to be borne by the laboratories nor the CLIA program. However, the State has the authority to charge those laboratories in their CLIA-exempt program according to any fee schedule they determine is appropriate. Federal surveys of a sample of the CLIA-exempt laboratories will be billed according to the Federal fee schedule in 42 CFR Part 493, Subpart F. SAs will not be paid for work done in excess of that prescribed by CLIA.

6410 - State Agency Responsibility for Staff Training and Development

(Rev. 1, 05-21-04)

6410.1 - Staff Training

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA is responsible for providing continuing education to employees. In conjunction with, and subject to, the approval of the Regional Training Administrator (RTA), SAs must have a procedure for identifying the training needs of the surveyors. That procedure must insure that SOM revisions, RO instructional letters, and the results of regular and Federal Monitoring Surveys (FMS) are included in the training agenda. Training may be provided in a variety of forms: in-service training; formal education; State, regional or national conferences; seminars or workshops. Costs for all courses and training must be within approved fiscal limitations.

6410.2 - In-Agency Training

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA must have its own program of staff development which responds to the needs of new employees for orientation and basic training, and to the needs of experienced employees for continuing development and education.

6410.3 - Outside-of-Agency Training

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In evaluating the appropriateness of any outside training activity for CLIA funding, SAs and the RO must consider the degree to which the trainees will benefit when carrying out the CLIA survey and certification program.

6412 - Role of the CMS RO With State Agency Program Administration

(Rev. 1, 05-21-04)

The RO is the CMS representative at the regional level for all CLIA survey and certification functions. The RO is responsible for:

- Reviewing and recommending action on each budget submittal;
- Furnishing program guidance and policy interpretation;

- Coordinating communications with the SA representatives, accredited providers, and laboratories on CLIA survey and certification activities; and

- Consulting on a regular basis with the SA, contractors or representatives for mutual assessment of program activities, achieving stated objectives, and establishing future goals.

Before approving each State budget submittal, the RO evaluates all information available and determines answers to the following questions:

- Is the plan of program activities appropriate to national CLIA annual and biennial goals?

- Do the workload and activity plans and staffing estimates properly place emphasis on fulfilling program goals?

- Does the budget request represent a consistent application and understanding of approved principles of reasonable cost to the SA's specific circumstances?

6414 - CLIA Budget - RO Procedures

(Rev. 1, 05-21-04)

6414.1 - General

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CLIA is a self-*funded* program. Fees from compliance determination and oversight covering all CLIA-related expense must be established and collected. There are no other funds available from any source to administer the program other than from those laboratories subject to CLIA requirements.

6414.2 - Regional Administrative Responsibilities

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The ROs have the primary responsibility for the efficient and effective administration of the CLIA program in the States in their respective regions. It is the RO's responsibility to:

- Issue the budget call letter to each State;

- Furnish the SA with administrative, budget and program guidance, policy interpretation, and leadership;

- Review, negotiate, and recommend action on each SA budget and subsequent quarterly expenditure reports;

- Coordinate communications relating to CLIA between the SAs and other CMS components;

- Consult with SAs to develop mutual agreement on the conduct of program activities, the achievement of stated objectives, and the establishment of future goals;

- Make determinations of allowable State costs submitted for Federal payment; and

- Control payment of funds to SA for costs incurred in administering CLIA.

Before approving each State budget submittal, the RO considers the following questions:

- How does the plan of program activities appropriately address the pertinent priorities and program emphases?

- Does the workload activity plan and the staffing estimate reflect the proper emphasis needed to fulfill the priorities listed in the budget call letter?

- *Has* the RO approved all appropriate reasonable costs that are peculiar to each SA's specific circumstances? If not, has the RO communicated this and a proper explanation to all concerned parties?

- Do all approved SA budgets reflect a consistent application and understanding of the programmatic, administrative, and fiscal principles and guidelines set forth in the SOM and the budget call letter?

6416 - Budget Call - RO Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Each fiscal year (usually the February or March preceding the new fiscal year) CO issues a budget call letter. This letter serves as official notification to begin the budget process with each State for the coming fiscal year. The call letter provides national program emphasis including the workloads to be accomplished during the next fiscal year and should be adhered to closely.

Upon receipt of the budget call letter, the RO prepares State call letters to inform the States of the national and regional goals and priorities for CLIA. Upon receipt of each State's proposed budget, *t*he RO records the date received. This is the actual beginning of the negotiated budget process between the SAs and *the RO*.

Each budget submission requires close attention and proper scrutiny. It is imperative that the RO manage the SA's CLIA activity, including budgets, aggressively for efficiency and productivity. Contracts and purchases planned by the SAs and approved by the RO, especially large purchases of computer hardware and software, must be guided by the latest Office of Management and Budget (OMB) circulars and CMS standards, policies, and guidelines. It is imperative that costs be contained and appropriately managed. Therefore, when the RO encounters any unusual plans or purchases, it assures that they are supported by adequate written justification and that the RO is convinced of the actual need to support efficiency and productivity.

It is important that the RO question and challenge unsupported spending levels, or **supported** requests that the RO does not feel are needed or the program cannot afford. Aggressive monitoring throughout the year can help to lower the cost of managing the CLIA program. Questions or problems the RO has regarding State budgets may be directed to the CO budget staff.

It is important that CLIA budget requests, funding requirements and expenditure reports be submitted separate from those for the Medicare and Medicaid programs. CLIA specific forms have been developed and must be used for CLIA program expenditures.

6418 - Regional Allocations

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CO provides State-specific budget allocations to the Regions . The allocations reflect both the needs and special priorities of each program workload, as well as national and regionally-specific priorities. The RO must be aware of and apply these constraints and priorities when negotiating the CLIA budget with the States and during the review and approval of subsequent quarterly expenditure reports. It is important that the required workload be accomplished within the approved budget. The RO should communicate significant problems or changes to the CO as soon as they are identified.

6420 - The SA Agency Annual Activity Plan

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In accordance with established yearly schedules, the SA completes the Form CMS-102, (Exhibit 116), and forward it to the RO. Include a description of planned program activities for the ensuing fiscal year and a Form CMS-105, "Planned Workload Report, Clinical Laboratory Improvement Amendments Program," (Exhibit 119). Working with SA and CMS CO, the RO assesses the amount of activity planned and the proposed cost to conduct the work by each State and helps to keep the costs in line for the nation as a whole. From this information and in discussions with the State and CO, the RO will be able to determine the adequacy and appropriateness of the programs planned by each State as they relate to the legislatively mandated goals and budget estimates. The information on the activity plan should agree with the State budget request.

6422 - Planning the Annual Workload - SA Procedures

(Rev. 1, 05-21-04)

The need for professional skills and additional personnel can only be ascertained after the workload is identified and a plan for accomplishing the work is outlined. Since the survey and certification program requires that laboratories be inspected within a biennial timeframe, the SA sets goals by categories of laboratory. The SA establishes schedules for surveys of the laboratories. The activity plan is to establish a program which permits survey and certification work to be done on an orderly basis throughout the year and with an even workload distribution over the 1- and 2-year cycle.

6424 - Elements in the Annual Activity Plan - Planned Workload Report - SA Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

For CLIA survey purposes, there are three types of certificates provided to laboratories. These include Certificates of Compliance, Certificates of Waiver (COWs) , and Certificates of Accreditation. For those holding a Certificate of Waiver, a survey may be conducted to investigate complaints. Also, a random sample of laboratories with a certificate of waiver is selected by CMS for validation surveys. Those holding a Certificate are inspected once every two years and are evaluated in accordance with Federal regulations. Complaint inspections may also be performed. Those holding a Certificate of Accreditation are randomly inspected at an administrative goal of five percent. The specific validation surveys are assigned by the RO. If complaints are received about any laboratory, a survey can be scheduled to investigate the complaint.

The workload to be reflected in the State CLIA workload plan is to include initial surveys, re-visits or contacts, follow-up visits, and complaint visits for the various schedules of laboratories. The narrative plan is to conform to and confirm the numerical counts planned. Form CMS-105 (Exhibit 119), is to be used in developing CLIA SA workload plans.

The Planned Workload Report lays out the SA Plan to conduct the surveys and other related activities for the fiscal year by laboratory schedule as it relates to workload volume and specialties. The SA identifies the estimated workloads and then translates them into narrative staffing and activity plans and project related costs.

6426 - Format for the Annual Activity Plan - SA Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA uses any format for presentation of the SA annual activity plan. The SA includes the topics essential to the RO's management and budget review that are:

a. A narrative explanation (as necessary) for significant figures included on the workload data sheet.

b. A plan for using professional staff in survey and certification activities when more than one surveyor is required:

- Division of responsibilities for survey;
- Deployment of teams in relation to specific areas of workload; and
- Geographic deployment.

c. A plan for meetings with appropriate special interest groups, e.g., informational and educational programs for Ombudsmen, consumer groups, State and county laboratory and medical societies, to discuss issues and concerns regarding CLIA implementation.

d. A list of CLIA activities delegated to personnel organizationally located outside the SA.

e. The names and health professions or specialties of currently qualified surveyors.

f. A description of the State's use of any laboratory testing or evaluation program in connection with CLIA activities.

g. An outline of program training planned for *the* staff:

- Staff training meetings;
- Formal courses attended;
- Seminars;
- In-service training programs; and
- Special problems of decentralized agencies.

6428 - Survey Team Composition and Workload Report-CMS-670 (Exhibit 74) - SA Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The Form CMS-670 *(Exhibit 74)* is intended to provide CMS with the work-power utilization information needed to determine the total number of hours spent on each type of CLIA laboratory survey-related activity. From this and combined with other CLIA cost information, CMS can compute the costs of performing the CLIA-related work and can compute the amount of money to be paid to a given SA to pay for the work performed. Laboratory surveyors, other State employees or contractors and others, including RO employees, involved in the CLIA-related processes must keep an accurate record of the number of hours spent working on a given laboratory's survey or similar CLIA activities. All payment to the State for survey work-power costs will be matched against the CMS-670 data. Once the Form CMS-670 data has been received, CMS computes the cost of survey-related activities and initiates any necessary action to create a bill for costs not already paid for by the laboratory.

REMINDER: Hours spent performing State required activities that are in excess of those activities mandated by CLIA are not billed to CLIA. The SA does not complete a Form CMS-670 for those hours.

The SA prepares the Form CMS-670 for *every* type of CLIA survey-related activity including:

- Initial surveys;
- Recertification surveys;
- Recontacts;
- Complaint surveys;
- Re-visits;
- Validation surveys;
- Sanction activities; and
- Hearings/appeals.

For the most part, the SA completes a Form CMS-670 after concluding all survey-related activities, including follow-up contacts and resolution of corrective action. The SA includes time spent on each activity and based upon employee records, beginning with

the pre-survey preparation time and ending with the closeout of the survey activities, on the Form CMS-670. (See Exhibit 74.)

Time spent by the RO staff conducting the oversight sample reviews of accredited and CLIA-exempt laboratories will be billed based upon the charges set forth in 42 CFR Part 493, Subpart F.

6430 - Basis for Determining CLIA-Related Costs - SA Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Public Law 100-578 mandates that the CLIA program be completely funded by the laboratories being regulated. The total cost of the work expended by all CLIA personnel, both Federal and State, is to be paid by the regulated laboratories. More specifically, each laboratory is to pay all costs incurred in regulating that laboratory, including the costs of survey, complaint investigation, hearings and appeals (if the SA and CMS are sustained) or other related CLIA outlays such as administrative and enforcement overhead.

There are circumstances in which the specific laboratory may not be specifically billed for the cost of the CLIA work-power expenditure, e.g., if a laboratory appeals an action and the ALJ sustains the laboratory or a settlement in favor of the laboratory is reached prior to the official hearing, the appeal-related work-power outlay (Federal and State) are entered on a CMS-670 *(Exhibit 74)*, but the laboratory is not billed directly for these expenses. The SA prepares a Form CMS-670 for the nonappeal-related work-power outlays and a separate Form CMS-670 is prepared for those work hours spent in preparation for the appeal, hearing and related expenses. In either case, the SA and CMS are paid for all CLIA work-power expenditures. The laboratory is billed for the survey-related costs that preceded the decision leading to the appeal, but not for the appeal costs.

