State Operations Manual

Chapter 6 - Special Procedures for Laboratories

Table of Contents
(Rev. 230, Issued: 07-11-25)

Transmittals for Chapter 6

Program Background and Actions Related to Certification

State Agency and *CMS* Roles and Relationships with other Federal Agencies

Proficiency Testing

The Survey Process

Sample Validation Surveys of Accredited Laboratories

Sample Validation Surveys of *State Laboratory Licensure Program*

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

6226 - Simultaneous Validation Surveys - General

- 6226.1 - Simultaneous Validation Survey - Definition
- 6226.2 - Purpose
- 6226.3 - Relationship to Comparative Validation Surveys
- 6226.5 – Team Size

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

- 6227.1 - Importance of Coordinating Pre-Survey Arrangements
- 6227.2 – Surveyor Responsibilities
- 6227.3 - Pre-Survey Arrangements for Accredited Laboratories
  - 6227.3.1 - Coordinating With Accreditation Organization (AO) Contact Person
  - 6227.3.2 - Arrangements With Laboratory
  - 6227.3.3 - *Coordinating With Accreditation Organization Inspector*
- 6227.4 - Pre-Survey Arrangements for *State Laboratory Licensure Program*

6228 - Onsite Activities - Simultaneous Validation Surveys

- 6228.1 – Entrance Conference
- 6228.2 – Fact-Gathering
- 6228.3 - Pre-Exit Discussion
- 6228.4 – Exit Conference

Other Activities

6230 - CLIA State Agency Performance Review (SAPR)

6232 - CLIA Federal Monitoring Survey (FMS) - *Identification of the Number and Type*

6234 - *Performance of* FMS *on CLIA Surveyors*

- 6234.1 - Definition
- 6234.2 - Purpose
- 6234.*3* - *CLIA*-FMS *Types*
- 6234.4 - *SA Responsibilities for Survey*

6236 - CLIA-FMS Procedures

- 6236.1 - *Pre-FMS Procedure* - Scheduling of Surveys
- 6236.2 - *FMS Assessment Survey Activities*
- 6236.3 - *Post FMS Procedures - Survey Findings*
- *6236.4 - Feedback and Documentation of the FMS to the SA Surveyor and the SA Supervisor*
- *6236.5 - FMS Assessment Follow Up by the SA and CMS Surveyor*

Adverse Actions

6312 - Adverse Hearing Decisions by Administrative Law Judge (ALJ)
6314 - Readmission to CLIA Program
6316 - Laboratory Registry
6318 - Freedom of Information Act (FOIA)

Budget and Administration

6400 - The CLIA Federal/State Relationship
6402 - Federal Administrative Responsibilities
6404 - Nature and Source of Payments to States
    6404.1 - Funds for Clinical Laboratory Improvement Act Related Activities
    6404.2 - Laboratory Remitted Funds
6406 - State Agency Administrative Responsibilities
6408 - State Agency Responsibility for Records and Reports
6410 - State Agency Responsibility for Staff Training and Development
    6410.1 – Staff Training
    6410.2 - In-Agency Training
    6410.3 - Outside-of-Agency Training
6412 - Role of the CMS RO With State Agency Program Administration
6414 - CLIA Budget - *CMS* Procedures
    6414.1 - General
    6414.2 - *CMS* Administrative Responsibilities
6416 - Budget Call *Letter – Annual Budget Process*
6418 - Budget Awards
6420 - *The SA Budget Request*
    6420.1 - Form CMS-102, "Clinical Laboratory Improvement Amendments Program Budget/Expenditure Report"
    6420.2 - Form CMS-105, "Clinical Laboratory Improvement Amendments Program Accomplished/Planned Workload Report"
    6420.3 - Form 1465A, "State Agency Budget List of Positions for the Clinical Laboratory Improvement Amendments Program"
    6420.4 - Form 1466, "State Agency Schedule for Equipment Purchases for the Clinical Laboratory Improvement Amendments Program"
    6420.5 - Annual Activity Plan
6422 - *The SA Quarterly Expenditure Reports*
    6422.1 - Form CMS-102, "Clinical Laboratory Improvement Amendments Program Budget/Expenditure Report"
    6422.2 - Form CMS-105, "Clinical Laboratory Improvement Amendments Program Accomplished/Planned Workload Report"
    6422.3 - Form CMS-1466, "State Agency Schedule for Equipment Purchases for the Clinical Laboratory Improvement Amendments Program"

Program Background and Actions Related to Certification

6000 - Background

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, amended §353 of the Public Health Service Act *(PHSA)* (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. Except as provided at 42 CFR 493.3, entities that meet the definition of a laboratory at 42 CFR 493.2 must 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 licensed or approved in accordance with State requirements if located in a State with a CMS approved State laboratory licensure program.

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 located in and licensed or approved 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients;

- 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.

- 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; (See *section* 6010.1.2.1)

- Laboratories located in and licensed or approved by a State with a CMS-approved State laboratory licensure program (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 substance use disorder testing (such as for alcohol and/or drugs) solely for employment purposes (such as disciplinary, administrative, or legal action).

NOTE: Any entity (including any facility or component of a facility) performing substance use disorder testing (including drug or alcohol testing and/or screening) where the test results may be used for the purpose of offering, referring or making available treatment to the individual, must obtain an appropriate CLIA certificate and meet the applicable CLIA standards or cease testing.

If a laboratory is performing testing subject to CLIA and does not obtain the appropriate certificate, it is in violation of §353 *of the PHSA* and subject to specified penalties. Such cases or suspected cases should be forwarded to *CMS* for referral to the *Office of the Inspector General (*OIG*)*. (See *section* 6036)

6006 - Application and Certificate Process

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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, *section* 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; generating fee coupons; collecting certificate and inspection fees; and entering application and fee data into the CLIA database. A CMS contractor issues the CLIA certificate through the *Quality, Certification and Oversight Reports (QCOR).*

6006.1 – Certificate of Registration

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A Certificate of Registration is issued initially to any laboratory that applies for a Certificate of Compliance or Certificate of Accreditation and pays appropriate registration fee(s). A Registration Certificate is valid for no more than a period of two years. When a laboratory applies for a Certificate of Compliance, the Certificate of Registration only indicates 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 an inspection 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 Department of 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, the Certificate of Registration indicates only that the laboratory is registered with CMS. It permits the laboratory to operate until CMS receives verification of accreditation approval. Laboratories must provide CMS with proof of accreditation by an approved accreditation program within 11 months of issuance of the Certificate of Registration.

When a laboratory has been granted accreditation, a confirmation checkmark is entered into the CLIA *D*ata *S*ystem by the approving *accreditation organization (*AO*)* along with the AO inspection date and inspection specialties information.

6006.2 – Certificate of Waiver

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A Certificate of Waiver (CoW) is issued to a laboratory that performs only tests categorized as waived tests and pays the appropriate fee. Waived tests are those that have been determined to be so simple that if performed incorrectly will pose no risk of harm. The initial list of tests approved for CoW status are listed at 42 CFR 493.15, however, the list has been extended and can be viewed at accessdata.fda.gov.

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. *Laboratories with a CoW may be subject to a complaint investigation by State Agency (SA) surveyors or CMS.*

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

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A Certificate for Provider-performed Microscopy (PPM) procedures is issued to a laboratory in which a *licensed* physician, midlevel practitioner, or dentist 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 during a patient's visit. A certificate for PPM procedures 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. The laboratory that holds a PPM certificate is subject to quality system requirements for nonwaived tests. However, such a laboratory is not routinely inspected but may be included in an inspection sample of non-waived laboratories or a complaint *investigation by SA surveyors or CMS*.

6006.4 – Certificate of Compliance

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A Certificate of Compliance is issued to a laboratory after an inspection finds the laboratory to be in compliance with all applicable requirements. The certificate will reflect the effective date for each approved specialty/subspecialty. A Certificate of Compliance may also be reissued to a laboratory that has one or more *c*ondition-level deficiencies that do not pose immediate jeopardy (see *section* 6262).

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

6006.5 – Certificate of Accreditation

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A Certificate of Accreditation is issued to a laboratory after the accrediting organization certifies the laboratory according to its certification requirements. The Certificate of

Accreditation 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 loss of accreditation status.

In the event of a *c*ondition-level noncompliance determination as a result of a random sample validation or complaint survey, a laboratory with a Certificate of Accreditation is subject to a full review by CMS or its designee. A Certificate of Accreditation may be issued to an accredited laboratory that is out of compliance at the *c*ondition-level provided a credible Allegation of Compliance (AoC) is received by CMS or its designee, and the non-compliance does not constitute immediate jeopardy, even if a hearing is pending.

6006.6 – Effective Dates

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The effective date of the initial Certificate for PPM procedures, Certificate of Registration, or a Certificate of Waiver for new laboratories is the date the CLIA application, Form CMS-116 (Exhibit 125) is entered into the CLIA *D*ata *S*ystem.

The effective date of the Certificate of Compliance is the date the laboratory is surveyed and found in compliance with the CLIA requirements.

The effective date of the Certificate of Accreditation 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Laboratories applying for a Certificate *for* 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. 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 an accredited institution, evidence of Continuing Education (CE) credits in laboratory practice, appropriate laboratory experience, etc.

Laboratories may choose to use primary source verification (PSV) to confirm personnel credentials and provide PSV documentation as evidence of compliance with the

personnel requirements stated in 42 CFR Part 493, Subpart M. The use of a PSV report as evidence of meeting CLIA personnel qualifications is **optional** for the laboratory. The laboratory may provide both direct observation of documents, PSV documents, or a combination of both to achieve compliance.

PSV is the process of confirming an applicant's credentials by verifying that a degree, certificate, or diploma was received; that licenses were granted; and, by confirming reported work history, such as company names and locations, dates, and positions held. Verifications are obtained either directly from an institution, former employers, or their authorized agents.

6008 - Assignment of CLIA Identification Numbers

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CLIA identification numbers are shown under the CMS Certification Number (CCN) column in certain CMS data systems.

CLIA identification numbers are 10-digit alphanumeric numbers issued by the CLIA *D*ata *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 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 certified 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.

Once a laboratory is assigned a number, it retains this number even if it withdraws from CLIA, has its certificate 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.

6009 - Multiple CLIA Certificates at the Same Location

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Each CLIA certificate represents a laboratory, and each laboratory is responsible for complying with the applicable CLIA requirements. They are not to be referred to as "shared laboratories." Entities that have questions concerning Medicare or Medicaid billing (including, but not limited to, the sharing of expenses) should be informed that these are not CLIA quality and safety issues.

Multiple laboratories may operate at the same physical location (e.g., same building or suite, as applicable) with separate CLIA numbers, as long as each laboratory can demonstrate that it is operating as a separate and distinct entity. Laboratories that operate at the same physical location and use the same testing personnel and equipment must meet the following conditions:

- All records (e.g., quality control, procedure manuals, personnel competency) must be kept separate and distinct for each laboratory and must clearly show that each laboratory is operating independently.

- The hours of operation must be specified for each laboratory and be separate and distinct. The times of testing cannot overlap and cannot be simultaneous.

6010 - Regulatory Exceptions for a Multiple Site Certificate Location

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Each location where laboratory tests are performed must file a **separate** application, unless it meets one of the following exceptions as outlined in 42 CFR 493.35(b)(1)-(b)(3), 493.43(b)(1)-(b)(3), or 493.55(b)(1)-(b)(3). *Caution should be used when determining if an entity can be issued one certificate for multiple sites. Each exception stands alone and must not be combined with another exception.*

6010.1 - Mobile Laboratory Units and Temporary Testing Sites

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- A mobile unit is generally considered to be a movable, self-contained operational laboratory with its own personnel, equipment, and records, with equipment installed and located permanently within the mobile unit.

- If a vehicle is used solely to transport laboratory equipment from the primary site/home base to another site where testing is performed, the transporting vehicle is not a mobile unit.

If a mobile laboratory operates in more than one State, *CMS* determines which state should perform an inspection.

Each mobile laboratory that moves from testing site to testing site or has a temporary testing location, should provide the SA with the primary site/home base or central dispatch phone number, so that the SA can obtain an updated schedule of the location(s) of testing and the hours of operation. Records may be maintained in the mobile vehicle or at the primary site/home base. Reports should reflect the primary site/home base address and indicate which mobile unit performed each test. The vehicle identification number may be used to distinguish mobile laboratory *vehicles*.

6010.1.1 - Mobile Laboratory Units

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

- A mobile unit is generally considered to be a movable, self-contained operational laboratory with its own personnel, equipment, and records, with equipment installed and located permanently within the mobile unit.
- If a vehicle is used solely to transport laboratory equipment from the primary site/home base to another site where testing is performed, the transporting vehicle is not a mobile unit.

If a mobile laboratory operates in more than one State, the RO determines which state should perform an inspection.

Each mobile laboratory that moves from testing site to testing site or has a temporary testing location, should provide the SA with the primary site/home base or central dispatch phone number, so that the SA can obtain an updated schedule of the location(s) of testing and the hours of operation. Records may be maintained in the mobile vehicle or at the primary site/home base. Reports should reflect the primary site/home base address and indicate which mobile unit performed each test. The vehicle identification number may be used to distinguish mobile laboratory vans.

6010.1.2 - Temporary Testing Sites

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Exception (b)(2): 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. (42 CFR 493.35(b)(2), 493.43(b)(2), or 493.55(b)(2)).

- The facility must either be Not-for-profit, or a Federal, State or local government facility (e.g., Women, Infants and Children (WIC) clinics).

- Not-for-profit status is a legal designation.

- Limited public health testing is not defined in the regulation.

- The testing is limited to 15 or fewer tests, and those fifteen tests must be listed on the license application. Those fifteen tests may be solely comprised of moderate complexity tests, solely comprised of waived tests, or comprised of a combination of moderate and waived tests.

- A Certificate of Waiver laboratory is eligible if it only performs 15 or fewer waived tests.

- The various sites under this certificate may only perform tests within the 15 tests listed on the certificate application.

- An entity performing any high complexity testing cannot use this exception for a multi- site certificate.

- The multi-sites cannot perform tests that are outside of those listed for the CLIA certificate they are operating under. The name of the tests must be shown on the CLIA application for this exception. (Although certificates are currently issued by specialty/subspecialty, the tests must be verified and shown on the CLIA application Form CMS-116.)

- The location designated as the primary site on the CLIA application/certificate must perform testing and hold the certificate.

- The primary site must also identify the type of testing performed at each site. If any of the multi-site laboratories is located in more than one State, the SA contacts *CMS* to determine which State conducts the inspection.

6010.1.2.1 - Home Health Agencies (HHAs) and Hospices Temporary Testing Sites

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Home Health Agencies

A parent HHA with multiple branches may apply for one CLIA certificate as long as these sites are under one HHA provider number, i.e., parent and branch.

Subunits that operate independently and have a unique provider number should each apply for a separate CLIA certificate.

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

NOTE: If the health care worker only assists the patients and provides the patient's self-testing result to the health care provider, a certificate is not required.

Hospices

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

6010.2 - Laboratories Performing Limited Public Health Testing

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Exception (b)(2): 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. (42 CFR 493.35(b)(2), 493.43(b)(2), or 493.55(b)(2)).

- The facility must either be Not-for-profit, or a Federal, State or local government facility (e.g., Women, Infants and Children (WIC) clinics).
    - Not-for-profit status is a legal designation.
- Limited public health testing is not defined in the regulation.
- The testing is limited to 15 or fewer tests, and those fifteen tests must be listed on the license application. Those fifteen tests may be solely comprised of moderate complexity tests, solely comprised of waived tests, or comprised of a combination of moderate and waived tests.
- A Certificate of Waiver laboratory is eligible if it only performs 15 or fewer waived tests.
- The various sites under this certificate may only perform tests within the 15 tests listed on the certificate application.
- An entity performing any high complexity testing cannot use this exception for a multi- site certificate.
- The multi-sites cannot perform tests that are outside of those listed for the CLIA certificate they are operating under. The name of the tests must be shown on the CLIA application for this exception. (Although certificates are currently issued by specialty/subspecialty, the tests must be verified and shown on the CLIA application Form CMS-116.)
- The location designated as the primary site on the CLIA application/certificate must perform testing and hold the certificate.

- The primary site must also identify the type of testing performed at each site. If any of the multi-site laboratories is located in more than one State, the State Agency (SA) contacts the Regional Office to determine which State conducts the inspection.

6010.3 - Laboratories within Hospitals

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Exception (b)(3): 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. (42 CFR 493.35(b)(3), 493.43(b)(3), or 493.55(b)(3)).

- This exception applies only to laboratories within hospitals. This includes teaching hospitals of universities. Other types of entities are not eligible.

- "Under common direction" means that all of the multiple site laboratories must be under the direction of the same laboratory director.

- "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.

- Where it is unclear whether laboratories in multiple sites on a campus meet the applicable criteria, such as with a hospital occupying multiple buildings on a university campus, the SA consults with *CMS* to determine if the hospital is eligible for a single certificate.

The fact that the laboratory is owned by a hospital does not necessarily make it a hospital laboratory for purposes of the multi-site exception. In many of these cases, a multiple site certificate CANNOT be issued. Additional information should be requested at each requirement under 42 CFR 493.35(b)(3), 493.43(b)(3), or 493.55(b)(3))

6012 - Chemical Toxicity Public Health Laboratories Exceptions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Centers for Disease Control and Prevention (CDC) worked with the Association of Public Health Laboratories (APHL) to establish and prepare the national Laboratory Response Network (LRN) to ensure that there are robust, adequate laboratory testing services available in the event of a chemical terrorism attack.

A *Chemical Toxicity Public Health Laboratories* (CT PHL) will be issued an effective CLIA certificate at their highest level of testing, regardless of whether they are testing human samples or not. This policy applies to only the laboratories designated by APHL. This allows the laboratory to operate within the scope of CLIA, ensure quality patient testing and avoid delays should an untoward event occurs. These laboratories may hold either a certificate of compliance or certificate of accreditation depending upon whom they select as their survey agency, as do all enrolling laboratories. A new CT PHL is surveyed immediately and within the surveyor's availability using the CLIA Outcome-Oriented Survey Process (OOSP). Subsequent surveys should be performed following the survey agencies' routine biennial schedule. If a CT PHL already has a CLIA certificate, but has added chemical *toxicity* testing to its test menu since its last survey, the surveyors should visit and review only this testing in the interim until the next biennial survey.

All CT PHL surveys will be entered into the CLIA database by *CMS*. Survey findings are entered in to the "Notes" portion to identify these laboratories in the system, but do not identify them in any fields that could be observed externally.

6014 - CLIA Certificate Status Changes

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Certificate of Waiver or Certificate *for* PPM

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

Certificate of Compliance to Certificate *for* PPM or Certificate of Waiver

A laboratory operating under a Certificate of Compliance that is no longer performing nonwaived testing (excluding PPM procedures), may request to change to either a CoW or a certificate for PPM procedures. The laboratory must submit a new CLIA application (Form CMS-116). For specific instructions on the application process, see *section* 6006. 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 *D*ata *S*ystem; therefore, a new certificate and fees will be system generated. The certificate will be issued after the fees are paid.

Certificate of Accreditation to Certificate *for* PPM

When a laboratory that operates under a CLIA Certificate of Accreditation decides to

conduct PPM procedures ONLY, the laboratory may downgrade its Certificate to a CLIA Certificate for PPM procedures. The laboratory must submit a new CLIA application (Form CMS-116). For specific instructions on the application process, see *section* 6006. It may not continue to hold a Certificate of Accreditation. (The laboratory may continue voluntarily to be accredited by an AO. However, this accreditation would not be for CLIA purposes.)

Certificate of Compliance to Certificate of Accreditation

A laboratory requesting a change from a Certificate of Compliance to a Certificate of Accreditation must be in CLIA *c*ondition-level compliance. Once a credible AoC is received, and compliance is verified, the certificate change data may be entered into the CLIA *D*ata *S*ystem. A laboratory can elect to retain the Certificate of Compliance until the certificate expiration date and subsequently change the certificate status. If the laboratory elects to change its certificate status prior to the expiration date of the current CLIA certificate, the data system must be updated. The laboratory must submit a new CLIA application (Form CMS-116). For specific instructions on the application process, see *section* 6006. A new certificate will be generated once the data is entered into the data system; therefore, a Certificate of Registration and fees will be system generated. The Certificate of Registration will be issued once the appropriate fees are paid. The laboratory then continues the process for a Certificate of Accreditation.