If the SA and CMS are sustained in the ALJ hearing or the laboratory agrees to the findings or settles prior to the hearing in a SA/CMS favorable decision, the SA documents on the Form CMS-670 all costs related to the action, e.g., hearing preparation, documentation, staff preparation time including the time spent preparing the Form CMS-670. The laboratory is billed for those costs and the State is paid from the funds received. Unsubstantiated complaint costs are not be billed to the laboratory by CMS, but rather are paid from the administrative funds of CLIA. In such cases, the Form CMS-670 that the SA submits initiates payment. No bill goes to the laboratory.

As the SA schedules each laboratory survey, it maintains a record of the time spent in preparing for and conducting and closing out the survey, including the monitoring and recontacts involved in resolution and the preparation for an administrative hearing of a laboratory appeal. As each CLIA survey or support activity is performed, the SA records the time spent on the activity. Thus, any time spent preparing for a laboratory survey and time spent in follow-up contacts to ensure compliance are shown for all CLIA SA or RO personnel involved. Telephone discussions, report preparation, on-site visits and even

the time spent preparing the Form CMS-670, are chargeable work-power expenditures. The SA reports the total time consumed for each laboratory action in hours at the close of the action in a Form CMS-670, identifying the type of action that precipitated the work-power expenditure. CMS records and stores the data when received. CMS then multiplies the total hours reported by the dollar hourly rate computed for each State CLIA budget for that fiscal year. The computed dollar figure becomes the amount of the bill that is submitted to the laboratory involved in the specific CLIA action and which the SA claims payment.

Use the Form CMS-670 for reporting CLIA work-power expenses by both State and Federal oversight personnel. It is the mechanism for generating a laboratory bill and a State claim for payment for work-power expended.

6432 - Promotional and Public Informational Activities - SA Procedures

(Rev. 1, 05-21-04)

The §1864 agreement assigns significant responsibilities to the SA for conducting public information (PI) activities. Similar activities are carried out by CMS. The SA answers queries about CLIA when at all possible. CLIA queries are referred to the RO only if the information being requested is not available at the SA level or if it is clearly one that must be responded to by appropriate CMS authorities.

Certain other professional relations activities fall into the dual categories of public information and public relations. SA personnel are to develop and maintain ongoing relationships with members of the health professions and their organizations. The SA should encourage employees to participate as speakers, panelists, or consultants at meetings of professional organizations (laboratory or medical technologist associations, hospital associations, and medical societies) in the interest of furthering compliance with CLIA standards and objectives. These costs may be reasonable costs subject to CLIA funding.

6434 - The State Budget Request

(Rev. 1, 05-21-2004)

In the CLIA budget process, CMS' CO and RO staffs obtain input from the States and laboratories to develop the baseline data needed to formulate each State budget. This data is used to develop the CLIA workload estimates, expenditure, time parameters, and hourly rates. This is a negotiated process that starts with CMS' preparation of the Budget Call Letter. Input for the Budget Call Letter includes an estimated unit cost of each workload, time parameters, and a derived hourly dollar rate for the staff conducting agreed-to work.

The RO forwards the Budget Call Letter to the States which develop workload estimate and corresponding budgets by completing the Form CMS-102 (Exhibit 116); Form

CMS-105 (Exhibit 119); Form CMS-1465A, "State Agency Budget List Of Positions," (Exhibit 47); and CMS Form-1466 "State Agency Schedule For Equipment Purchases," (Exhibit 54). The completed Form CMS-102, Form CMS-105, Form CMS-1465A, and Form CMS-1466 and the narrative supporting documentation are forwarded to the RO which analyzes the data presented and works with the SA to assure that the workload estimates are accurate and reasonable for each *of* these workload*s*: Initial Surveys; Re-surveys, Follow-up Visit/Surveys, Complaint Surveys/Visits estimates. Once agreement on the workload estimates is achieved the number of Full Time Equivalent (FTE) employees is computed. Though the SA does not perform the oversight surveys for State-exempt laboratories, it is possible that SA may incur some related costs. If such costs do arise, it is important that they be identified to the RO so the RO can determine their appropriateness and advise the SA accordingly.

As the SA conducts CLIA work, the surveys are completed. The SA prepares the Form CMS-670 (Exhibit 74), to begin the laboratory billing and State payment processes. Each quarter the SA completes the Form CMS-102 detailing expenditures for the elapsed quarter and for the budget year to date. Analysis of this data will provide a complete status of revenues expended that can be compared to the total State approved budget. The SA should identify shortfalls and, if necessary prepare a Form CMS-102 and submit it for processing and approval.

Funds provided agencies as a result of the budget request are used only for necessary expenses and only for CLIA-related expenses. The SA may shift funds from one expenditure category to another, except equipment or laboratory surveyor training funds that may only be reprogrammed with prior approval.

6436 - State Budget Request, Clinical Laboratory Improvement Amendments Program, Form CMS-102 (Exhibit 116)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The budget request is a detailed estimate of CLIA survey program costs. The SA classifies such costs according to the category of the proposed expenditure. Explanations for the specific categories of expense are essential in both budget preparation and subsequent analysis. Therefore, the SA should make sure the budget request contains complete rationale regarding each line item. The detail in which these statements are developed makes possible a close estimate of financial needs and enables the RO to make more rational adjustments in the total operating budget. Line item justification consists of narrative statements providing specific rationale for budgetary needs.

The basis for estimating line item expenditures will be the number of laboratories the SA intend to survey in one year and the number of work hours needed. The SA includes in the estimates the number of surveys to be initiated due to complaints; for enforcement purposes, such as to verify the correction of action items identified during a prior survey; and follow-up contacts or discussions required to close out a survey-related workload item.

- **RO Assistance** - RO personnel are available to assist in preparing budget requests. The SA should consult with appropriate RO staff on any problem with the budget preparation process. Begin consultations as early as possible and submit the budget in accordance with the due date provided by the RO. Timely submissions help assure timely CMS completion of the budget approval process.

  The Form CMS-102 *(Exhibit 116)* is a multipurpose form designed to budget for and capture line item expenditures by State agencies for laboratory survey activity. The State agencies will complete and certify the Form CMS-102 prior to the start of each Fiscal Year as part of it's yearly budget submission. This data, when reviewed and approved by CMS regional and central offices, will serve as the approved state budget for the fiscal year.

- **Agency** - Insert the name of your State.

- **Region/State Code** - Insert the CMS Regional Office to which the State is assigned.

- **FY Quarter Ending** - Leave blank for initial budget submission; complete only when reporting actual expenditures.

- **Budget Period** - Insert the fiscal year for which the budget request is being made.

- **Request** - Indicate if the submission is a regular, i.e., whole year budget submission, or a supplemental budget request for additional funds for the remainder of the fiscal year.

Section A - Salaries

1 (a,b,c), 2, 3

The budget justification is to describe the type of staff being employed in the conduct of the CLIA workload, broken into the two categories, Professional (surveyor, non-surveyor, and supervisor) and Clerical. The SA estimates the number of staff years in full-time equivalents. This will provide the actual work years of personnel involved in the CLIA workload. Place the number of FTEs in column (a), and STAFF YEARS, and the yearly salary cost column in (b), AMOUNT. The SA adds the estimated staff years and the estimated yearly salaries and inserts those amounts in the respective column next to Total Salaries.

Section B – Other Direct Costs

4, 5 - Rate / Retirement Contributions and Fringe Benefits

Enters the computed rate and dollar value of retirement contributions and fringe benefits mandated by State/Federal law, Union/Management or Employee/Management agreements or other legally binding contracts/agreements. Explains the computation in the budget request narrative.

6 - Travel

Enters the estimated travel costs for CLIA personnel, including where appropriate, the per diem or the subsistence in lieu of per diem, applicable to the CLIA survey program. Derives estimated costs based on provisions of State law, regulation and administrative procedures applicable to travel of State employees. Indicate in the narrative budget justification an estimate of the expected number, type and extent of trips. For out-of-State travel, indicate the number of trips, purpose and basis for charges to the CLIA program. Include the basis for charges for all out-of-State travel other than to meetings arranged by CMS.

7 - Communications

Enters the estimated costs to be incurred for telephone services, including costs for teleconferences, mail (including express mail), special handling, postage and postage stamps, postage meters, insurance on mailed items, postage due-charges, FAX costs and other communication-related expenses. The narrative budget justification should also address any unusual requests, such as for mobile phones, modems and similar items.

8 - Office Supplies

Enters the estimated cost of office supplies to be used by CLIA personnel only. Include the costs of paper, pencils, pens, envelopes, clips, pencil sharpeners and other usual desk materials, file baskets, books and other required desk reference materials, photocopier supplies, FAX supplies, computer equipment-related supplies, and other reasonable CLIA-related supplies.

9 - Office Space

(See §§6524-6534.) Enters the costs of office space, considering possible variations, and describe as follows:

- **Agency in Identifiable Space**

Enters the costs of space that can be attributed to CLIA personnel use only. Analysis of the budget request and estimates must contain the following elements for each location:

- Total rental cost/pro rata cost of CLIA space;

- Square feet of space/CLIA-related square footage;
- Cost per square foot; and
- Services included in the rental.

The SA identifies, also, office space that is State-owned and includes it either separately or as part of the State's indirect cost rate.

- **Office Space - Agency in Shared Space** - Analysis of base period expenditures and the budget estimate must contain these elements:
    - Total cost of space to the agency;
    - Basis of proration;
    - Locations where CLIA staff are housed; and
    - Estimate of square feet allocated to all State programs and those used by CLIA personnel.

State-owned space should be identified as such.

- **Office Maintenance** - Includes in the budget estimate narrative, a breakout of the major items of expense, e.g., light, heat, janitorial service, machine repair. If office maintenance, in whole or in part, is included in the rental contract, the SA notes this fact. The SA need not separate the amount.

10 - Equipment

Enters the reasonable costs of equipment to support CLIA-specific positions such as desks, chairs, computers and computer-related equipment, file cabinets, tables, and other machines (FAX machines, photocopiers, etc.) necessary for CLIA operational, administrative or management needs. Equipment authorized in the present fiscal year, which will not be purchased by the end of the fiscal year, must be requested in the budget for the succeeding fiscal year if the SA still needs it. In addition to line item justification, the SA documents the budget estimate through the use of the Form CMS-1466 (Exhibit 54.)

11 - Training

The budget estimate should provide for the cost of training CLIA personnel. The SA uses the number of employees to be trained rather than FTE's when computing this figure and includes the cost of the courses to be taken, the cost of travel and per diem associated with training sessions. The narrative justification should indicate the types of courses to be taken by employee type and by number of employees to be trained.

12 - Consultants

Provides the estimated cost of consultants or those who are not State employees but who are used on a part-time, temporary, or fee-for-service basis to perform CLIA-related work.

13 - Subcontracts

Provides the estimated cost of subcontracts to be employed in the conduct of CLIA-related work. Subcontract costs attributable to CLIA survey activities are allowable and payable. The budget justification should provide in detail, the reasons for, and approximate cost of each separate subcontract.

14 - Miscellaneous

Provides the estimated cost of other items that have not been reported in any of the preceding classifications, breaking them into compatible groups of expenses (sections a, b, c, and d), if possible. The SA uses narrative justification to explain all proposed expenditures.

15 -Total Other Direct Costs

Enters the total of lines 4-14.

16 -Total Direct Costs

Enters the total of lines 1-15.

Section C – Indirect Costs (Approved Rate X Base)

17 and 18

Provides the rate negotiated and approved by the HHS Division of Cost Allocation for use during the fiscal year, together with the line item base it is applied against. Expenditures included in this category must not be duplicated under direct costs.

Section D – Total Budget Requested

19

Enters the sum total of lines 16 and 17.

Leave blank for initial budget submission. Data entry is only required when reporting actual expenditures during the fiscal year (amounts to be reported and non-cumulative, i.e., report only the current balance as of the quarter ending).

Section E – Hourly Rate Requested

Divides the Total Budget Requested by the Total Number of Staff Years and divide again by the Hours Available per Staff Year to derive Hourly Rate, as in the example.

Example:

Budget Amount..	..$100,000
Divided by Staff Years	2
Equals.	...$ 50,000 per Staff Year

$50,000 divided by 1,600 hours in the Staff Year Formula equals a $31.25 hourly rate.

6438 - Form CMS-105, Planned Workload Report - CLIA (Exhibit 119) - SA Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The Form CMS-105 *(Exhibit 119)* provides the State's estimate of the number of laboratory surveys it expects to perform in a budget period. The workload plan will list by laboratory type the number of surveys to be conducted in the Fiscal Year. (This form also accompanies the States quarterly and cumulative expenditure reports.)

The SA uses the Form CMS-105 only to estimate the laboratory survey workload under CLIA. The SA provides an estimate of the planned workload for each laboratory schedule. The laboratory schedule can be found in the CLIA user fee regulation.

A completed Form CMS-105 should accompany a Form CMS-102 *(Exhibit 116)* and an analytical budget justification narrative anytime a CLIA budget request or supplemental budget request is submitted to the RO. It is essential that the estimates of planned workloads be as accurate as possible. Accurate workload estimates can be developed from prior workload history, where one exists, and results in a more accurate and timely budget approval.

The SA:

Heading - Inserts State name and Federal fiscal year in the appropriate boxes.

Column (a), Number of Sites - In reviewing the workload plans for the year, determines the number of separate laboratory sites that will be visited for surveys, follow-up visits and complaints.

Column (b), Initial Visits - Enters the planned number of initial compliance determination surveys (laboratory surveys) to be conducted for each type of laboratory. (See 42 CFR 493.638ff for the schedule of laboratories and fees to be charged.) Include a five percent sample of those that hold a Certificate of Accreditation since a sample of those laboratories are to be inspected for compliance in accordance with the SA oversight role and responsibility.

Column (c), Resurvey Visits - Enters the total number of non-initial compliance surveys planned. This figure is to reflect the number of other than first time laboratory surveys to be conducted in a fiscal year.

Column (d), Follow-up Visits - Enters the number of follow-up surveys planned for the fiscal year. These are visits to verify compliance or to verify a completed plan of corrective action or for some other enforcement purpose. Prior history may indicate that a portion of all laboratories require actual follow-up visits as opposed to re-contact via telephone or mail to finalize the laboratory compliance survey report. Follow-up visits are not routinely required by CLIA.

Column (e), Complaint Visits - Enters the number of complaint surveys planned for the fiscal year.

Column (f), Total Visits - Provides the totals to column (f) and computes the totals at the bottom of the form. Signs and dates the form and submits it with the Form CMS-102.

6440 - Form CMS-1466, State Agency Schedule for Equipment Purchases (Exhibit 54) - SA Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Usage - This form has a 2-fold purpose: The SA uses it when requesting budget approval of equipment purchases, and completes and submits it to the RO when an actual purchase has been completed. The form is applicable for CLIA, LTC and non-LTC equipment requests and purchases. A separate form must be prepared for equipment purchase for each program. When equipment is actually purchased, the SA prepares and forwards a Form CMS-1466 *(Exhibit 54)* with the appropriate program's budget expenditure report.

The SA:

Heading - Inserts the official name of the agency and the State name in the designated spaces. Indicates the period for which equipment funds are requested. Indicates if this is accompanying a regular budget submission or a supplemental budget submission.

Column (a), Description of Equipment - Enters the items of equipment being requested or reported as purchased. Uses an asterisk or other notation to note items previously approved by the RO but which are being re-budgeted or requested again. On the bottom or reverse of the form explains why the purchase was not completed in the prior budget period.

Column (b), Number of Items on Hand - Lists the number of similar items on hand in the State CLIA survey unit at the time the form is prepared. If a new and different item is being shown, shows "None" in this column.

Columns (c) and (d), Number of Units (Additional-c) or (Replacement-d) - Lists the number of units being requested in the appropriate column, (c) or (d).

Column (e), Unit Cost - Enters the unit cost of each item in column (a).

Column (f), Gross Cost - Computes and enters the gross cost for each item in column (a) by multiplying the number of units in columns (c) or (d) by the unit cost, column (e).

Column (g), Trade in Value if Replacement Item - Computes and enters the trade-in-value of item identified in column (d) as a replacement for existing equipment.

Column (h), Net Cost - Enters the amount shown in column (f) for each item listed in column (a), less any amount shown in column (g).

Total Net Cost of Equipment - Enters the sum of all amounts shown in column (g) above. For CLIA, enters this amount on the Form CMS-102 *(Exhibit 116)*, item 6.

Date, Signature, Title - Dates and signs the Form CMS-1466. Shows the title of the individual signing the schedule.

6442 - Form CMS-1465A, State Agency Budget List of Positions, (Exhibit 47)

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Usage - The SA uses the Form CMS-1465A *(Exhibit 47)* for all program position approvals. Separate forms and approvals are required for each of the programs: Title XVIII NON-LTC, Title XVIII LTC, Title XIX and CLIA. The SA uses the most recently approved form or computer form format to assure proper information collection.

The SA:

Heading Information: Name of Agency - Inserts official name of the agency.

State - Enters name of State.

Fiscal Year - Enters the Federal period for which funds are being requested.

Position Title/Name - Lists each position type employed and the names of each employee actually occupying each position type. This will help the SA distinguish between the number of positions it has filled as opposed to the number allocated. Differences could mean substantially different approved budget levels. This information may prove useful when determining the number of employees that require training in a given discipline. Remember that individual employees are trained, not the number of full-time equivalents employees.

City Where Located - Provides this for all position types and employees. Monitors differences and changes in staffing levels by location.

No. of Pos. (Number of Positions) - After completing the Position Title/Name columnar entries for all positions, enters the number of actual allocations for each position, e.g., the actual number of employees occupying that position title.

Staff Years - Computes the actual number of staff-years by Position Title. Representations of full and part-time employees are no longer necessary. Rather, it is important to compute the number of work or staff years using the work hours employed by each Position Title. Includes anticipated overtime usage by all categories of positions in this computation.

Funds Required - For each Position Title, computes the budget dollars required by multiplying the total work years for each Position Title times (X) the total dollar figure computed for and relevant to that Position Title. Includes overtime in the calculations for all the positions listed.

If possible, the SA discerns from the Position Titles which are professional and which are clerical positions. If the SA cannot, do whatever is necessary to clarify and classify all positions accordingly. Once the SA has classified the positions into the two types, total the staff years and dollar amount for each of the two categories.

6444 - State Budget Request Submittal - Clinical Laboratory Improvement Amendments

(Rev. 1, 05-21-04)

6444.1 - List of Materials and Order of Assembly

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA assembles the budget documents in descending order, as follows:

- Form CMS-102, "Budget Request, Clinical Laboratory Improvement Amendments Program," (Exhibit 116);
- Form CMS-105, "Planned Workload Report, Clinical Laboratory Improvement Amendments Program," (Exhibit 119);
- Form CMS-1465A, "State Agency Budget List of Positions," (Exhibit 47);
- Form CMS-1466, "State Agency Schedule for Equipment Purchases," (Exhibit 54);
- State justification arranged in line item order; and
- Any exhibit referred to in the line item justification.

6444.2 - Routing and Number of Copies

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA forwards the proposed budget package (the original and one copy of each document) to the RO. The SA submits the budget in accordance with the due date provided by the RO but no later than July 30 preceding the Federal fiscal year to be funded. The deadline ensures that CMS can complete the budget approval process in time to prevent an interruption in cash flow when one fiscal year ends and the succeeding year begins.

Effective October 2002, State Agencies are required to use the automated Survey and Certification / CLIA reporting system to submit their final negotiated yearly budgets to the CMS regional offices. State Agency users will enter negotiated budget data into the various records and formats of the system. Once negotiations with the regional office are complete, the State certifying official will review the data, finalize the record, then certify the record, which will act as an electronic signature. The certifying official is the executive officer of the state agency charged with the duties of administering (or supervising the administration of) the CLIA program.

6446 - Developing Budget Approval - RO Procedures

(Rev. 1, 05-21-04)

6446.1 - Budget Request Package

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In response to the budget call letter, the RO receive a CLIA budget submittal from each SA using the automated Survey and Certification / CLIA Reporting System. The data is transmitted electronically, from State to RO, RO to CO. The automated copy of the data should be certified by the approved State certifying official using the approved "electronic signature" feature of the system. Each budget package should contain:

- Form CMS-102, "State Agency Budget Request, Clinical Laboratory Improvement Amendments Program," (Exhibit 116);
- Form CMS-105, "Planned Workload Report, Clinical Laboratory Improvement Amendments Program," (Exhibit 119);
- Form CMS-1466, "State Agency Schedule For Equipment Purchases," (Exhibit 47);
- Form CMS-1465A, "State Agency Budget List of Positions," (Exhibit 54); and
- The narrative budget plan that explains hiring, training plans, equipment purchases, budget exceptions, and variances or omissions in general. Documentation should be sufficient to support the budget plan. Narratives should be retained within the regional office and made available to CO only upon request.

6446.2 - Basis for Budget Approval

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

State budget proposals must be submitted to the region in accordance with the approved automated Survey and Certification / CLIA reporting system procedures. Regional offices may approve State budget submissions only after proper certification by the approved State certifying official. The RO approving official must obtain Central Office clearance prior to taking any approval action on a State budget request. RO approval schedules should be developed to ensure that budget approvals are completed on or prior to September 30 of the fiscal year to ensure that funding authority can be made available to the State prior to the start of the upcoming fiscal year. The basis for approving the line item budget is the number of facilities to be surveyed and the amount of staff and money

needed to survey them. The 1988 amendments to CLIA mandate that all laboratories be surveyed every two years. Thus, the budget plan should address itself to the basic question of how the SA will accomplish this goal. It is important that the RO evaluate the accomplishments of the past performance period to determine the goals that need to be set and accomplished for the next performance period. Budget constraints or unexpected revisions may *affect* hiring or any of the myriad of budget line items. Revised national and regional priorities may also impact upon workload plans and accomplishments, so the RO should be flexible and diplomatic in subsequent negotiations with the SA. The RO should not rely solely on written justification when approving a State's CLIA budget.

6446.3 - Line Item Negotiation and Approval

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The budget approval is a detailed concurrence or revision to State estimated survey program costs. The RO negotiates the budgets by line item, according to the category of the proposed expenditure. The approval process is between the RO and the SA. The RO should be able to explain any adjustments and the method used to compute each amount.

The RO should caution the State that funds provided agencies, as a result of the budget approval, must be used only for necessary expenses and that financial shortfalls may occur that would dictate reduction of budget allocations to each State after approval. This will reduce the potential for adverse consequences should there be a need to reduce expenditures.

6446.4 - Payable Reasonable Costs

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA is entitled to receive advances to and payment of all reasonable costs for performing the CLIA survey workload. CLIA funds cannot be used to pay the SA for any non-CLIA related expenses incurred. Though CLIA-dedicated support staff will better facilitate the computation of CLIA-related expenses for budgeting purposes, it is possible that shared staff, who are involved in supporting multiple programs, may be employed. Since CLIA will pay States only for CLIA-related expenses, proper proration of expenses is mandatory.

Reasonable costs include all necessary expenses in accordance with the standards and are described in the manual. Any class or kind of administrative expenditure that is properly chargeable to Federal CLIA funds under approved plans may be funded by CLIA revenues. SAs are expected to exercise due care in the expenditure of funds, understanding that the funds must be used only for CLIA-approved activities and procurement.

6446.5 - Projected Workload

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The projected workload, program emphases, the SA's hiring and training plans, and the experience of the 12-month preceding period, if appropriate, are the primary factors for the RO to consider when approving the line item budget. The RO uses these factors as a guide, negotiate the budget in a fashion that assures that national and regional goals are met. When the RO makes changes to the State's proposal, it provides the rationale for the proposed change. The RO rationale should include:

- The revised estimate;
- The rationale for the change; and
- The basis for computing the revised estimate.

6446.6 - CO Assistance

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CO personnel are available to assist with negotiating budget approvals. The RO may consult with CO staff on any issues that are troublesome. The RO should raise concerns or issues as early as possible in the budget process. Prompt consultation can minimize the impact of many problems.