Certificate of Accreditation to Certificate of Compliance

In order for a laboratory to request a change from a Certificate of Accreditation to a Certificate of Compliance, the laboratory must submit a new CLIA application (Form CMS-116) to the appropriate *SA*. For specific instructions on the application process, see *section* 6006. The CLIA system must be updated and a Certificate of Registration with appropriate fees will be system generated. The Certificate of Registration will be issued after the fees are paid. The laboratory then continues the process for a Certificate of Compliance.

6016 - Notification of Change in Laboratory Operations and Retention Requirements

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When a laboratory provides written notification or, as necessary, a new Form CMS-116 concerning changes listed in *section* 6016.1, the SA enters the information into the CLIA *D*ata *S*ystem and retains a copy of the laboratory's documentation (i.e., Form CMS-116). The SA must not accept oral notices of change or intent to change.

6016.1 - Change in Laboratory Operations

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Laboratory Changes that Require Submitting a New Form CMS-116

A new Form CMS-116 MUST be obtained when any of the following laboratory changes takes place*:*

- Initial Application
    - *When applying for the temporary testing site exception, a list of the temporary testing sites must be included on or attached to the Form CMS-116. For temporary testing sites at patient homes, no individual addresses need to be submitted but should be available upon request.*
- Survey, Initial or Recertification
- Certificate *Type* Change
- Reinstatement of CLIA certificate
- *Adding a multiple site exception, including temporary testing sites, to an existing CLIA certificate*
    - *A list of temporary testing sites must be included on or attached to the Form CMS-116. For temporary testing sites at patient homes, no individual addresses need to be submitted but should be available upon request.*
- Laboratory Director Change (Provider-Performed Microscopy (PPM) *Certificate or* Certificate of Compliance)
- *Type of Control (Ownership Type)*

Laboratory Changes for which Written Notification (at minimum) is Acceptable

At a minimum, written notification must be obtained when any of the following laboratory changes take place:

- Name of the Laboratory
- Location (Physical location)
- Location (Mailing Address)

- Location (Corporate Address)
- Tax ID (EIN)
- Specialty or Subspecialty Change
- *Total Test Volume Change*
- Telephone and Fax Numbers
- *Email Address and requests to receive future notifications via email*
- *Reinstatement- Activate without Gap*
- *Changes to* Multiple Site *Information*
    - *Laboratories must submit written notification when changes occur to the number or location of temporary testing sites. For temporary testing sites at patient homes, no individual addresses need to be submitted but should be available upon request.*
- Change in Accreditation Organization
- Voluntary Closure/Termination
- Personnel-Technical Supervisor

Written notification includes an email, fax, or hard copy *letter*. The written notification must include the laboratory's name, CLIA number, the name of the Laboratory Director and*/or* Owner, the change(s) being made, and the signature of the Laboratory Director or designee. In lieu of written notification, a new Form CMS-116 form is also acceptable. Please note, *that each section of* the Form CMS-116 *applicable to the certificate type* must be completed in its entirety *when a Form CMS-116 is submitted for changes. If a laboratory requests a revised certificate, the* revised certificate *will be issued to the laboratory once the appropriate fees are paid.*

6016.1.1 - Change in Laboratory Director for Certificate of Accreditation Laboratories

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Once a laboratory becomes accredited by an Accreditation Organization (AO) (as indicated by the confirmation checkmark in the ASPEN Web *Form* CMS-116 on the AO Info tab), and the laboratory pays all CLIA fees, the certificate type will change from a Certificate of Registration to a Certificate of Accreditation (CoA). From this point on, the AO will be responsible for the qualification and entry of laboratory director changes into the CLIA *D*ata *S*ystem.

Example 1: A *SA* receives an initial application for a Certificate of Accreditation and the laboratory has marked one of the approved accrediting organizations as the AO to which they have applied for accreditation for CLIA purposes. Does the indicated AO qualify the laboratory director and enter the name and title into the ASPEN Web CLIA 116?

Response: No. Initial applications are entered by *SA* personnel. This includes performing the qualification of the laboratory director and entry of the name and title.

Example 2: The laboratory has been entered into the ASPEN Web CLIA 116, has paid its registration fee and received its Certificate of Registration. The laboratory has now requested to change the director. Does the AO indicated on the initial application qualify and enter the new laboratory director?

Response: No. The SA remains responsible for qualifying any laboratory director and entering the name and title changes while the laboratory holds a Certificate of Registration. The SA should send a replacement Certificate of Registration after making the changes.

Example 3: The laboratory holds a Certificate of Compliance. The laboratory has requested a change in certificate type to a Certificate of Accreditation. Does the AO indicated on the request for the certificate type change (also known as a status change) qualify and enter the laboratory director?

Response: No. The request for a status change is treated the same way as an initial application.

Example 4: Due to state laboratory licensing laws, the laboratory needs to know when a change in laboratory director is entered by an AO so that it can qualify the new laboratory director per state regulations. Is there a report the laboratory can access to monitor such changes?

Response: Yes. There is a nationwide report in ASPEN Web CLIA 116 that can be accessed by date range. CASPER report 104 can also be used. Remember that due to

the overnight upload of data from ASPEN to CASPER, the information in CASPER will be a day behind the report in ASPEN, which shows real time data. The advantage to CASPER report 104 is that it can be accessed for an individual state or region.

Example 5: When a CoA laboratory sends in a Form CMS-116 with requested changes, including a laboratory director change, to the *SA*, is the Form CMS-116 forwarded to the AO or *CMS*?

Response: Neither. The *SA* keeps the Form CMS-116 as documentation of the requested changes and notifies the laboratory that changes other than specialties and laboratory directors will be performed by the SA personnel, but that any changes to specialties and laboratory director should be handled by the laboratory's AO and the laboratory should use whatever form of documentation the AO requires to submit those changes. The AO's do not use government forms.

Example 6: Can the AOs change the demographic information associated with the laboratory in ASPEN Web CLIA-116?

Response: No. While the demographic information is visible to the laboratory's confirmed AO, the AO user is restricted from entering changes to those fields.

Example 7: Will a *revised* certificate be automatically generated if my SA personnel make a change to the laboratory director on a Certificate of Accreditation while it is still under its registration certificate?

Response: No. The CLIA *D*ata *S*ystem is programmed to do that only for AO users because they do not have access to that field in ASPEN Web CLIA 116. Remember AO users can't make laboratory director changes while the laboratory is still under a Certificate of Registration. *If a laboratory requests a revised certificate, the SA will process the request, and the revised certificate will be issued to the laboratory once the appropriate fees are paid.*

Example 8: If a CoA laboratory fails to notify an SA about a laboratory director change as required by state licensure requirements, will an alert be sent to the SA?

Response: No. The ASPEN Web CLIA 116 does not feature alerts, but the new Director Change search function on the ASPEN Web CLIA 116 search page or CASPER report 104 will allow the SA to find CoA laboratories that have had laboratory director changes. (Also see Example 4)

Example 9: Will the AO attach the Laboratory Director qualifications in the ASPEN Web CLIA 116?

Response: No. The AO does not have the security rights to save attachments to the ASPEN Web CLIA 116 record. The documentation used by the AO for the laboratory director qualification will be maintained by the AO in accordance with its own

standards.

6016.1.2 - Change in Specialty or Subspecialty (Certificate of Compliance)
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Based on the timing of the notification of a change in specialty or subspecialty, the SA should determine if a revisit needs to be performed. The timing may allow for the new specialty or subspecialty to be reviewed during the recertification survey. If a revisit needs to be performed, the SA determines whether the revisit should be onsite or offsite depending on the added specialty or subspecialty and equipment in place at the laboratory. The SA should contact CMS for further guidance if needed.

6016.2 - Retention Requirements
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

According to Section XI of the CMS Records Schedule, Form CMS-116 needs to be kept by the SA/*CMS* for at least seven years. If State law states that the Form CMS-116 needs to be kept for a longer period or in specific formats, then the SA may maintain the forms for the duration and in the form mandated by State law.

6018 - *Replacement and* Revised Certificates
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Replacement certificate means an active CLIA certificate that is reissued with no changes made.

Revised certificate means an active CLIA certificate that is reissued with changes to one or more fields displayed on the certificate, such as the laboratory's name, address, laboratory director, or approved specialties/subspecialties. For purposes of 42 CFR 493, revised certificates do not include the issuance, renewal, change in certificate type, or reinstatement of a terminated certificate with a gap in service.

If a laboratory requests a replacement or a revised certificate, the SA will process the request and the replacement or revised certificate will be issued once the appropriate fees are paid.

6020 - Fee Adjustments
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The CLIA *D*ata *S*ystem is a computerized system that maintains demographic and CLIA user fee billing data on every laboratory that is certified 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), the billing and collection of laboratory user fees and the issuance of certificates.

Authorized users can query the CLIA *D*ata *S*ystem 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 *D*ata *S*ystem. 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 are available through the CLIA *D*ata *S*ystem reporting functions. Consult with your supervisor or *CMS* to obtain specific instructions/training on how to use the CLIA *D*ata *S*ystem, or any of the current available CLIA *D*ata *S*ystem Users' Guide(s).

6022 - CLIA Data System

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The CLIA *D*ata *S*ystem is a computerized system that maintains demographic and CLIA user fee billing data on every laboratory that is certified 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), the billing and collection of laboratory user fees and the issuance of certificates.

Authorized users can query the CLIA *D*ata *S*ystem 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 *D*ata *S*ystem. 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 are available through the CLIA *D*ata *S*ystem reporting functions. Consult with your supervisor or *CMS* to obtain specific instructions/training on how to use the CLIA *D*ata *S*ystem, or any of the current available CLIA *D*ata *S*ystem Users' Guide(s).

State Agency and *CMS* Roles and Relationships with other Federal Agencies

6024 - Consultative CLIA Activities

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Centers for Disease Control and Prevention (CDC) - provides scientific and technical assistance to CMS in the promulgation of CLIA regulations and CLIA related efforts.