How the SA establishes and maintains controls is less important than the fact that a control system is in place for the CLIA workload. A by-product of the control system should be management information that is useful in managing the pending workload. Thus, some ability to capture data about workloads scheduled, pending and completed by laboratory schedule and employee type (to the extent possible) should exist in whatever system or mechanism the SA chooses to use. Whatever form the controls take, it is important that documentation of actions involving the laboratories be retained in a retrievable format that allows for review of the data, if necessary. Individual laboratory case records should be permanent case records that are accessible for review and analysis at a later date. It is also essential that the RO maintain the laboratory action control records so that they can be readily accessed should the need arise. The RO uses established controls for following up on pending CLIA actions, scheduling surveys or complaint visits, PoC follow-up visits, and other CLIA-related activities.

6448 - RO State Agency Budget Review - Form CMS-102

(Rev. 1, 05-21-04)

A review of the line items in the Form CMS-102 (Exhibit 116) should reveal that they conform to the guidelines that follow. It is important that the RO obtain an explanation of all line items that contain no money amounts. Blanks or zeros in items such as office space, communications, and supplies or equipment should be explained in writing. If the cost for one or more line items is included in the indirect cost allocation rate reported on the form, it should be so stated and explained.

6450 - Employee Salaries and Wages - RO Procedures

(Rev. 1, 05-21-04)

6450.1 - Distribution of Staff Time for Program Purposes

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CLIA funds may be used to pay CLIA-only program expenditures. However, some personnel may be involved in multiple program activities. The RO should determine that a method for capturing the appropriate manpower split by program is developed when such time-sharing occurs. The proper pro-rata splits must be employed and documented to facilitate proper budget preparation, approval, and execution. Distribution of shared staff time to the appropriate separate program areas of State activity is required.

In the event staff are shared, the RO requests that periodic studies be conducted that will determine the proper prorate formula. A prorated portion of the cost of such studies, work sampling, data recording, and reporting is also a necessary and reasonable CLIA-related expense.

6450.2 - Determination of Necessary Staff

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The following method may be used by the SA to determine a proper split of costs for CLIA versus other State program administration costs:

- Determine the number of inspections and related manpower needed to fulfill the requirements of the CLIA laboratory inspection program; and

- Determine manpower requirements which are related to the requirements of other programs.

The ratio of countable CLIA activities to the sum total of the countable activities of all programs can be applied to the cost of the total multi-program activity.

Using this prorate method is acceptable when miscellaneous costs cannot be specifically identified as a CLIA or other program-specific expense. However, specific applications of this general principle will have to be developed jointly by the SA and the RO. This method permits adjustments for circumstances a particular agency may encounter. However, it is possible that such difficult to identify charges may already be accounted for in the indirect cost allocation rate and should not be included here. If the RO is in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, contact CO. They will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case. There are instances in which commonly-shared personnel, such as a typing pool, may be covered by agreement with the Department in the indirect cost allocation. If it were included in the Indirect Cost Allocation, inclusion in another line item would create double billing for this item. Since no two indirect cost allocation agreements are exactly the same, the RO should not presume that what goes for one SA goes for the others in its region.

All such SA proposals to use sampling or prorate formulas must be approved by the RO before charges can be made under them. The RO may conduct studies, or direct that the SA conduct them to verify results.

6452 - Retirement Contributions and Fringe Benefits - RO Procedures

(Rev. 1, 05-21-04)

Retirement and fringe benefits that are in accordance with State and Federal laws are acceptable as CLIA reimbursable expenses. It is possible that these charges may already be accounted for in the indirect cost allocation rate and should not be included here. If in doubt, the RO should contact CO. CO will contact the Office of Assistant Secretary for Management and Budget, HHS to determine if these costs should be included here.

6454 - Travel - RO Procedures

(Rev. 1, 05-21-04)

The cost of travel, including, where appropriate, per diem or subsistence, in lieu of per diem, may be charged to CLIA. The travel must be done in accordance with the State's laws, regulations, and administrative procedures applicable to travel by State employees.

6454.1 - CLIA Laboratory Survey and Administrative Travel

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Laboratory survey travel includes travel to and from a facility:

- To conduct laboratory inspections;
- For revisits or to verify PoCs;
- To perform laboratory complaint or oversight inspections; and
- For meetings with CMS personnel on CLIA-related activities.
- Administrative travel is defined as travel for management purposes related to the CLIA laboratory inspection program:
- To attend agency administrative staff meetings related to CLIA;
- To attend State CLIA program meetings or activities conducted or sponsored by CMS; and
- For planning or liaison visits to other agencies concerning certification.

Travel to participate in sanction meetings or negotiations or to appear before an ALJ in a hearing (to provide testimony or support for a sanction activity against an alleged non-compliant laboratory) may also be charged to CLIA.

6454.2 - Travel Involving Multiple Program Activities

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Travel expenses for an employee performing multiple program activities (Medicare/Medicaid and CLIA) for the State should be prorated in accordance with the distribution of direct personal service time spent on each program involved in and recorded for each trip. Alternatively, such trip records may be accumulated for an accounting period and prorated accordingly. For example, if at the end of the period such records showed that two-thirds of the employee's productive time while in travel status was devoted to the State survey and certification program, and one-third of the time was devoted to CLIA activities, then the agency would charge one-third of the total travel cost to CLIA (including transportation, per diem, etc.) and the other two-thirds to the other appropriate program funds.

6454.3 - Training and Conference Travel

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

This category of travel includes that travel which is not directly related to the line operations of surveying laboratories, consultation, and administration, as described above. Examples of travel performed are:

- Incident to orientation and basic training of new employees; and
- For meeting the needs of experienced employees for retraining.
- Also included is travel relating to:
- Conferences;
- Meetings;
- Training;
- Workshops; and
- Seminars if the agenda material is directly related to the laboratory survey functions of the agency.

Travel for such purposes may be funded by CLIA.

It is possible that some common travel charges may already be included for payment by the indirect cost allocation and should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect allocation rate, the RO should contact CO. They will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case.

6456 - Communications and Supplies - RO Procedures

(Rev. 1, 05-21-04)

6456.1 - Basis for Charges

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Communications and supplies should be direct CLIA charges if separable from other program costs and identifiable as to unit cost. These expenses may be charged on a prorata basis if used for multiple program purposes. For example, if long distance calls are routed through a switchboard or can otherwise be identified as to program, the CLIA

calls can be made a direct charge. Otherwise, all long distance charges should be prorated, using an identifiable and justifiable method or formula. It is neither equitable nor legal to charge the CLIA program for installation and rental of telephones used exclusively by other programmatic State staff. If CLIA and non-CLIA personnel share lines and telephones, payment must be on a prorata basis. The SA method of proration or the formula used must be included in their budget supporting documentation. Any blank or zero in this item must be explained. If it is included in the indirect cost allocation rate, it should be so stated.

6456.2 - Communications

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Such items as services including teleconferences (except such items as are payable on travel expense accounts), postage, postage meter charges, printed stamped envelopes, registry and special delivery or express mail fees, insurance charges on fourth class mail, or postage due charges for CLIA employees and CLIA-program related activities are chargeable to CLIA.

For services such as satellite training or conferences, the SA has been advised to contact the RO to determine if the expense is a reasonable expense. The RO weighs the facts on an individual basis when such an inquiry is received. If found to be reasonable and necessary, it may be incorporated in the CLIA-approved budget. Expenses that, in some instances, may be justifiable as reasonable are those for:

- *Cell* phones,
- Modems, and
- FAX machines and other communication related expenses.

If the RO concurs that the circumstances do indeed substantiate such an expense, the RO may include it in the approved budget computations. It is incumbent upon the SA to be in close consultation to assure that any planned unusual expenses are approved.

6456.3 - Supplies

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The items that follow are payable by CLIA if they are used to support CLIA personnel and CLIA-related activities:

- Such general office supplies as paper, pencils, folders, unstamped envelopes, clips, etc.;

- Non-consumable items such as staplers, pencil sharpeners, file baskets, books, electronic calculators and planners, computers not purchased as part of a major computer system, etc., which do not exceed Departmental and/or OMB dollar guidelines for cost-per-unit procurements;

- Printing or duplicating expenses and the cost of procuring forms such as printed or duplicated general office forms; and

- Costs of transportation or shipment of any of the above items.

The cost-per-unit above shall apply unless a different amount is specified by State law, in which case the amount so specified shall control. If purchases are co-mingled with other than CLIA program purchases of the same nature, documentation and justification of the expenses, on a prorata basis is necessary.

It is possible that some common communication and supply charges are included for payment in the indirect cost allocation agreement negotiated by the State or SA with HHS. If so, they should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, the RO should contact CO. They will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case.

6458 - Office Space - RO Procedures

(Rev. 1, 05-21-04)

6458.1 - Cost of Office Space

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The cost of office space for CLIA laboratory survey functions is a proper charge against CLIA funds. The rules governing all such rentals and leases are the same for CLIA as they are for all other CMS rentals and leases. These guidelines replicate those rules and guidelines. Such charges may take the form of:

- Rent, service, and maintenance cost in privately owned buildings;

- Monthly rental charges based on the cost of initial construction or purchase of publicly owned buildings; or

- Meeting the costs of service and maintenance in lieu of rent in publicly owned buildings.

In addition, charges may be made for repairs and alterations to either privately or publicly owned buildings. Payment usually should be made only for periods of

occupancy. If unusual situations arise and no precedent exists, the RO consults with CO before the RO approves the State request.

6458.2 - Standard of Comparable Rental

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Charges against CLIA funds for office space must follow other CMS guidelines and may not exceed the rental rate of comparable privately owned space in the same or similar locality. Because the rental rate of comparable privately owned space is not a fixed amount for any particular locality, the rental rates may vary within a locality as well as between localities. However, a realistic determination of the rental rate of comparable privately owned space must be made.

The basis and documentation for the establishment of the rental rate of comparable privately owned space should be kept on file in the SA. The RO may want to obtain a copy of the documentation in any precedent setting situation.

6458.3 - Privately Owned Space

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Charges against CLIA funds for privately owned space, including expenses of services and maintenance, repairs, and alterations, must not exceed the rental rate of equivalent space and facilities in the same or similar locality. (See §6286.)

6458.4 - Space in Publicly Owned Buildings

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The following standards apply to charges for office space in a publicly owned building:

- Actual Cost which is the amount charged for office space in a publicly owned building must not exceed actual costs over a long-run period. The SA is required to produce records of actual costs if the RO wishes to examine them; and

- 75% Rule which is the amount charged for office space in a publicly owned building may not exceed 75% of the lowest comparable rental for privately owned space unless there are special considerations justifying a greater charge. Use of this standard should be used only as an interim measure in the absence of actual cost data. This allows the SA to claim costs that are not in excess of 75% of the lowest cost of privately owned space. The SA is allowed to do this without prior review or approval by the RO.

When a monthly rental charge based on the cost of initial construction or purchase of publicly owned buildings exceeds 75% of lowest comparable rental for privately owned space or when the cost of service and maintenance in lieu of rent in publicly owned buildings exceeds 75%, the SA is required to obtain prior approval from your office. The RO may wish to consult with CO prior to granting approval for such expenditures.

It is possible that some common space charges are included for payment in the indirect cost allocation agreement negotiated by the State or SA with HHS. If so, they should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, the RO should contact CO. CO will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case.

6458.5 - Charges Based on Meeting Cost of Service and Maintenance

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When the total charges for service and maintenance in a publicly owned building exceed 75% of the lowest comparable rental for privately owned space, the SA must submit, prior to its claim, the following data for review and approval by CMS:

- Total useable floor space and the amount of space allocated to the CLIA laboratory inspection program personnel;
- Total costs of service and maintenance and the portion to be charged to CLIA funds;
- The elements of cost; and
- The rental cost of comparable privately owned space with at least three statements of appraisals.

6460 - Equipment - RO Procedures

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Form CMS-1466 *(Exhibit 54)* should be attached to the budget package the RO is reviewing. Purchases planned should conform to the latest CMS hardware and software acquisition guidelines. Documentation to support the proposed purchases should be complete. Reasonable purchases of equipment to support CLIA specific positions are permitted. Such purchases may include computer systems and computer-related equipment, office furniture and file cabinets, and other machines (Fax machines, photocopiers, etc.) necessary for CLIA operational, administrative, or management needs.