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, § 222 of the *PHSA*, 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.

6026 - *CMS* Role

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS *is* responsible for ensuring that CLIA laboratories provide appropriate quality services and the SAs operate in accordance with the *Section* 1864 agreement using CLIA policies and procedures. Their major responsibilities are as follows:

- Reviewing survey and certification reports submitted by the SA;
- Initiating all adverse actions, imposing alternative sanctions in addition to or in lieu of principal sanctions, canceling or suspending all or part of the laboratory's approval to receive Medicare payments, as applicable, based on SA/*CMS* recommendations, and issuing of final notices;
- Monitoring and surveillance of SA expenditures and approval of SA budgets for the provision of cost efficient and effective survey and certification activities;
- Assisting with training, projects, workgroups and policy development, and problem resolution;
- Coordinating with the SA the orientation of all new CLIA surveyors and

staff;

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

- Conducting onsite surveys of federally and State-operated CLIA-certified laboratories;

- Performing transfusion-related fatality surveys and investigations according to CMS policies and procedures;

- Coordinating follow-up of complaints with SAs and AOs and communicating findings;

- Performing *SA* Performance Reviews (SAPR) and Federal Monitoring Surveys (FMS) to ensure SA conformance with CMS policies and procedures;

- Providing technical assistance to SAs and laboratories;

- Implementing CMS CLIA policies and procedures in their respective States and ensuring consistent application by the SA; and

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

6028 - Laboratories Under Direct *Federal* Jurisdiction

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The following facilities may fall under the direct *federal* jurisdiction if they test human specimens and report out the results for purposes of diagnosis, assessment or treatment of the subject. Where they do, all survey and certification activities are to be performed by *CMS* staff.

- Federal laboratories subject to CLIA

- State laboratories within their region

- Indian Health Service laboratories

Since Indian health tribal facilities may or may not be under *f*ederal jurisdiction, *CMS* determines whether *CMS* or the SA has jurisdiction. If they are run by the Department of the Interior/Bureau of Indian Affairs, they are considered federal laboratories and therefore are inspected by *CMS*. (See SOM Chapter 1, *section* 1018A)

CMS is also responsible for designating all federal jurisdictional laboratories as such in the CLIA *D*ata *S*ystem.

6030 - *CMS* Review of State Agency (SA) Certification Activities

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CLIA has a single set of regulations applicable to all types of laboratories or entities performing laboratory tests based on test complexity. *CMS* 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. (See *section* 6230)

If *CMS* determination disagrees with the SA, the decision must be supported by evidence. *CMS* justifies the determination in writing and attempts to resolve the disagreement.

6032 - State Agency (SA) Role

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

State agencies are responsible for CLIA survey and certification activities (including most data entry) for non-Federal laboratories within their respective States. Lists of laboratories ready to be inspected are available to SAs through the CLIA *D*ata *S*ystem.

The SA makes determinations of compliance with CLIA requirements based on survey findings. The policies and procedures for these actions are in the SOM Chapters 5 and 6. In the area of laboratories, they include but are not limited to:

- Identifying and enrolling potential laboratory participants.

- Communicating effectively and timely in a verbal and written manner with laboratories, peers, supervisors and *CMS* according to standard operating procedures (SOPs).

- Managing the CLIA database using CLIA system applications according to procedure.

- Responding timely to complaints, as per *CMS* direction.

- Attending *CMS* training courses, as directed.

- Developing internal systems and processes to effectively and efficiently perform CLIA related duties and meet the State Agency Performance Review (SAPR) requirements.

- Providing technical assistance to laboratories concerning the regulations to enable laboratories to qualify for participation in the program (meet applicable requirements).

- Scheduling, preparing for, conducting and appropriately following up surveys in which the *SA* determines the laboratory's compliance with the CLIA requirements in accordance with the Outcome Oriented Survey Process (OOSP) and within stated timeframes.

- Citing deficiencies according to CLIA Principles of Documentation (PoD) as needed using the most appropriate citation.

- Soliciting and reviewing a PoC, recommending certification and recertification, and other follow-up actions.

- Recommending sanctions to *CMS* if laboratories do not meet the CLIA requirements.

- Conducting validation surveys of accredited laboratories per the SOM protocol.

- Performing periodic PT desk review and corresponding follow ups.

- Participating in federally directed efforts.

6034 - CLIA Laboratories - Compliance *w*ith Civil Rights Requirement

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 *CMS*. *CMS* must not assess the validity of such complaints. Rather, it must forward such complaints to OCR for review and investigation. As necessary, OCR forwards the complaint to the Department of Justice (DOJ) for evaluation, investigation, and disposition. *CMS* 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 user fee obligation.

6036 - Referrals to the Office of Inspector General (OIG) for CLIA Violations (e.g., Testing without a CLIA Certificate)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If a laboratory is operating without a CLIA certificate, the SA or *CMS* as applicable, notifies the laboratory that it is violating CLIA requirements 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, *CMS* will notify the OIG of the violation. If applicable, the SA forwards documentation to *CMS* within 20 days of the date the violation notice was sent to the laboratory. In addition, *CMS* also refers to the OIG:

- Cases of misrepresentation in obtaining a CLIA certificate;
- Laboratories that perform or represent themselves as a laboratory 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.

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

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS and the 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 the FDA registration and are not routinely inspected by the 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 the FDA and are routinely inspected by the FDA.

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

NOTE: *The definition of transfusion service for the purposes of the CMS/FDA MOU is different than the CLIA definition of transfusion service. (See SOM Appendix C, §493.1103)*

6038.1 – Inspections of Transfusion Services

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 the FDA and the 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.

Blood establishments that are registered with the FDA are routinely inspected by the 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.

According to the provision of the CMS/FDA MOU 225-80-4000, CMS' authority applies only at non-governmental facilities. Inspection of VA and DoD clinical laboratories is the responsibility of VA/VHA and DoD respectively under contracts with CLIA deemed-status organizations.

6040 - Transfusion-Related Fatalities

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Facilities, including laboratories, involved in the collection or transfusion of blood or blood products must report transfusion-related fatalities to the FDA's Center for Biologics Evaluation and Research (CBER), Office of Compliance and Biologics Quality. The FDA notification process, including contact information, can be found at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/notifying-fda-fatalities-related-blood-collection-or-transfusion*.

The FDA notifies CMS 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.) *Transfusion-related fatality investigations must not be referred to an AO for action. However, the AO or multiple AOs, as appropriate, will receive a copy of the Form CMS-2567 from CMS or SA when the investigation is complete.*

CMS evaluates the information received from the FDA. As applicable, *CMS* may request that a survey of the facility be performed. 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 *CMS* 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.

The investigation should also include a review of other transfusion reaction reports to ensure that proper procedures were followed and corrective actions implemented. *CMS* should assure that all measures are taken to correct the situation which led to the death as well as any other serious deficiencies uncovered in the course of the survey.

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 Complaints/Incidents Tracking System (ACTS). When performing investigations in accredited laboratories or laboratories in exempt states, follow standard policies and procedures for *CMS* authorization, review of deficiencies, and communication with the laboratory, the accreditation organization, and the exempt state.

CMS or SA will conduct the survey within 45 days of the notice. The information entered in ACTS is sufficient for reporting to *CMS*. Investigations of transfusion-related fatalities *may be* announced, since the facility is aware of the possibility of a follow up after the report is made to the 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 *CMS* conducts an unannounced survey.

CMS 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, *CMS* 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 and State tags should not be used on the 2567 given to the laboratory for the CLIA survey.) In addition, more than one location may be involved, for example, when the blood is tested in one facility and transfused in a different facility.

CMS or the SA will issue deficiencies and document the survey in ACTS using standard policies and procedures. Ensure that all documentation is included in ACTS.

Proficiency Testing

6042 - Proficiency Testing (PT)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 493.801(b)(4) and, if identified, carries one of the most severe sanctions in the CLIA law and regulations. The subpart also identifies successful participation in a CMS-approved PT program and how a laboratory may be reinstated when it has performed unsuccessfully. (Please see 42 CFR 493.2, Definitions, for unsatisfactory participation and unsuccessful participation.)

NOTE: The referral to another laboratory of a sample from a PT program by ANY laboratory of ANY certificate type is considered PT referral. If a laboratory enrolls and participates in PT, regardless of certificate type, all rules related to PT referral apply.

Notify *CMS* if PT referral is identified. For additional information on PT Referral, see *section* 6061.

PT Program Approval: Not-for-profit organizations or States may apply to *CMS* to become a CMS-approved PT program for specific subspecialties and analytes. *CMS* PT specialists perform an in-depth review of applications 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. Annual re-approval reviews are also conducted by *CMS* 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 - PT Enrollment and CASPER System Reports

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The SA or *CMS* has access to the following reports from the CASPER System:

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

To obtain directions on how to use the CASPER system, consult your supervisor or *CMS*.

6046 - PT Enrollment Information

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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. A condition level deficiency (42 CFR 493.801) is cited if a laboratory has not enrolled for even one of these tests if performed in the laboratory. If a laboratory fails to enroll and/or appropriately test PT samples, *CMS* may impose any of the sanctions described in 42 CFR 493, Subpart R. 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 493.801 is found, but instead the SA may recommend to *CMS* appropriate sanctions if the non-enrollment isn't corrected in a timely manner.

Each calendar year the PT programs transmit enrollment records to the PT Monitoring System within the CLIA *D*ata *S*ystem for each laboratory participating in their programs. Laboratory demographics and every test for which the laboratory has enrolled are listed on CASPER 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 onsite survey. If the SA or *CMS* wishes to verify enrollment more frequently, they may print out CASPER 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 *CMS* 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.

6048 - PT Participation and Testing Requirements

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A laboratory must meet the CLIA regulatory requirements for enrollment, participation, and testing as specified in Subpart H at 42 CFR 493.801. The SA, adhering to the time frames and guidelines in Appendix C of the SOM, reviews all related documentation. If failure to meet the specific requirements of 42 CFR Part 493 Subpart H is identified by the SA, appropriate actions may be initiated and sent to *CMS* for review and concurrence.