When the RO reviews the Form CMS-1466, it checks to see that the SA has included appropriate details and reasonable requirements. If purchasing new computer systems, peripherals, such as printers, being planned should appear on this form. If printers are not shown, the RO should question what the SA would use to print products. Software being purchased in conjunction with the hardware purchase would not be included on this form, but rather would show up as a miscellaneous item on the Form CMS-102 *(Exhibit 116)*. It is wise for the RO to review the software being considered. It should comply with CMS guidelines and software standards. Consultation with both the SA and CO may be necessary and is advisable if plans for unusual purchases are noted.

Equipment authorized in the present fiscal year that will not be purchased by the end of the fiscal year must be requested in the budget for the succeeding fiscal year if still needed by the SA. If hiring constraints are going to restrict staffing plans, it is advisable that the RO and the SA reevaluate the timing of planned equipment purchases. Planning equipment purchases sufficient to provide for those to be hired should be considered.

6462 -Training - RO Procedures

(Rev. 1, 05-21-04)

The budget request should provide for the cost of training CLIA personnel. The SA should use the number of employees to be trained, rather than full time equivalents (FTEs) when computing this figure. Included should be the cost of the courses to be taken, the cost of travel and per diem associated with training sessions. A narrative justification should indicate the types of courses to be taken by employee type and by number of employees to be trained.

It is possible that some training costs may have been included in the indirect cost allocation agreement negotiated by the State or SA with HHS. If so, they should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, the RO contacts CO. CO will contact the Office of Assistant Secretary for Management and Budget, HHS, where copies of the agreements are maintained, to determine if such is the case.

6464 - Consultants - RO Procedures

(Rev. 1, 05-21-04)

The SA should include the proposed cost of hiring consultants who are not State employees but who are used on a part-time, fee-for-service, or temporary basis to perform CLIA-related work.

6466 - Subcontracts - RO Procedures

(Rev. 1, 05-21-04)

The SA should include projected cost of subcontracts to be employed in the conduct of CLIA-related work. Subcontract costs attributable to CLIA survey activities are allowable and payable. The SA budget justification should provide the RO with the specific details, the reasons for, and approximate cost of each separate subcontract.

6468 - Miscellaneous - RO Procedures

(Rev. 1, 05-21-04)

Reported in these spaces should be any unusual budgeted items that have not been reported in any of the preceding classifications. To facilitate decision making, the SA should have attached to the budget package a narrative justification that explains all proposed expenditures. The RO should consult CO as necessary to resolve any questions.

6470 - Indirect Costs - RO Procedures

(Rev. 1, 05-21-04)

The indirect costs provided would be the rate negotiated and approved by the HHS Division of Cost Allocation for use during the fiscal year, together with the line item base it is applied against (approved rate x base). The Department negotiates these rates with States, SAs, or programs. The rate negotiated may be for a whole State or for each program or grant in a State. It is probable that no two rate formulas include the same provisions. It is important that CLIA not pay the SA for anything that the SA is going to be paid for by any other program or provision. Where doubt exists, the RO questions any budget item and assure that an investigation is initiated. If the SA is unfamiliar with what is included in the indirect cost allocation and cannot get clarification for the RO from their financial experts, the RO contacts CO. Provide as much detail as the RO can as early in the budget process as possible so that the Office of the Assistant Secretary for Management and Budget can be queried for an answer.

6472 - Hourly Rate Requested - RO Procedures

(Rev. 1, 05-21-04)

The dollar amount of the hourly rate of payment requested by the State is usually computed by dividing the total budget cost by the agreed upon number of available hours for actual survey-related activities.

6474 - Planned Workload Report - Form CMS-105 - RO Procedures

(Rev. 1, 05-21-04)

Form CMS-105 (Exhibit 119) provides the State's estimate of the number of laboratory surveys it expects to perform in the budget period. The workload plan will list by laboratory type (schedule) the number of surveys to be conducted in the fiscal year. The workload report should reveal in detail how the SA plans to do the work. The State is required to survey every laboratory that does not have a certificate of waiver, a certificate for PPM procedures, or is under Federal jurisdiction every two years. It is essential that the estimates of planned workloads be as accurate as possible and be at the levels mandated by national and regional goals. The RO will be able to determine the propriety of the workload plans by review of prior workload history, where they exist, and evaluation against regional and national goals. The workload plan submitted should be supported by the other parts of the budget plan. If it does not provide sufficient detail from which the RO can determine that the work paid for will be accomplished, the RO must obtain the needed information or clarification. Negotiate discrepancies to acceptable levels.

6476 - Schedule for Equipment Purchases - Form CMS-1466 - RO Procedures

(Rev. 1, 05-21-04)

6476.1 - Usage

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The Form CMS-1466 (Exhibit 54) serves two purposes: it is used when requesting initial budget approval of equipment purchases and is completed and submitted to the RO when an actual purchase has been completed. When equipment is actually purchased, the State should prepare and forward a revised Form CMS-1466 with the quarterly expenditure report, Form CMS-102 *(Exhibit 116)*.

6476.2 - Completion of the Form

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Name of Agency - The official name of the agency and the State will be inserted automatically when the State selects the type of form and the period for which equipment funds are requested.

Column (a), Description of Equipment - Entered here are the items of equipment being requested or reported as purchased. Items previously approved but which are being rebudgeted should be included and noted by the SA. The State submission for approval

will include supporting comments on the bottom or reverse of the form. It should also explain why a purchase was not completed in the prior budget period, if such is the case. If this justification is missing, the RO obtains the justification from the SA.

Column (b), No. of items on hand - The number of similar items on hand (in the SA's inventory) at the time the form was prepared should be listed. SA equipment planning for one program should not be co-mingled with those of another. If sharing is taking place, the equipment costs should be prorated.

If this purchase represents a new and different item, "None" should be shown in this column.

Columns (c) and (d), Number of Units (Additional) or (Replacement) - The number of units approved by the SA should be listed. Are these to be replacement units or additional units? Is employee sharing of equipment done currently? Is equipment sharing a realistic and manageable option? Do not arbitrarily dismiss such options as viable alternatives to one-for-one equipment purchases.

Column (e), Unit Cost - The unit cost for each item listed in column (a) should be entered here.

Column (f), Gross Cost - The SA computes and enters the gross cost for each item in column (a) by multiplying the number of units in columns (c) and/or (d) by the unit cost, column (e). Column c + column d (x) column e = gross cost, column (f).

Column (g), Net Cost - Shown here should be a summarized total amount for each item listed in column (a). This may be the same figure as that shown in column (f). If there are reductions that should be applied to the gross cost, thus increasing or lowering the net cost, the reduction should be explained and the proper Net Cost should be entered in column (g).

Total Net Cost of Equipment - This is the sum of all amounts shown in column (g) above. The SA should have entered this amount on the CMS-102, item 9. If the RO approves this amount, it enters the figure on the CMS-104 *(Exhibit 7)*, item 6, column (c).

Date, Signature, Title - The form must be dated and signed by the SA. The title of the individual signing the schedule should be shown.

6478 - Preparation of List of Positions - Form CMS-1465A - RO Procedures

(Rev. 1, 05-21-04)

6478.1 - Usage

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Form CMS-1465A (Exhibit 47) is to be used for all program position approvals. Separate forms and approvals are required for each of the following programs:

- Title XVIII NON-LTC;
- Title XVIII LTC;
- Title XIX; and
- CLIA.

It is important that the SA use the most recently approved form to assure proper information collection.

6478.2 - Form Completion

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Name of Agency - The official name of the agency and the State will be inserted automatically when the State selects the type of form and the period.

Fiscal Year - The SA enters the period for which funds are being requested.

Position Title/Name - The State should list each position type employed and the names of each employee actually occupying each position type. This will help the RO distinguish between the number of positions the SA has filled as opposed to the number they have allocated. Differences could mean substantially different approved budget levels. This information may prove especially useful when determining the number of employees that require training in a given discipline. Remember to count the number of employees who require training, not the number of FTEs.

City Where Located - This must be provided for all position types and employees. This will help the RO monitor differences and changes in staffing levels by location and may prove to be a source of information about the existence of multiple locations that may have larger program implications.

Number of Positions - After completing the position title/name columnar entries for all positions, the SA should enter the number of actual number of employees occupying that position title.

Staff Years - The State should have computed the actual number of FTEs by position title. Representations of full and part-time employees are no longer necessary. Rather, it is important to compute the number of work or staff years using the work hours employed by each position title. Overtime usage anticipated by all categories of positions should be included in this computation.

Funds Required - For each position title, the SA computes the budget dollars required by multiplying the total FTEs for each position title times the total dollar figure computed for and relevant to that position title and includes overtime in the calculations for all the positions listed.

The RO should be able to discern from the position titles, which are professional and which are clerical positions. If the RO cannot, it should do whatever is necessary to clarify and classify all positions accordingly. Once the RO has classified the positions into the two types, the RO may wish to total the staff years and dollar amounts for each of the two categories. If needed, the RO may transfer the totals to the appropriate lines of the Form CMS-102 *(Exhibit 116)*.

6480 - Line Item Approval for Personal Services - RO Procedures

(Rev. 1, 05-21-04)

In negotiating budgets, it is advisable to set a limit on the number of full-time equivalents chargeable to the CLIA program budget. With limits in place, a SA cannot exceed the approved full-time staff levels without prior consultation and authorization. This will enable the RO to monitor all discipline staffing, especially the actual number of on-board surveyors, and allow the RO to better analyze State requests and requirements for additional support staff.

6482 - Need for Additional Funds - RO Procedures

(Rev. 1, 05-21-04)

SAs should periodically check their current rate of expenditure. If it appears that expenditures may exceed the budget approved or the current allotment, the SAs should consult with the RO as soon as possible.

6482.1 - Adjustment in Quarterly Allotments

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

During the first three-quarters of the fiscal year (October - June), if the agency concludes that expenditures will exceed the current allotment, an information statement should be submitted to the RO. This statement should explain in which line items the SA believes additional funds will be needed and give the agency's reason for this conclusion. SAs may request an adjustment in the quarterly allotment schedule to make additional funds available at this time. A supplemental budget should be submitted when it appears funds will be exhausted before close of the fourth quarter of the fiscal year.

6482.2 - Supplemental Budgets

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

At the beginning of July each year, SAs should review their fiscal requirements for the balance of the fiscal year. If at this time it appears that additional funds will be required, the SA should submit a supplemental budget. The supplemental budget should be completed for the full fiscal year and include a statement concerning the anticipated expenditures in each category and the net additional amount needed. The supplemental request should be prepared on the same form(s) and in the same number of copies as a regular budget request. Supporting information comparable to the kind found on regular requests should accompany the supplemental budget.

Even though no supplemental budget is submitted at the time of the July review, SAs should continue to check their expenditure rate for the balance of the fiscal year. An end of year reconciliation and balancing of accounts will occur between CMS and each State. Actual expenses data will then be used by CMS as a basis for setting future fee schedules for the participating laboratories.

6484 - Need for Additional CLIA Funds - SA Procedures

(Rev. 1, 05-21-04)

Periodically, the SA should check its current rate of expenditure. If it appears that expenditures may exceed the budget approved or the current allotment, it should consult with the RO. The SA should take full advantage of line-item flexibility (see §6434) before concluding that additional funds are needed.

6484.1 - Adjustment in Quarterly Allotments

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

During the first three-quarters of the fiscal year (October - June), if the SA concludes that expenditures will exceed the current allotment, it submits an informational statement to the RO. This statement should explain in which line-items the SA believes additional funds are needed and give its reason(s) for this conclusion. The SA requests an adjustment in the quarterly allotment schedule to make additional funds available at this time and submits a supplemental budget when it appears funds will be exhausted before the close of the fourth quarter of the fiscal year.

6484.2 - Supplemental Budgets

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

At the beginning of July of each year, the SA reviews its fiscal requirements for the balance of the fiscal year. If at this time it appears that additional funds are required, the SA submits a supplemental budget that should be completed for the full fiscal year, and include a statement explaining the anticipated shortfall for each category and the net additional amount needed. The SA prepares the supplemental request on the same form(s) and in the same number of copies as a regular budget request and includes supporting information comparable to the kind found on regular requests.

Even though no supplemental budget may need to be submitted at the time of the July review, the SA continues to check its expenditure rate for the balance of the fiscal year.

6486 - State Agency Accounts and Reporting

(Rev. 1, 05-21-04)

The SA ensures that all estimates and reports of expenditures and other reports are prepared in accordance with appropriate budgetary and accounting methods and administrative practices adopted by the Secretary.