If the SA identifies any information on survey or by any other means that indicates the possibility that any PT sample has been referred to another laboratory for testing prior to an event cut-off date, *CMS* must be notified immediately. *CMS* will instruct and advise the SA surveyor of the appropriate actions the surveyor must take. The *SA* may contact *CMS* with any questions.

All documentation to support the finding of any PT referral is forwarded to *CMS* who will recommend appropriate sanctions in accordance with Subpart R. (See *section* 6061.)

6050 – Monitoring of PT Scores

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The SA routinely monitors their state's laboratory performance by reviewing CASPER Report 153, PT Unsatisfactory/Unsuccessful Report, from the PT Monitoring System.

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 *CMS*.

PT must also be reviewed during the onsite survey. Prior to the onsite survey, the SA will review CASPER Report 155, PT Individual Laboratory Profile, which will display the individual laboratory's PT performance. 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 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.

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

Unsuccessful participation in PT is defined as any of the following:
Unsatisfactory performance for the same analyte in two consecutive or two out of three testing events; repeated unsatisfactory overall testing event scores for two consecutive or two out of three testing events for the same specialty or subspecialty; or an unsatisfactory testing event score for those subspecialties not graded by analyte (i.e., bacteriology, mycobacteriology, virology, parasitology, mycology, blood compatibility, immunohematology, or syphilis serology) for the same subspecialty for two consecutive or two out of three testing events.

Unsatisfactory PT performance means failure to attain the minimum satisfactory score for an analyte, test, subspecialty, or specialty for a testing event.

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

Unsuccessful performance may be used interchangeably with unsuccessful participation for non-cytology PT.

A rolling time frame is used to determine unsuccessful PT performance wherein the

laboratory incurs either two unsatisfactory scores for two of three consecutive testing events or two consecutive testing events, for an analyte, subspecialty, or specialty. The time frame does not stop, nor does it re-set annually. It will be based on information available in the CASPER reports.

The SA will recommend sanctions or enforcement actions to *CMS* 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.

6054 - Unsuccessful Performance in Proficiency Testing

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If it is determined that a laboratory has performed PT unsuccessfully, the SA follows the procedures listed below.

All sanctions are imposed in accordance with 42 CFR Part 493 Subpart R and taken by *CMS*.

If an initial unsuccessful PT performance by a laboratory (that is, the laboratory has never performed unsuccessfully for the particular test, specialty, subspecialty, or analyte) is confirmed, the SA may recommend to *CMS* that the laboratory undertake additional training, obtain technical assistance, or both, rather than recommending the imposition of alternative or principal sanctions. No onsite survey is necessary to initiate this action.

NOTE: The SA may recommend training and/or technical assistance for an initial unsuccessful PT performance 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 493.803(c) for regulatory specifications.

If *CMS* agrees with the recommendation of technical assistance and/or training, a credible allegation of compliance to show that the laboratory corrected the problem that caused the unsuccessful performance should be obtained from the laboratory. Documentation of the SA determinations and follow-up should be maintained. For an initial unsuccessful PT performance, *CMS* 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 accurate by contacting either the PT program or the laboratory to review the results of the testing that caused the unsuccessful performance. After verification of the scores, the SA (with *CMS* consent –

  NOTE: This may be a blanket consent for SAs for all initial unsuccessful PT performance) sends the laboratory a letter proposing T&TA with a Form CMS-2567 citing the *c*ondition-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 documented as back into compliance by the SA.

- These actions for the initial unsuccessful PT performance must be entered into the CLIA enforcement database in a timely manner by *CMS*.

For a non-initial unsuccessful PT performance, the SA must verify that the scores are

accurate 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, *CMS* 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 *CMS* determines that another T&TA is warranted, follow the procedure noted above for an initial unsuccessful PT performance.

- If the failure is for the same test, 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 *c*ondition-level noncompliance to *CMS*.

- *CMS* then sends a letter along with the Form CMS-2567 citing the *c*ondition-level deficiency(ies) to the laboratory that proposes sanctions, including, but not limited to, a limitation of the laboratory's certificate in the area of failure, and cancellation of their Medicare and/or Medicaid payment immediately for no less than six months in the area of failure. If the effective date of the sanctions is not delayed (such as in the case of immediate jeopardy) or 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 may choose to use 2 routine PT events as their reinstatement PT, or they may obtain off-cycle re-instatement PT samples from their PT program or any other CMS-approved PT program.

- The scores of the re-instatement PT are entered into the CLIA PT database as 'non-routine' by the PT program and may be found at the bottom of CASPER 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.

To initiate the appropriate enforcement actions, use the guidance at Sections 6276-

6280. Please see the Notice of Proposed Limitation of the CLIA Certification and Suspensions of Medicare Payments When a Laboratory Has Failed to Participate Successfully in a Proficiency Testing Program.

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

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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. (See §493.845(c)(1)-(3)) An excused participation may be granted only if:

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

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

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

If the SA/*CMS* 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/*CMS* does not accept the circumstances given by the laboratory to justify its lack of participation, the SA/*CMS* 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 which will then be reflected in the CASPER reports.

6060 - Reinstatement After Failure to Successfully Participate in Proficiency Testing

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The laboratory must meet the requirements for reinstatement when:

- A laboratory has been required to cease testing an analyte or subspecialty without analytes or a specialty;

- The laboratory's certificate has been suspended or limited; or

- The laboratory voluntarily withdraws testing of the unsuccessful area of participation.

Reinstatement requires satisfactory performance on two consecutive PT events for the specialty, subspecialty, or analyte that the laboratory previously failed. Sustained satisfactory performance (two consecutive events) demonstrates that the laboratory has identified and corrected the area of failure that caused the original unsuccessful performance. A laboratory that has had its certificate suspended, limited, or cancelled due to unsuccessful PT participation may not be reinstated or receive Medicare or Medicaid payments for a period of at least 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 may be required to pay a fee to cover the cost of issuing the revised certificate.

The laboratory may voluntarily withdraw from testing prior to *CMS* sending the letter to impose (i.e., imposed sanction notice) 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 and has not received the imposed sanction notice, it will be considered as back in compliance. This may be completed in less than 6 months. The SA will monitor this in coordination with *CMS* 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 CASPER reports) 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. *CMS* will make the final determination whether reinstatement requirements are met.

6061 – PT Referral

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If the SA identifies or suspects PT referral is occurring or has occurred, whether during

an onsite survey, complainant's allegations, PT desk review, or other means, contact *CMS* immediately. If *CMS* directs the SA to investigate the potential PT referral, collect all information related to the PT referral including all records, interviews, and observations. *Send all PT referral documents for review to CMS immediately. CMS* will provide a recommendation for sanctions in accordance with Subpart R for all PT referral cases. See *section* 6276.2 for enforcement and sanction information related to PT referral.

Documentation forwarded to *CMS* should include, at a minimum:

- *Form* CMS-2567
- SOP for PT and the specific analyte, test, specialty, or subspecialty approved at the time of the survey
- Survey notes and evidence
- PT submission forms
- Any written communication between lab personnel
- Instrument printouts
- *Narrative from the surveyor*

If it is determined that PT samples or PT results have been referred to another laboratory, 'PT Referral' is cited. The SA prepares a *Form* CMS-2567 including the deficiencies related to the PT referral at D2000 and D2013. (Per Mandatory Citations).

Do not solicit an Allegation of Compliance 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.

The regulations divide the PT referral sanctions into three categories based on the severity and the extent of the referrals.

1. The first category is for the most egregious violations, encompassing cases of repeat PT referral or cases where the laboratory reports another laboratory's test results as its own.

For example, a laboratory may have two distinct sites, Laboratory A and Laboratory B, that operate under different CLIA numbers. Laboratory A has received PT samples to be tested as part of its enrollment in PT as required by the CLIA regulations. If Laboratory A were to refer PT samples to Laboratory B, receive test results back at Laboratory A from Laboratory B prior to the event cut-off date, and report to the PT program those results obtained from Laboratory B, the scores for the PT event would not reflect the performance of Laboratory A but the performance of Laboratory B. The PT scores would actually be reflective of the accuracy and reliability at Laboratory B rather than A, the purpose of the PT would be undermined.

2. The second category PT referral includes when a laboratory reports its own PT sample results but obtains test results for PT samples from another laboratory on or before *the* cut-off date.

   For example, a laboratory refers PT samples to *another* laboratory that operates under a different CLIA number before the PT event close date and, while the laboratory reports its own results to the PT program, it receives results from the second laboratory prior to the event close date. Such a referral situation allows the referring laboratory an opportunity to confirm, check, or change its results prior to reporting its results to the PT program.

3. The third category of PT referral *can include when a laboratory reports its own PT sample results but obtains test results for PT samples from another laboratory after the cut-off date, or when a* referring laboratory *sends PT samples for confirmatory, distributive, or reflex testing, even if they do* not receive test results from another laboratory prior to the event cut-off date and reports their own results.

   For example, a laboratory may place PT samples in an area where other patient specimens are picked up by a courier to take to a reference laboratory. The reference laboratory courier may take the PT samples along with the patients' specimens. The laboratory personnel notice that the PT samples are missing and contact the reference laboratory to inquire if they have received the PT samples along with the patients' specimens. The reference laboratory is instructed to discard the PT samples and not test them since they were picked up in error. In this case, the "referring" laboratory realized the error, contacted the receiving laboratory, and did not receive results back for any of the PT samples.

Inter-laboratory communication is also prohibited when laboratories perform tests on proficiency testing samples by CLIA regulations at 42 CFR 493.801(b)(4) (D2012).

When a laboratory with multiple testing sites or separate locations participates in any communications across sites/locations concerning PT sample results before the date by which the laboratory must report PT results to the PT program, the laboratory is in violation of the inter-laboratory communication prohibition and the SA should report this to CMS. Additionally, if a laboratory is on the receiving end of a PT referral, they should report it to CMS.

Laboratories experiencing poor performance for analytes using a PT program other than the one that is designated for CLIA compliance purposes or for analytes, tests, specialties, and subspecialties not listed in Subpart I 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 event cut-off date for reporting results to the PT program.

If a laboratory chooses to use PT samples from a CMS-approved PT program for the purpose of meeting the quality assessment requirements at 42 CFR 493.1236(c) and intentionally refers those samples to another laboratory, as stated at 42 CFR 493.801(b)(4), it may have its certificate revoked as stated in 42 CFR 493.1840. This refers to ALL samples purchased from a PT program; samples for tests listed in subpart I AND samples for tests not listed in subpart I that must be checked for accuracy twice per year for quality assessment (QA) purposes.

Laboratories with Certificates of Waiver are not exempt from the ban against referral of PT sample and other penalties required when PT referral has been substantiated.

6062 - Onsite Observation of Proficiency Testing

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS/SA *s*urveyors 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Cytology laboratories and individuals must enroll and successfully participate in a CMS-approved cytology PT program and achieve a passing score annually. See 42 CFR §493.855.

Pathologists and cytotechnologists are tested individually with test sets composed of slides exhibiting a progression of abnormality from unsatisfactory to cervical cancer. There are at least four test opportunities annually. If an individual does not score at least

90% on the first test, he/she can test a second, third, or fourth time:

- Initial Test - ten slides reviewed in two hours (If the individual does not obtain a score of at least 90%, they must be retested within 45 days. The individual may continue to examine slides at this time.);
- Second Test - ten slides reviewed in two hours (If the individual does not obtain a score of at least 90%, the laboratory must provide the individual with documented, remedial training and education in the area of failure, and assure every gynecologic slide examined subsequent to the notification of scoring less an 90% has been reexamined by an individual in the laboratory that has taken and scored at least 90% on their annual PT for the year until such time as the individual is retested;
- Third test - 20 slides reviewed in 4 hours (if individual does not obtain a score of At least 90% they must cease testing until they obtain 35 hours of documented, formally structured continuing education in diagnostic cytopathology, and are re- tested with a 20-slide test set and score at least 90%); and
- Fourth test- 20 slides reviewed in 4 hours (if the individual does not obtain a score of 90% they must cease testing and obtain an additional 35 hours of continuing education, and re-test).

CMS monitors the cytology PT results and conducts appropriate follow up on enrollment and performance failures during survey reviews.

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: 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.

- Approved State Programs (Exempt States) & Approved Accreditation Organizations (AOs): CLIA-exempt laboratories and accredited

laboratories will be overseen by their respective State Agencies or AOs.

- Systems of Testing: 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.

- Systems 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.

    - 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.

Enforcement Actions

The RO, in conjunction with the SA, will initiate intermediate sanctions that may include Civil Money Penalties, 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: (Also see §6250 Adverse Actions)

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

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

The Survey Process

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

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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. Both the SA and *CMS* use the same survey protocol.

The SA *and CMS are* responsible for conducting the onsite survey and entering the information concerning the results of the survey into the *CLIA Data System*.

The following protocols represent an outcome-oriented method to be used to conduct the survey. The focus of the survey is to assess how the laboratory monitors its operations and ensures the quality of its testing. The intended use of these protocols is to promote consistency in the survey process, and to ensure that a laboratory's operations are reviewed in a practical, efficient, and effective manner so that at the completion of the survey there is sufficient information to make compliance determinations. While the purpose of the protocols and guidelines is to provide direction in preparing for the survey, conducting the onsite survey, and analyzing, evaluating, and documenting survey findings, the surveyor's professional judgment is the most critical element in the survey process.

CMS' objective is not only to determine the laboratory's regulatory compliance but also to assist regulated laboratories in improving patient care by emphasizing those aspects of the regulatory provisions that have a direct impact on the laboratory's overall test performance. CMS promotes the use of an educational survey process, especially on the initial laboratory *surveys* to help laboratories understand and achieve the quality system concepts. It is the surveyor's objective, using professional judgment, to determine, based on observation of the laboratory's (past and current) practices, interviews with the laboratory's personnel, and review of the laboratory's relevant documented records, *if the laboratory is performing* quality *clinical laboratory* test*ing*.

Surveyors should make every effort to minimize the impact of the survey on laboratory operations, patient care activities, and to accommodate staffing schedules and departmental workloads as much as possible. In facilities providing direct patient care (e.g., physician offices, clinics, residential care facilities, and hospitals), surveyors should avoid interrupting or interfering with patient care. Surveyors should respect patient privacy and confidentiality at all times in all survey settings.

6101 - The Outcome-Oriented Survey Process (OOSP)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The *outcome-oriented survey process* (OOSP) is intended to direct the surveyor to those requirements that will most effectively and efficiently assess the laboratory's ability to provide accurate, reliable, and timely *clinical laboratory* test results.

In the *OOSP* the surveyor reviews and assesses the overall functioning of the laboratory and evaluates the laboratory's ability to perform quality testing; that is, the surveyor evaluates the laboratory's quality system. The quality system requirements in the Introduction to Subpart K and the General Laboratory, Preanalytic, Analytic, and Postanalytic Quality Assessment requirements are appropriate guides for the surveyor to organize the review.

In the *OOSP, the* emphasis is placed on the laboratory's quality system as well as the structures and processes throughout the entire testing process that contribute to quality test results. The surveyor selects a cross-section of information from all aspects of the laboratory's operation for review to assess the laboratory's ability to produce quality results. The surveyor reviews the cross-section of information to verify that the laboratory has established and implemented appropriate ongoing mechanisms for monitoring its practices and identifying and resolving problems effectively.

If the findings from the review of the laboratory's ongoing mechanisms for ensuring quality test results are sufficient to make the determination of compliance and if the evaluation does not warrant a more in-depth review, the surveyor concludes the survey and proceeds to the exit conference (see *section* 6126).

NOTE: Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services, includes guidelines and instructions for the listed regulatory requirements and encompasses all types of laboratory facilities. Surveyors should take care, therefore, to only cite to the portions of this document that are applicable to the laboratory operations and the complexity of testing performed and are regulatory in nature. Guidelines and instructions are not to be cited.

6102 - Scheduling Surveys
(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

6102.1 – Scheduling Priorities
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When scheduling surveys use the following priorities:

- Complaint surveys indicating possible immediate jeopardy;
- Laboratories with other complaint investigations pending;
- Initial surveys;
- Recertification surveys;
- *Follow-up/Revisit surveys;*
- *Validation (non-complaint) surveys;*
- *Special Surveys for Certificate of Waiver and Provider-performed Microscopy Laboratories.*

Scheduling surveys - There are *two* activities associated with scheduling surveys:

- *Contacting the laboratory to schedule the date and time of the survey using scheduling guidelines, geographic areas, and appropriate survey timeframes.*
- *Providing the appropriate forms to the laboratory (Forms CMS-116, CMS-209, etc.)*

For efficiency when scheduling, attempt to cluster surveys geographically, to include initials, recertifications, complaints, and validations. Extenuating circumstances require *CMS* review. In instances where the State requires a laboratory survey at a different time frame than CLIA, the State *should* meet both survey scheduling requirements as efficiently as possible.

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

1. Initial Surveys: In order to permit observation of actual testing during the initial survey, schedule the initial survey to occur at least 90 days after the data entry date of the *Clinical Laboratory Improvement Amendments (CLIA) Application for Certification*, Form CMS-116, but no later than 12 months after the data entry of the Form CMS-116.

For example: Form CMS-116 data entry date is May 12, 2015. Initial survey should be conducted between August 10, 2015 (90th day after May 12, 2015) and May 11, 2016 (365th day after May 12, 2015). If after the 90 days a representative from the laboratory states that laboratory testing is not being performed because equipment is not ready, etc., *please notify CMS*. 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.

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, 2014. Recertification survey should be conducted between December 31, 2013, and July 4, 2014.

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 *CMS.*

To enhance survey effectiveness and efficiency, except in the case of complaints or other instances in which you would conduct an unannounced survey, consider *providing* the following forms to the laboratories before the scheduled survey date. Request that the laboratory complete the forms and either return them *prior to the onsite survey* or hold them for review during the onsite survey.

- Laboratory Personnel Report (CLIA), Form CMS-209 (required) with directions for completing or updating information, *including all testing personnel since the last survey and any* new personnel or changes in positions or status; and

- *The laboratory should accurately complete the Form CMS-116.*

Request the following information be accessible and retrievable at the time of survey:

- Standard operating procedure manual with all test procedures (e.g., package inserts and supplemental information, as necessary);

- Reference laboratories' client services manual, if applicable;

- Records of tests referred to other laboratories;
- Personnel records, including:
    a. Diplomas, certificates, degrees, *transcripts*;
    b. Training and experience;
    c. Continuing education;
    d. Competency assessment;
    e. Duties/responsibilities;
    f. Personnel changes; and
    g. Primary Source verification (PSV) reports if applicable.
- Quality control records, including:
    a. *Corrective and or r*emedial action information;
    b. Calibration and calibration verification records;
    c. Statistical limits; and
    d. Instrument maintenance and function checks records.
- All proficiency testing (PT) records, including:
    a. Test runs with PT results;
    b. Direct printouts;
    c. *Corrective and or r*emedial actions for unsatisfactory results;
    d. Copies of the signed PT attestation forms provided by the PT program; and
    e. For nonwaived tests and procedures that are not listed in Subpart I, verification of test or procedure accuracy twice yearly.
- Quality system assessment plan and documentation:

For each of the systems:

a. Policies and procedures to monitor, assess, and correct identified problems;

b. Documentation of ongoing assessment activities, including:

1. Review of the effectiveness of corrective actions taken;
2. Revision of policies and procedures to prevent recurrence of problems and address complaints; and
3. Discussion of assessment reviews with staff.

- Safety information; and
- Patient testing records:

a. Requisition (patient charts may be used);

b. Work records (direct printouts); and

c. Patient test reports (patient charts may be used)

6102.2 – Survey Due to Unanticipated Events

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The SA or *CMS* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Changes in location of a laboratory within a State do not ordinarily require a special onsite survey. The laboratory is expected to continue to uphold the standards of operation detailed in its most recent survey. An onsite 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 onsite visit is performed, the SA conducts a complaint survey focusing on the issues that led to question the laboratory's

ability to maintain standards. The SA documents the justification for performing special onsite surveys and maintains this documentation in the laboratory's official file.