It is CMS' desire and intent to accept State practice in the manner in which funds received from the Federal government are handled and accounted for, and in a State's choice of a depository, subject to the general accountability required under Section C, Fiscal, of the agreement. However, funds advanced to a State must be identifiable on a State's records. Establishing a separate account usually does this. The Fiscal and Reports Sections, along with instructions established by CMS for receiving advances of funds and submitting reports, have been drafted with a view to following State patterns to the fullest extent possible.

6488 - Support for Expenditures - SA Procedures

(Rev. 1, 05-21-04)

The SA must provide, through SA accounting and statistical records, support for all expenditures incurred in connection with survey and certification activities. No particular kind of accounting record, method or procedure is required. The State's accounting records and supporting documents must permit verification by Federal fiscal audit and CMS administrative review of all charges, together with the status of the advances made to the State.

If the SA is receiving grants-in-aid administered by HHS in connection with its regular program, it uses the accounting and procurement methods and procedures described in SA approved plan for such grant-in-aid programs. The SA is responsible for securing the necessary data from local or district offices, and assuring the validity of all data used for budgetary and other purposes.

6490 - Certificate of Authority - SA Procedures

(Rev. 1, 05-21-04)

A certificate is placed on file with CMS stating the official title of the State person authorized to submit an estimate of funds, to certify fiscal documents and to represent the SA in fiscal matters.

The SA forwards two copies of the certificate to the RO. If the authority passes to a new office, or the scope of the authorization is changed, the SA submits a new certificate.

6492 - Cash Basis - SA Procedures

(Rev. 1, 05-21-04)

The method of financial reporting recommended is the "cash basis." Thus, the data is based upon "cash accounting" which requires that charges against CMS CLIA funds be entered on SA records when formal vouchers, electronic transactions or other documents that may initiate payment are prepared.

6494 - Limit on Expenditures - SA Procedures

(Rev. 1, 05-21-04)

The total amount approved in the SA annual budget shall be the limit on expenditures for the fiscal year.

6496 - Periodic Analysis of Accounts - SA Procedures

(Rev. 1, 05-21-04)

Since total expenditures for a fiscal year may not exceed the amount approved for that period, the SA reviews the status of accounts at least once each month. This allows the SA to observe expenditure trends as they occur and helps the SA to avoid both over-expenditure of funds and over-accumulation of large amounts of unliquidated obligations. It also provides early identification of any need for supplemental funds.

6498 - Cash Balances and Expenditure Authority - SA Procedures

(Rev. 1, 05-21-04)

Unexpended funds on hand at the end of each quarter are available for expenditure in the succeeding quarter without formal reallotment. However, this is NOT applicable if the succeeding quarter is in a new fiscal year - no new obligations may be incurred after the last day (September 30) of the fiscal year**.** This provision applies to all funds on hand whether they were received in a CMS advance or from other sources. Formal reallotment is not a prerequisite for expenditure of any funds on hand.

6500 - Unliquidated Obligations - SA Procedures

(Rev. 1, 05-21-04)

Fiscal controls should provide current information on unliquidated obligations. For purposes of CMS financial reporting, unliquidated obligations are defined as bills received, but not yet prepared for transmission to the State fiscal officer for payment, or obligations incurred for which there is acceptable evidence of a commitment or promise to pay for goods, facilities, or services in any category of expenditure, whether or not the goods or services have been received or a bill rendered. Examples of unliquidated obligations are:

- Equipment which had been ordered, but not paid for (whether or not received); and

- Items charged on a semi-annual or annual basis. For example, for an item charged for an annual basis, the unliquidated obligation reported for the first quarter in the year would represent one quarter of the estimated annual charge. The unliquidated obligation reported in the second quarter would represent one-half of the estimated annual charge. Should the obligation not be paid off at the expected time, the SA continues to report the accumulated amount due.

6502 - Nothing to Report on a Given Line - SA Procedures

(Rev. 1, 05-21-04)

If there is nothing to report on a given line, the SA should so indicate by the use of a dash (-) or a zero (0).

6504 - SA Forwarding Materials to the RO

(Rev. 1, 05-21-04)

The RO may request that the SA forward documentation to the RO supporting the SA laboratory survey-related activities. If required to do so, the SA retains a copy of the materials for SA records and sends the original to the RO. Copies of all material must be legible and must contain the appropriate signatures.

6506 - State Agency Files Used for Case Control and Reporting

(Rev. 1, 05-21-04)

The RO may also need more specific information about some aspect of SA CLIA operations, or may need other special tabulations and reports concerning an area of program activity. RO may need:

- The number of applications pending for various lengths of time;
- Laboratory survey schedules; and
- The progress made through consultation with a facility.

The SA may use this additional data for SA own purposes as well. All such data is to be readily available from SA records.

Many States are employing their own unique filing system and finding improved methods of control and ways of incorporating additional data such as licensure information, details on the improvements in the quality of service through consultative efforts. The SA may use any technique as long as it affords a positive control over pending cases and provides for adequate tallying and documentation of certification activities. The data extracted from the system for RO reports is rudimentary and easily tallied. Therefore, the case control system probably does not warrant employing data processing equipment. In some cases, the SA already use data storage and retrieval equipment, so it would actually be less expensive and simpler to employ existing equipment than to use a manual case control system.

6508 - SA Establishment of Case Controls

(Rev. 1, 05-21-04)

It is of utmost importance that the SA initiate and maintain proper workload controls. A good workload control system helps to encourage good management practices. Though this section uses the word "system" to describe a mechanism that can help track workload pending and accomplishments, it does not arbitrarily categorize such as a computer-based control system. A simple manual case control system may be something as unsophisticated as a card system that can be used to track the progress of each CLIA workload. Most States already have control systems in place which track other programmatic (survey) workloads. Many are quite sophisticated and computerized. Similar mechanisms may be adapted to CLIA or new more responsive systems may need to be designed to accommodate the CLIA workload. The type of physical system used is less important than the actual capture of the basic information needed to establish and maintain management control over the workload. The SA should make sure any control system considered, whether manual or automated, is able to facilitate the establishment, update and storage of the basic control data. It must also provide the controls that allow for management of pending workloads, laboratories to be surveyed, resurveyed, and hearings pending. Data retention capability should be for a minimum of three years.

6510 - Payment by Electronic Transfer of Funds - SA Procedures

(Rev. 1, 05-21-04)

All State agencies with an approved budget will be paid by electronic transfer of funds through the use of DHHS, Division of Federal Assistance Financing's Payment Management System known as SMARTLINK II. The SMARTLINK II User's Manual (Exhibit 121) details the equipment the SA need to implement the system, provides guidelines for maintaining security to the system and explains how the SA request payment using the system. It also provides the information the SA need about installing the DHHS-supplied KERMIT communications package and other system specific procedures.

6512 - State Expense Reporting

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CLIA requires that certification fees be sufficient to cover the costs of implementing and administering this oversight program. There are no exceptions. Funds to run the program come from billing laboratories for all costs related to administering all aspects of the CLIA program, including payment of all Federal and State CLIA-related program expenditures. The SA is entitled to receive advances to and payment of all "reasonable costs" for performing CLIA-related work, including the cost of the personnel required to perform the CLIA-related work. CLIA funds cannot be used to pay the SA for any non-

CLIA-related expenses incurred. To administer the CLIA program, it is probable that each SA will employ CLIA dedicated staff. CLIA laboratory compliance surveys will be performed by CLIA approved and dedicated surveyors. Though CLIA dedicated support staff will better facilitate the computation of CLIA related expenses for budgeting purposes, it is possible that shared staff involved in supporting multiple programs may be employed. CLIA will pay States only for CLIA-related expenses, so proper proration of expenses is mandatory.

"Reasonable costs" include all necessary expenses that are in accord with these standards and within the limits of the approved SA CLIA budget. CLIA revenues will fund any class or kind of administrative expenditure that is properly chargeable to Federal CLIA funds under plans approved by the DHHS. Allowable costs are further defined in OMB Circular A-87, "Cost Principles for State and Local Governments," (Exhibit 122). The SA should exercise due care in the expenditure of funds, understanding that the funds must be used only for CLIA-approved activities and procurement. The completed Form CMS-102 (Exhibit 116), is to accompany the Form CMS-105 (Exhibit 119), and the budget plan and documentation, as a budget request package that is forwarded to the RO in response to the yearly Budget Call Letter. The Form CMS-102 line items are addressed in general and specifically in the following procedures.

States are required to submit their quarterly expenditure reports, via the automated reporting system, to their respective regional offices no later than 45 days following the end of each fiscal quarter. Final adjustments, when necessary, to quarterly expenditure reports are due to the region no later than 60 days following the end of each fiscal year. Regional offices will approve both quarterly as well as year end final adjustments to quarterly expenditure reports within 15 days following submission of reports by the State.

6514 - Employee Salaries and Wages - the Distribution of Staff Time for Program Purposes - SA Procedures

(Rev. 1, 05-21-04)

CLIA funds are to be used only to pay CLIA program expenditures. However, it is recognized that some personnel may be involved in multiple program activities. Though the magnitude and scope of the CLIA program is such that time-sharing may not occur or even be readily possible, it may by necessity, occur. Thus, an important administrative goal must be to assure that a method for capturing the appropriate work-power split by program is developed, when such time-sharing occurs. The SA should employ the approved methods for determining the proper pro-rata splits and document them to facilitate budget preparation, approval, and execution. It is necessary for the SA to distribute shared staff time to the appropriate separate program areas of State activity.

In the event staff is shared and a cost proration is necessary to determine the related costs for each program, a prorated portion of the cost of such studies, work sampling, data

recording, and reporting is a necessary CLIA-related expense. Studies determined necessary or requested by the RO are a necessary and reasonable CLIA expense.

6516 - Determination of Necessary Staff - SA Procedures

(Rev. 1, 05-21-04)

The SA may use the following method to determine a proper split of costs for CLIA versus other State program administration costs. The SA should determine the number of surveys that are planned for each program and determine the amount of staff needed for CLIA surveys and survey-related activity. Workload plans should fulfill the specific requirements of the CLIA laboratory survey program. The SA determines commonly shared staff and estimates the staff requirements for each program. The ratio of countable CLIA activities to the sum total of the countable activities of all programs can be applied to the cost of the total multi-program activity. Using the ratio derived is acceptable when miscellaneous costs cannot be specifically identified as a CLIA or other program-specific expense. However, the SA should develop specific applications of this general principle jointly with the RO, to allow for circumstances a particular agency may encounter, and ensure the comparability of such activities between programs. Such tools for deriving SA staffing estimates must be approved by the RO before charges for payment can be made. Studies may be conducted to verify the comparability of the activities or to validate the proposed formula for adjustments made in charging expenses to CLIA.

6518 - Retirement Contributions and Fringe Benefits - SA Procedures

(Rev. 1, 05-21-04)

Retirement benefits and fringe benefits that are reasonable costs and in accordance with State and Federal laws are acceptable and payable under CLIA.

6520 - Travel - SA Procedures

(Rev. 1, 05-21-04)

The cost of travel, including, where appropriate, per diem, or subsistence in lieu of per diem, is charged to CLIA in accordance with provisions of State law, regulations, and administrative procedure applicable to travel of State employees.

6520.1 - CLIA Laboratory Survey and Administrative Travel

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Laboratory survey travel includes travel to a facility:

- To conduct laboratory surveys;
- For re-visits or recontacts with a facility about compliance action items, or plans of actions;
- To perform laboratory complaint or oversight surveys; and
- For meetings with CMS personnel on CLIA-related activities.

Administrative travel is defined as travel within the State:

- For management purposes related to the CLIA laboratory survey program;
- To attend agency administrative staff meetings related to CLIA;
- To attend State CLIA program meetings or activities conducted or sponsored by CMS; and
- For planning or liaison visits to other agencies having to do with certification.

Travel to participate in sanction meetings or negotiations, or to appear before an ALJ in a Hearing (to provide testimony or support for a sanction activity against an alleged non-compliant laboratory) may also be charged to CLIA.