6102.4 – Change of Testing Performed by a Laboratory

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If a laboratory, other than a laboratory with a Certificate of Waiver *(CoW) or PPM*, begins to perform additional tests, a SA survey or resurvey may be required. (For laboratories with a Certificate of Waiver that want to expand services to include nonwaived testing, see *section* 6014 and *section* 6018). 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 - Announced and/or Unannounced Surveys

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Section 353(g)(1) of the *PHSA* provides for either announced or unannounced surveys, but it is generally CMS' policy to use announced surveys. Complaint *and onsite follow-up/*revisit surveys must be conducted on an unannounced basis. For either an initial CLIA survey or recertification CLIA survey, an unannounced survey may be performed after one appointment is cancelled by the laboratory. For announced surveys, allow up to two weeks' notice.

*T*he laboratory should be notified in writing (e.g. email, mail*, etc.*) and followed up by telephone *as necessary*. Notification **may** include the actual date and time of the survey. Use this communication to notify the laboratory about the potential consequences of cancelling an appointment. Request that the laboratory notify the SA, as appropriate, if its laboratory operations are not conducted during usual hours of operation or only on specific days and times. Surveys are to be conducted during the laboratory's routine hours of operation. Confirm the laboratory's certificate type and advise the laboratory to notify the SA of any changes that would necessitate a different certificate.

Validation surveys of accredited or CLIA-exempt laboratories are typically announced, except for simultaneous validation surveys of laboratories accredited by certain accreditation organizations (See *sections* 6227.3.1 - 6227.3.2). In cases where there is significant evidence of noncompliance in the survey findings of the accreditation organization or CLIA-exempt *SA*, *CMS* has the latitude to treat such a survey as a complaint survey, which is unannounced. (See SOM Chapter 5 "Complaint Procedures" for guidance regarding complaint investigations.)

6106.1 - Testing Outside the Certificate Type

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

In accordance with 42 CFR 493.1775, if it is verified that the laboratory that has been issued a *CoW* or a Certificate for *PPM* Procedures 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 requesting an appropriate certificate. If the laboratory fails to do so within 30 days, the SA enters a complaint survey into *the CLIA Data System and* recommends referral to *CMS*. The SA completes a Statement of Deficiencies and Plan of Correction (Form CMS-2567) to indicate the findings of the survey and solicits a PoC or AoC from the laboratory. The SA attaches any documentation that can be used in the adverse action process to substantiate the recommendation to the survey kit and puts a check mark in the kit as "*Forward to RO*." The SA notifies *CMS* that *CMS* needs to review the kit for enforcement. The SA refers to *section* 6014 if the laboratory wants to add nonwaived tests.

6106.2 - Accredited Laboratories

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Laboratories accredited by a CMS approved organization are deemed to meet the requirements of 42 CFR Part 493. When *CMS*/SA receives notification from a laboratory, which was previously inspected by *CMS*/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 *CMS*/SAs biennial survey schedule. A laboratory requesting a change from a Certificate of Compliance *(CoC)* to a Certificate of Accreditation *(CoA)* remains under CMS' jurisdiction until the *c*ondition-level deficiencies are corrected. If any standard-level deficiencies are pending, 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., *c*ondition-level non-compliance exists, the matter is referred to *CMS*. A laboratory's accreditation cannot be recognized until it has corrected its *c*ondition-level deficiencies.

Withdrawal or Denial of Laboratory Accreditation

When an accreditation organization withdraws or denies a laboratory's accreditation, *CMS* will authorize the SA to conduct a complaint investigation to determine compliance with all CLIA requirements. (See SOM Chapter 5, "Complaint Procedures"). *CMS* 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 and processes the change in certification type.

6106.3 - CLIA-Exempt Laboratories

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Laboratories exempt through an approved State licensure program are subject to validation

surveys conducted by *CMS* or its designee. A validation survey of a CLIA-exempt laboratory is conducted to ensure that the exempt laboratory meets CLIA compliance. *CMS* laboratory surveyor applies the CLIA regulations during a validation survey. When *c*ondition-level deficiencies are determined, CMS directs the State to take appropriate enforcement action. (See *section* 6208)

6108 - Laboratory Refuses to Allow Survey

((Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 *CMS*, i.e., by email, telephone, or fax. The CLIA regulations at 42 CFR 493.1771 and 493.1773 permits the SA to cite the laboratory for refusal to allow a survey on a *Form* CMS-2567. In addition, the regulation at 42 CFR 1001.1301 permits 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. *CMS* will make the referral to the OIG. (See *section* 6270)

6110 - Survey Team Size and Composition

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Each SA surveyor must meet the education and training qualifications in *Chapter 4, section* 4009. If more than one surveyor is performing the survey, all surveyors are to survey together during the same time interval.

6112 - Pre-Survey Preparation

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Prior to each survey, review the laboratory's file, including CLIA-database information. To determine the size of the survey team and the expected time required for the survey, consider the number of sites under the certificate, the scope and volume of testing, and the test complexity.

1. **Personnel -** Include the completed or updated Form CMS-209 in each survey package. Use this information during the onsite survey to evaluate positions currently held by employees in accordance with the requirements. Focus on new personnel since the last survey.

2. **Services Offered** - Review the CLIA application, the list of tests and specialties/subspecialties, *laboratory services manual,* and any

correspondence from the laboratory to determine the complexity of tests performed. Ascertain whether the laboratory has changed analytes, specialties or subspecialties, or added/deleted tests or procedures since the last survey.

3. **PT** - Review PT records to ensure that the laboratory is enrolled and participating in an approved program for each PT listed in Subpart I, specialty, subspecialty, analyte, or test for which testing is performed. Note any unacceptable, unsatisfactory, or unsuccessful scores and any specialty, subspecialty, analyte or test that is not evaluated by the proficiency testing program provider. Use this information to target particular tests for review during the survey.

4. **File Review**-Evaluate the laboratory's ability to maintain compliance between surveys by reviewing its file for:

   - Previous survey results, *allegations of compliance,* and plans of correction by noting patterns, number, nature of deficiencies, and dates of correction;

   - Enforcement action(s) taken or in progress, e.g., limitations of the certificate or voluntary withdrawal of a specialty, subspecialty, analyte or test due to unsuccessful proficiency testing or loss of qualified personnel; and

   - Complaint allegations noting frequency, significance, severity and, if substantiated, the resolution.

5. **Initial Survey -** Preparation for an initial survey may focus on the personnel qualifications, verification of data in the Form CMS-116, specialty/subspecialties, test volumes, and any correspondence with the laboratory prior to the survey.

6114 - Entrance Interview

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The entrance interview sets the tone for the entire survey. Be prepared, positive, courteous, and make requests, not demands. Upon arrival, present the appropriate identification, introduce other team members, inform the facility's administrator, director, or supervisor of the purpose of the survey, the time schedule, and explain the

survey process. Identify a contact person and establish a communication level based on the degree of technical knowledge of the contact person.

If the laboratory consists of multiple testing sites, verify all information concerning testing performed at each site. If one or more sites do not meet the multiple site exceptions in the regulations (42 CFR 493.35(b), 493.43(b) and 493.55(b)), explain the reason and have the owner/operator/director complete Form CMS-116 for each applicable site. (Refer to *section 6010* for information concerning conducting surveys of multiple testing sites under one certificate.)

Inform the laboratory that the survey will include a tour of the *laboratory*, record review, observation, and interviews with personnel involved in the preanalytic, analytic, and postanalytic phases of the testing process. Establish personnel availability and discuss approximate time frames for survey completion. Determine whether the deficiencies, when identified, are to be discussed with testing personnel, and explain that an exit conference may be held to discuss survey findings. Refer to *section* 6124 and *section* 6126, for additional information regarding the exit conference.

Request that the laboratory collect any documents, records, or information that may be needed to complete the survey and solicit and answer any questions the laboratory may have concerning the survey process.

6116 - Information Gathering

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The technique for information gathering includes observation, interviews, and record review and these are usually performed concurrently. The information gathering process is critical in the determination of quality laboratory testing. Gather sufficient information to evaluate the laboratory's operations without being overly intrusive or gathering excessive information. As each laboratory is unique in the services offered, the order of gathering information may be different for each survey. The timing for observing testing and the availability of staff for interview may determine the sequence of the survey.

Consider the laboratory's compliance history (including, but not limited to, deficient practices and Plans of Correction). Verify the correction of all previously cited deficiencies and continued compliance with CLIA regulations. Pay particular attention to deficiencies that the laboratory has failed to correct. Refer to enforcement requirements at 42 CFR Part 493, Subpart R, if needed.

6116.1 - Organizing the Survey

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Consider the following variables when making determinations for organizing the survey and the areas to be reviewed:

- Purpose of the Survey:
    - *a.* Initial or recertification:
    - *b.* Complaint;
    - *c.* Follow-up; and/or
    - *d.* Validation.
- Pre-Survey Information:
    - *a.* Problematic PT;
    - *b.* Previous survey deficiencies;
    - *c.* Complaints; and/or
    - *d.* Enforcement actions.
- Size and Organization of the Laboratory:
    - *a.* Type of instruments/test procedures;
    - *b.* Type of information system(s);
    - *c.* Number of supervisors and testing personnel;
    - *d.* Number of testing sites;
    - *e.* Scheduling of testing (e.g., Stat, daily, weekly shifts);
    - *f.* Number of specialties/subspecialties;
    - *g.* Test volume;
    - *h.* Record availability; and/or
    - *i.* Type of patients/clients served.

6116.2 - Observation of *Laboratories* and Processes

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Observe the laboratory's physical layout. These observations should include specimen collection and processing, "prep" and clean-up areas, testing and reporting areas, and storage areas. Whenever possible, observe specimen processing and test performance, noting information which would precipitate revisiting an area, interviewing personnel,

or requesting records for review. Observe and verify that reagents, kits, and equipment correlate with test menu, clients served, and results reported. Also observe whether staffing and space appear adequate for test volume. Schedule the survey date/time to observe personnel performing specimen processing, testing, and reporting of results in each specialty/subspecialty of service. If it is not possible to observe testing, ask for a verbal walk-through of the procedure. Do not distract staff when observing operations and personnel activities.

Focus observations on:

- Specimen integrity;
- Quality control performance;
- Skills and knowledge of personnel regarding:
    - *a.* Performance of testing;
    - *b.* Evaluation of test results;
    - *c.* Identification and resolution of problems; and
- Interactions of personnel regarding:
    - *a.* Availability of supervisor to staff;
    - *b.* Communication among personnel at all levels within the laboratory and with clients; and
    - *c.* Interaction of laboratory director in laboratory's operations.