6520.2 - Travel Involving Multiple Program Activities

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Travel expenses for an employee performing multiple program activities (Medicare/Medicaid and CLIA) for the State is to be prorated on the basis of direct personal service based upon time spent on each program involved in and recorded for each trip. Alternatively, such trip records may be accumulated for an accounting period and prorated accordingly. For example, if at the end of the period records showed that 2/3 of the employee's productive time while in travel status was devoted to the Medicare/Medicaid survey and certification program, and 1/3 of the time devoted to CLIA activities, then the agency would charge 1/3 of the total travel cost to CLIA (including transportation, per diem) and the other 2/3 to the Medicare/Medicaid survey and certification program funds.

6520.3 - Training and Conference Travel

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

This category includes travel not directly related to the line operations of inspecting laboratories, consultation, and administration, as described above. Examples are travel performed (1) Incident to orientation and basic training of new employees in areas appropriate to SA activities in the laboratory survey and certification program; and (2) For meeting the needs of experienced employees for retraining. Also included is travel relating to conferences, meetings, training institutes, workshops, and seminars if the agenda material is directly related to the laboratory survey functions of the agency. Travel for such purposes may be funded by CLIA.

6522 - Communications and Supplies - SA Procedures

(Rev. 1, 05-21-04)

6522.1 - Communications

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Telephone services chargeable to CLIA include:

- Teleconferences;
- Postage;
- Postage meter charges;
- Printed stamped envelopes;
- Registry and special delivery or express mail fees;
- Insurance charges on fourth class mail; or
- Postage due charges incurred by CLIA employees and for CLIA program-related activities.

For services such as satellite training or conferences, contact the RO to determine if the expense is a "reasonable" expense that is payable in accordance with the CLIA-approved budget. Expenses for *cell* phones, modems, FAX machines and other communication-related expenses may, in some instances, be justifiable, and, thus, chargeable to CLIA in accordance with the previously approved budget. The SA should consult with the RO to assure payment.

6522.2 - Supplies

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The following items are chargeable to CLIA if they are used to support CLIA personnel and CLIA-related activities:

- General office supplies such as paper, pencils, folders, unstamped envelopes, clips;
- Non-consumable supplies such as staplers, pencil sharpeners, file baskets, books, which do not exceed a $50 per unit cost;
- Printing and duplicating expense and the cost of procuring forms such as printed or duplicated general office forms; and
- Costs of transportation or shipment of any of the above items.

The $50 unit cost for non-consumable items shall apply unless state law specifies a different amount, in which case the amount so specified shall control. If purchases are commingled with other than CLIA program purchases of the same nature, the SA documents and justifies the expenses on a prorated basis.

6522.3 - Basis for Charges

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Communications and supplies should be direct CLIA charges if separable from other program costs and identifiable as to unit cost. The SA charges these expenses on a prorated basis if used for multiple program purposes. For example, if long distance calls are routed through a switchboard or can otherwise be identified as to program, the CLIA calls can be made a direct charge. Otherwise, all long distance charges are to be prorated, using an identifiable and justifiable method or formula. It would not be equitable to charge the CLIA program for installation and rental of telephones used exclusively by other State staff. If CLIA and non-CLIA personnel share lines and telephones, payment is computed on a pro-rata basis. If an employee is engaged in multiple program activities, including CLIA-related activities, CLIA is to be billed only on a prorated share basis. The SA includes the documentation of the method of proration or the formula used.

6524 - Office Space - SA Procedures

(Rev. 1, 05-21-04)

The cost of office space essential for CLIA laboratory survey functions is a proper charge against CLIA funds. The rules governing all such rentals and leases are the same for CLIA as they are for all other CMS rentals and leases. These guidelines replicate those rules and guidelines. Such charges may take the form of:

- Rent, service, and maintenance cost in privately-owned buildings;
- Monthly rental charges based on the cost of initial construction or purchase of publicly-owned buildings; and
- Meeting the costs of service and maintenance in lieu of rent in publicly-owned buildings.

In addition, charges may be made for repairs and alterations to either privately or publicly-owned buildings. Payment will be made only for periods of occupancy unless approval is received from CMS for payment for periods of nonoccupancy.

Charges against CLIA funds for office space must follow other CMS guidelines and thus, may not exceed the rental rate of comparable privately-owned space in the same or similar locality. Although the rental rate of comparable privately owned space is not a fixed amount for any particular locality, and the rental rates may vary within a locality as well as between localities, it is expected that a realistic determination of the rental rate of comparable privately-owned space be made. The basis and documentation for establishing the rental rate of comparable privately-owned space is to be kept on file.

6526 - Privately-Owned Space - SA Procedures

(Rev. 1, 05-21-04)

Charges against CLIA funds for privately-owned space, including expenses of services and maintenance, repairs, and alterations, must not exceed the rental rate of equivalent space and facilities in the same or similar locality.

In negotiating a lease for privately-owned space, the SA includes cancellation or conditional clauses in rental agreements. The following guides are applicable with respect to the rental of space in privately-owned buildings when renewing an existing lease or when obtaining new or additional space under a lease:

6526.1 - Cancellation Clause

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When executing or renewing leases, the SA should make every effort to include a reasonable right of cancellation (30 days, if possible) in favor of the State, if such right can be included in light of rental rates, probable permanency of occupancy, and other pertinent factors. The SA should attempt to secure a cancellation clause in all rental agreements covering space for more than 1 year.

6526.2 - Lease Not Exceeding One Year

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When the SA is unsuccessful in securing a cancellation clause, it should make an attempt to secure leases not to exceed one year's duration, if possible, with an annual renewal option for an extended period, such as three years or longer.

6526.3 - Consulting the RO

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Where neither of the above is possible, the SA consults the RO at least 30 days in advance of the date the lease is to be signed.

6528 - Space in Publicly-Owned Buildings - SA Procedures

(Rev. 1, 05-21-04)

The following standards apply to charges for office space in a publicly-owned building:

6528.1 - Actual Cost

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The amount charged for office space in a publicly-owned building must not exceed actual costs over a long-run period. The SA is required to produce records of actual costs for examination as necessary. The SA will:

- Not include the cost of land as part of the cost of initial construction or the purchase of publicly-owned buildings in deriving the rental charges. This exclusion is based on the fact that land has no actual physical depreciation. The State would always have the land as an asset long after the building had become obsolete or been demolished, and value could be realized.

- Establish the estimated useful life of the building if depreciation is included as an element of cost. In case the building is vacated before the end of its useful life, adjust past claims for amortization to a reasonable depreciation basis.

6528.2 - Cost After Building Amortization

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

After the initial cost of a building has been amortized, the SA charges only the costs of service and maintenance.

6528.3 - 75 Percent Rule

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The amount charged for office space in a publicly-owned building may not exceed 75 percent of the lowest comparable rental for privately-owned space unless there are special considerations justifying a greater charge. The use of this standard as an expedient interim measure in the absence of actual cost data, enables the SA to claim costs that are not in excess of 75 percent of the lowest cost of privately-owned space without prior review or approval by the RO.

6528.4 - Ratio of Charge-to-Rental Rates in Privately-Owned Space

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Experience gained in analyzing the elements of rental rates in privately-owned space shows that approximately 75 percent of the rate represents the expense of service, maintenance, and depreciation. The portion in excess of 75 percent of the rental rate of comparable privately-owned space generally represents taxes and profit on investment that would ordinarily accrue. Therefore, whenever a charge is made for space in a publicly-owned building that is not in excess of 75 percent of the lowest cost of comparable privately-owned space in the same or similar locality, the SA assumes that such charge is reasonably related to the expense of service, maintenance, and depreciation. The SA verifies the reasonable relationship of such charges to actual costs over a long-run period. When a monthly rental charge based on the cost of initial construction or purchase of publicly-owned buildings exceeds 75 percent of lowest comparable rental for privately-owned space or when the cost of service and maintenance in lieu of rent in publicly-owned buildings exceeds 75 percent, the SA obtains prior approval from CMS.

6528.5 - Charge Based on Cost of Initial Construction or Purchase

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When rental charges are based on costs of initial construction or purchase of a publicly-owned building and such charges exceed 75 percent of the lowest comparable rent for privately-owned space, the SA submits justification for review and approval by CMS prior to acquisition or occupancy of the space.

6528.6 - Charges Based on Meeting the Cost of Service and Maintenance

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When the total charges for service and maintenance in a publicly-owned building exceed 75 percent of the lowest comparable rental for privately-owned space, prior to the SA's claim, the SA submits the following data for review and approval by CMS:

- Total useable floor space and the amount of space allocated to the CLIA laboratory survey program personnel;
- Total costs of service and maintenance and the portion to be charged to CLIA funds;
- The elements of cost; and
- The rental cost of comparable privately owned space, with at least three statements of appraisals.

6530 - Repairs and Alterations - SA Procedures

(Rev. 1, 05-21-04)

Charges may be made for repairs and alterations in privately or publicly-owned space necessary to the maintenance of proper facilities for efficient administration of the State survey unit.

6530.1 - Maintenance Repairs

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA includes maintenance repairs such as painting, repairs to plaster, patching roofs and minor repairs to doors, elevators and electrical equipment in the rate for service and maintenance.

6530.2 - Major Repairs and Replacements

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Major repairs and replacements, such as structural changes in buildings, new roofs, and new heating systems may be amortized over a period of years provided the total cost for space on an annual basis does not exceed lowest comparable rental, or in the case of publicly-owned buildings, 75 percent of the lowest comparable rental for privately-owned space. If the cost is amortized, the repairs and alterations must be of a permanent nature. Repairs and alterations that remain the property of the agency are usually classified as moveable equipment.

6530.3 - Alterations

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Normally, quarters completely adequate for the SA should be obtainable from the lessor, and the cost of necessary alterations would be borne by the landlord. However, where the landlord is unwilling to bear the cost of necessary alterations, CMS funds can be authorized to meet the cost of alterations provided the proposed alterations are needed for better utilization of the space, and the improvements are not obligations of the lessor under the terms of the lease. In some situations, lessors will not agree to make necessary alterations but will offer space at a relatively low rental rate. In such cases, the SA should try to negotiate an arrangement under which the lessor would make necessary alterations and the SA would amortize the cost by an increase in rent for a stipulated length of time. Before agreeing to an arrangement providing for repair or alteration, the SA should secure approval from the RO.

6532 - Identifiable (Direct) Costs - SA Procedures

(Rev. 1, 05-21-04)

When locating program personnel in extra identifiable space, the SA charges CLIA for the cost of such space.

Where SA CLIA program personnel share space with the SA regular personnel, the SA apportions the cost of such space between the programs. The apportionment is based upon the SA proration plan and must be approved by CMS. The method approved will apply only to rental fees paid for locations where SA program personnel share occupancy. The SA should re-evaluate the basis for prorating rental costs when changes in physical facilities or other conditions may result in inequitable cost sharing.

The SA submits the SA's rental cost apportionment plan each year as part of the budget documentation. Approval of the budget constitutes approval of the plan of apportionment.

6534 - Office Maintenance - SA Procedures

(Rev. 1, 05-21-04)

6534.1 - Definition

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Office maintenance includes services such as light, heat, time clock and water service, towel and janitor service, and machine repair service prorated on the same basis as rent, provided such services are not already included in rental costs.

6534.2 - Basis for Charges

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

If associated office maintenance costs, in whole or in part, are included in the SA's rental contract, the SA does not separate them; however, it notes their inclusion. The SA charges maintenance costs that are not included in rentals on the same basis as rental costs.

6536 - Equipment - SA Procedures

(Rev. 1, 05-21-04)

6536.1 - Definition and Quality of Office Equipment

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Items which are of a non-expendable nature, i.e., they have a life expectancy of one year or more and a probable resale, salvage, or trade-in value, are classified as office equipment if they have a unit cost in excess of 50 dollars. However, if State law specifies a different amount, the amount so specified shall apply. The quality of items should not exceed the quality of similar office equipment in general use in other SA offices.

6536.2 - Title to and Accountability

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Title to and accountability for office equipment purchased for State survey program purposes, or for shared use with other State or Federal programs, shall rest with the State. However, the purchase price(s) of individual pieces of office equipment may be shared with other State or Federal programs. Where the costs of equipment are prorated between Medicare and other programs such as CLIA, the SA should use the same proration in crediting residual value to the Medicare, or CLIA program for all disposed

equipment. Where Medicare-only, CLIA-only, or Medicaid-only funds are used to fully fund equipment, the SA credits 100 percent of the residual value to the appropriate funding program, either Medicare, Medicaid or CLIA, but not all.

6536.3 - Purchase of Equipment

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6536.3.1- State Practice

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA follows established State law or regulations for procurement of equipment for the State survey program.

6536.3.2 - Purchases Related to Budget Process

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Funds for equipment purchases are to be requested by State agencies and approved by CMS as part of the budget process. The SA should try to predict SA equipment needs during pre-budget planning, and request all needed equipment in the budget submittal. To estimate equipment needs, the SA determines the condition of equipment on hand and the appropriateness of the equipment for the tasks to be performed. The SA should also consider proposed staffing increases in SA budget projections.

The total expended for equipment during the budget period cannot exceed the total funds allocated for equipment for that period without prior approval of the RO.

6536.3.3 - Items Deleted by CMS

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

After reviewing an agency's estimate for equipment, CMS may delete an item or restrict the purchase of an item. If upon review of the CMS deletions, the SA want to resubmit the request it should do so. The SA submits the request with added supporting information. However, until the restriction is removed, the item cannot be purchased with Federal funds.

6536.3.4 - Purchase of Items Not Included in Budget Submittal

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Although the SA is expected to anticipate the bulk of its equipment needs, the SA may occasionally find a need for equipment that was not included in its budget submittal. The

SA must secure approval of the RO before purchasing such items of equipment. However, if sufficient uncommitted funds are available, the SA may purchase items not included in the budget approval without prior RO approval when the unit cost of the item is 50 dollars or less, and the item is of a kind approved in any previous budget period, e.g., tables, chairs, and coat racks. The SA lists such items and identifies them in the equipment schedule submitted at the end of the quarter in which purchased.

6536.3.5 - Reporting Equipment

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA maintains an inventory of equipment, following usual State inventory practices, and makes an annual physical count of equipment items for comparison against the inventory records. In the event of equipment loss or substantial damages due to theft or fire, the SA submits a statement concerning such losses to the RO as soon as possible.

6536.4 - Rental of Equipment

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Situations may occur where it will be advisable to rent certain office equipment instead of purchasing it. The rental of office equipment is allowable if it is not contrary to State law or regulations. Expenditures for equipment rental are considered "necessary" if:

- The rental is for a short period of time;
- The equipment is not available for purchase (leased telephone lines, electrostatic photocopy machines, etc.); or
- It can be shown that renting rather than purchasing an item of equipment is advantageous in terms of cost.

Secure prior approval from the RO if the SA wishes to rent equipment for more than 90 days.

6538 - Retirement and Social Security - SA Procedures

(Rev. 1, 05-21-04)

6538.1 - Retirement Contributions

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Retirement contributions include SA cost (not employees' share) of contributions to retirement funds such as State retirement or social security.

6538.2 - Prorating Costs

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Where SA prorate personal services costs of State survey personnel, it prorates the retirement costs for these personnel.

6540 - Other Expenses - SA Procedures

(Rev. 1, 05-21-04)

"Other" expenses include expenditures that can be properly charged to the State survey program, but have not been provided for in any of the preceding classifications. Examples of such items are discussed below by category.

6542 - Consultants - SA Procedures

(Rev. 1, 05-21-04)

Consultant services are generally defined as being furnished by persons who are not State employees, but who will be used on a part-time, temporary, or fee-for-service basis to provide needed skills to the State survey program.

6544 - Training of State Agency Personnel - SA Procedures

(Rev. 1, 05-21-04)

The reasonable costs of training personnel engaged in CLIA survey and related activities are chargeable to the CLIA program when the training is related to its responsibility for survey, certification and related enforcement activities.

Training may include attendance at job-related meetings, conferences, seminars, workshops, and satellite training conferences or training courses. Training is to be related to SA CLIA-related responsibilities. Examples of professional meetings for which attendance may be justified and funded, subject to prior RO approval are periodic and annual meetings of regional or national laboratory and medical technologist professional societies and organizations such as, but not limited to, the American

Society of Clinical Pathologists (ASCP), the American Society of Medical Technologists (ASMT), American Clinical Laboratory Association (ACLA), American Society for Cytotechnology (ASC), College of American Pathologists (CAP), and the Clinical Laboratory Management Association (CLMA).

6544.1 - Funding

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CMS will fund the entire cost of approved training of all employees. Funding for SA training is subject to the following considerations:

- Out-of-State attendance must be in accord with established State rules and regulations.

  NOTE: When Federal requirements mandate that the training is necessary, SA travel policy for out-of-State travel is not an excuse for non-participation in the Federal training.

- Federal funds may not be used to attend any meetings or events if the attendee is paid by the sponsoring organization to attend or to speak or render other services in connection with the meeting.

- Attendance will not significantly impair work activities.

6544.2 - Requesting Approval

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Funds for conferences and short-term training activity is normally requested, in advance, in the annual budget submittal. The SA submits any training that has not received prior CMS approval in the approved budget, in advance, to the RO for approval. Approval is to be on a case-by-case basis.

At the SA's request, CMS will include a dollar authorization for short-term training activity over and above the cost of attendance at CMS-sponsored meetings within the funds approved for each fiscal year. This authorization covers travel, per diem, admission fees, and any other costs related to attendance at the meetings.

If the SA believes it necessary to exceed the allotment, see §6546. The SA can make expenditures for short-term training activities without consulting the RO for specific authorization provided the following conditions are met:

- No single meeting is attended for more than 5 working days;

- The proposed attendees are State CLIA employees who regularly perform CLIA-related functions;

- The training is related to your CLIA-related responsibilities;

- The SAs do not charge a higher percentage of the cost of the CLIA-related portion than is appropriate. The appropriate portion attributable to Medicare/Medicaid or other programs is to be charged to those programs;

- A Form CMS-102 (Exhibit 116) is submitted as a supplemental budget request, in advance, if the event was not previously approved in the budget process. If the employee entered on duty during that quarter or later, the SA charges the percentage applicable to the employee in the budget approval; and

- Ensures that there is adequate documentation of every expenditure, following State practice, for subsequent audit.

Where one or more of the preceding conditions are not met with respect to any particular meeting, the SA furnishes detailed justification well in advance of the planned training/event date.

The authorization of funds for short-term training is in addition to the cost of attending any meetings called by CMS. The SA should consult with the RO for budget information about proposed CMS meetings as part of the process of preparing the budget submittal.

6544.3 - Justification for Attendance

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Where it is necessary to furnish detailed justification for attendance at short-term meetings, either in the original budget or later on in the fiscal year to the RO, (because, for example, the criteria in subsection B above are not met or the allotment is exhausted), the SA provides the following information:

- Name, position and title of each person proposed for attendance;

- A list of previous out-of-State training meetings attended by each proposed attendee during the current fiscal year (other than CMS-sponsored meetings) which were charged to Federal funds;
- An itemized listing of proposed expenditures for attendance, including travel, per diem, and admission fees; and

- Name, location, and dates of the meeting and a copy of the course announcement or bulletin, if available. Also, the SA submits a copy of the agenda or a list of the subject matter on the agenda and the name and address of the sponsoring organization. Where the description of the subject matter does not clearly establish that it relates to CLIA responsibilities, the SA provides an explanation of how the subject matter relates to CLIA responsibilities.

6544.4 - Fiscal and Reporting Considerations - the Amount Requested for Travel Costs of Such Activity

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA shows the total amount approved on the Form CMS-104 (Exhibit 118) for the CLIA program (the *"State Agency Budget Expenditure Report"*, Form CMS-435 *(Exhibit 45)* for the Medicare and Medicaid programs).

The SA does not break down the amounts expended for specific meetings, conferences or events. However, the SA maintains detailed records of all expenditures for audit purposes.

6544.5 - Educational and Training Leave

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Educational leave is leave granted for specialized professional or technical study in an accredited educational institution. Training leave is leave granted to an employee for attendance at short-term courses that will run longer than five working days, outside the agency. Approval of educational or training leave can only be granted if it is for purposes related to carrying out CLIA responsibilities. Additionally, State rules, regulations and practice must permit the taking of leave for such purposes. The SA obtains approval of training or educational leave, in advance, from the RO. Such proposals are evaluated individually and specific circumstances and special problems are given proper consideration. The SA includes the following in its requests:

- Employee's name, type of appointment held, position and grade (salary), length of service with the SA, previous experience and education;
- Description of any other specialized training or courses taken by the employee within the previous 24 months;
- Name and location of training institution;
- Title and description of training in sufficient detail to demonstrate its scope, content, and how it relates to CLIA responsibilities. A copy of the training course announcement may help to fulfill this requirement;
- A statement indicating how this training will benefit the employee's work and improve the agency's activity;
- The training period showing the number of days and hours the employee will be absent from duty;

- A statement from the supervisor dealing with the ability of the unit to forego the services of the trainee during the training period; and

- The cost of tuition, fees, and books in detail. A copy of the training course announcement may help to fulfill this requirement.

6544.6 - Agreements by Employees to Continue on the Job

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In order to discourage resignation of an employee for whom there has been a considerable expenditure for formal training, some States require the employee to sign an agreement that she/he will remain on the job for a certain length of time (e.g., six months) after completing the training. If State regulation or practice provide for such agreements, the SA has the selected employee sign such an agreement after having obtained CMS approval for the activity.

6546 - Miscellaneous - SA Procedure

(Rev. 1, 05-21-04)

Items illustrative of this category, for example, are:

- Bonding and public liability;

- Equipment rental;

- SA cost (not employee's share) of workmen's compensation;

- Group insurance;

- Unemployment insurance; and

- Proportionate share of merit system of civil service charges.

Multi-program pro ration of costs always applies.

6546.1 - Bonding

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Where a new bond or an amendment to an existing bond is required in relation to receiving and handling CLIA funds, the cost of the bond, when borne by the State, or the additional cost attributable to an amended bond, is a proper charge.

6546.2 - Public Liability

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

An appropriate share of the cost to protect against financial responsibility for injury to person or property is properly charged to CMS when such expenses are in the form of premiums for public liability or property damage insurance. The cost of awards, judgments, or settlements arising from injury to person or property are not chargeable to CMS.

The share of public liability and property damage insurance costs properly chargeable to CMS, in the case of motor pool or personally-owned vehicles used in the discharge of SA official business, is proportionate to that share of all travel of personnel of the agency which is devoted to activities directly concerned with the CLIA program.

The other items mentioned above may be prorated or charged directly as appropriate. If prorated, the method of prorating should be appropriate and acceptable to the State and to CMS. Thus, the costs of workmen's compensation, group insurance, or unemployment insurance would usually be charged directly for employees whose salary costs are prorated in the same ratio as the salary costs.

6548 - Goods, Facilities, Services From Other Staff or Local Agencies

(Rev. 1, 05-21-04)

6548.1 - Definition

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The definitions of the terms "goods," "facilities," and "services" and the criteria for application of the standards are those in effect for SA grant-in-aid relationship with the Department of Health and Human Services. Additional definitions are covered within the Federal Acquisition Regulations (subpart 31.6, "Contract with State, Local, and Federally Recognized Indian Tribal Governments") and OMB Circular No. A-87, "Cost Principles for State and Local Governments."

6548.2 - Centralized State Services

(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In some States services of an administrative nature (including certain commodities) such as accounting, printing, civil service, or central purchasing are furnished to various operating agencies of the State by specialized service departments outside the health department or other agency having an agreement or State plan with DHHS under §§1864 or 1903 of the Act. The SA allocates an equitable part of such charge to the State CLIA

program if the services are necessary and are ones from which the program derives a benefit similar to that accruing to other units of the agency, and provided:

- The pro-rata charge to the CLIA program does not include costs attributable to the general expense of State government in carrying out the coordinating, fiscal, and administrative functions of government;

- The charge is based on reasonable cost; and

- The costs are extra, identifiable, and readily ascertainable either by segregation or as a prorated share of the cost of such facilities or services.

The SA describes the basis of the service agency's charge, including the method of proration and the services provided and submits it for prior approval. The SA identifies such costs separately in the CLIA budget submittal.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R35SOM	04/18/2008	Revisions to Chapter 6 - “Special Procedures for Laboratories	04/18/2008	N/A
R01SOM	05/21/2004	Initial Issuance of Pub 100-07	N/A	N/A