At all times respect patient privacy and do not interfere with patient care and confidentiality.

6116.3 - Interviews

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Interview the staff to confirm observations and obtain additional information, as necessary. Obtain information to identify personnel interviewed, such as name or code.

Ask open-ended questions, e.g., probes from the *interpretive* guidelines, and if necessary, repeat or restate the response given by the *laboratory personnel* to confirm what was said. Information obtained through interviews can provide evidence to support a deficiency. The surveyor must document who was interviewed and should note the specific date and time of the interview or confirmation.

During the interview of personnel, evaluate their knowledge and skills for performing tests, identifying problems and the methods for corrective and remedial actions. Interviews should include as many staff members as necessary to form a judgment as to the ability of staff to perform their duties. Determine the validity of any allegations prior to leaving the laboratory. Do not cite deficient practices without verification. Extend the original survey to investigate the allegation of non-compliance.

6116.4 - Record Review

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Gather relevant information that will reflect the laboratory's ability to provide quality testing from all areas of the laboratory including records encompassing the time period since the last certification survey. Determine all new tests, new test methods, and new equipment added since the prior survey and review documentation relevant to as many of these factors as possible when reviewing laboratory records. The *number* of records selected and reviewed is not intended to be statistically valid, but rather a representative cross-section of various records.

Avoid predictable patterns of gathering information (e.g., same tests or time periods). Do not allow the laboratory to select the records for review. Consider the types of clients and/or facilities that the laboratory serves, e.g., nursing homes, pediatric, dialysis units, public health clinics, and cancer clinics. Choose a variety of patient records across the laboratory's spectrum of clients. When test information must be gathered from medical records, be considerate when handling these records, as they contain confidential information. If possible, review medical records in the presence of office or laboratory personnel with consideration for confidentiality.

Subpart K delineates the laboratory's responsibility for performing its own internal reviews. This is an excellent starting point for an outcome-oriented survey. Review a cross-section of information selected from records of quality system assessment activities within each of the four systems. Review a cross-section of information while simultaneously assessing the laboratory's ability to provide quality test results as well as its ability to identify and correct problems. Refer to the quality system assessment portions of the regulations as a guide for organizing your selection and review of information to assess the laboratory's overall compliance. Investigate further any problems identified but not addressed by the laboratory's quality system assessment. If the laboratory is failing to effectively monitor its own system and correct its problems, you can direct the laboratory to the requirements and the relevant sections for its particular setting.

Make copies of any records needed to support deficient practice findings.

Ensure that reviews of PT (Subpart H), Facility Administration (Subpart J), Quality System (Subpart K), and Personnel (Subpart M) include the following:

1. *PT*

Laboratories must be appropriately enrolled and participating in a CMS approved PT program(s) for each Subpart I analyte, specialty and subspecialty that they perform.
Laboratories also must perform biannual accuracy verification that meets 42 CFR 493.1236(c)(1) for any nonwaived tests that they conduct, that do not fall under Subpart I. Verify that both requirements have been met for the entire period of time the laboratory has been performing each test or procedure (not just shortly before the survey).

If the laboratory has unacceptable PT scores or unsatisfactory performance in a specialty, subspecialty, analyte, or test since the last survey, review the specific record, corrective action, and any other data such as education and training of staff associated with PT remediation. Include both patient test results and QC records which were assayed in the same run as the failed PT in the review. In addition:

- Verify that the laboratory has reported results under the appropriate methodology/instrumentation used for test performance, e.g., automated vs. manual hematology;

- Verify that the laboratory did not engage in inter-laboratory communications regarding the PT sample(s) prior to the event cut-off date;

- Verify that the laboratory did not refer its PT samples to another laboratory for testing prior to the event cut-off date;

- Verify that PT samples were handled, prepared, processed, examined, tested, and reported, to the extent practical, in the same manner as patient samples. PT samples must not be sent to another laboratory for analysis prior to the event cut-off date; and

- For tests where there is no PT available and/or those nonwaived tests performed by the laboratory that are not included in Subpart I, determine whether the laboratory verifies the accuracy of each test or procedure at least twice a year.

2. Facility Administration

Review records for the appropriate retention times and ensure the laboratory adheres to appropriate safety, arrangement, space, ventilation, and contamination procedures. If the facility provides transfusion services, verify that the arrangement is current, the blood products are stored appropriately, and transfusion reactions are investigated and reported to the appropriate authorities in a timely manner.

3. Quality System

General Laboratory, Preanalytic, Analytic, and Postanalytic System Quality Assessment-

Using the patient test requisitions, test records, test results, and test reports or, as applicable, patient charts, review all phases of the laboratory testing processes, including instructions for specimen storage. If possible, when reviewing individual patient test results, correlate test requisition(s) or medical record information with final report(s).

Refer to Postanalytic Systems Quality Assessment for guidance in reviewing and correlating patient test results. After determining the patient population serviced by the laboratory, e.g., geriatrics, public health clinics, dialysis units, health fairs, and hospitals, review the following:

- A cross-section of patient test results encompassing all specialties and subspecialties of testing performed in the laboratory in sufficient numbers to determine if results vary significantly from expected population norms;

- Worksheets or instrument printouts, looking for outliers, trends, etc., when tests are performed in batches;

- Several worksheets, instrument printouts, or medical records over time for tests performed at random;

- Test results that are disproportionately abnormal or normal; and

- The correlation of initial test results and/or test results of various analytes of a patient over time.

Review QC practices and evaluate whether the laboratory is following its own QC protocols or those procedures specified by the manufacturer. Review QC results, including outliers, shifts, trends, and corrective actions taken, when necessary.

Refer to the establishment and verification of performance specifications at 42 CFR 493.1253 for guidance in reviewing the laboratory's policies and criteria for adding a new method, test system or analyte to its test menu.

Correlate reported patient test data with QC data and/or quality systems assessment

records to ensure proper performance and documentation of controls. Review original test data (instrument printouts or computer files). Verify that patient results have not been reported when QC data was unacceptable according to the laboratory's protocol.

Consider the following in relation to the laboratory's patient population:

- New methodologies and equipment;
- QC and calibration materials used;
- Source and availability of QC limits;
- Evaluation and monitoring of QC data; and
- Corrective action for QC failures.

Personnel:

Review personnel records to determine compliance regarding whether individuals in *the* positions *listed on the Form CMS-209* meet the CLIA personnel qualification and responsibility requirements stated in 42 CFR, Part 493, Subpart M. This includes the positions of laboratory director (LD), clinical consultant (CC), technical supervisor and consultant (TS, TC), general supervisor (GS), testing personnel (TP), cytology general supervisor (CGS), and cytotechnologist (CT). The process for verification of personnel qualifications requires surveyors to observe direct evidence of meeting academic requirements. Laboratories are required to complete the *Form* CMS-209 listing all testing personnel, individuals in the above positions, and ***including any contract personnel***. Refer to subpart M for additional information concerning personnel training, experience, competency, qualifications, and responsibilities.

General Qualification Guidance

- When initially surveying the laboratory, surveyors evaluate the qualifications of the LD, TS or TC, CC, GS, CT, CGS, and a sample of TP (including point of care personnel and respiratory therapy technicians, if applicable). Surveyors are NOT required to evaluate qualifications for every TP.

- For subsequent surveys, surveyors evaluate all changes to personnel (for the positions of LD, TS or TC, CC, GS, CT, CGS) that have occurred since the previous survey, in addition to another sample of TP (including point of care personnel).

- Certain laboratory positions are **NOT** evaluated by the surveyor; examples include phlebotomists.

- Request appropriate documents to be provided within a reasonable timeframe (such as the time it takes to complete a survey or within one week afterwards). Appropriate documents include but are not limited to: academic credentials such as degrees and transcripts.

- Qualifications need only be provided at the highest level of academic achievement applicable to CLIA for the position held by the individual. It is not necessary to review a high school diploma, for example, of an individual whose position requires an advanced degree.

- Laboratories are required to maintain documentation on its personnel in addition to paper records on point-of-care testing personnel that perform testing throughout a medical facility.

- Surveyors may not require an individual to test for and obtain a General Education Degree (G.E.D.). If records for a high school diploma or G.E.D are not available and a high school diploma or G.E.D. is required, **this individual is not qualified.**

- If a high school is closed, it is possible for the individual to solicit documentation from the local school board or State Board of Education to verify graduation.

Primary Source Verification

Primary source verification (PSV) is the process of confirming an applicant's credentials by verifying that a degree, certificate, or diploma was received; that licenses were granted; and, by confirming reported work history, such as company names and locations, dates, and positions held. Verifications are obtained either directly from an institution, former employers, or their authorized agents.

Laboratories may choose to use PSV to confirm personnel credentials and provide surveyors PSV documentation as evidence of compliance with the personnel requirements stated in 42 CFR, Part 493, Subpart M. The use of a PSV report as evidence of meeting CLIA personnel qualifications is **optional** for the laboratory. Surveyors will continue to accept direct observation of documents, and the laboratory may also achieve compliance through a combination of the two.

- **NOTE**: The PSV company is **NOT** responsible for determining whether a given individual meets the personnel requirements under CLIA; PSV

companies merely confirm that the asserted training, degrees, and credentialing have been achieved or conferred.

- It is always the responsibility of the laboratory to ensure that its personnel meet the CLIA requirements, and CMS, its agents and accreditation organizations retain full authority to determine compliance with those requirements. The PSV report is one tool that can be used by the surveyor and laboratory to determine if the applicant meets the personnel requirements. The laboratory is responsible for ensuring that individuals' qualifications meet the personnel requirements.

- CMS is not issuing standards to be applied to PSV companies - laboratories are responsible for assessing the services offered by PSV companies.

- As needed, surveyors will continue to ask LDs to provide additional documentation on their employees' qualifications when they find the PSV reports inadequate to confirm compliance.

- If there are required elements in the personnel regulations that the PSV company does not verify, it is the LD's responsibility to ensure that these personnel qualifications are met by other means.

- Each LD should collect and maintain documentation and records as may be necessary to provide any information that is not included in the PSV report. Laboratories electing to use the PSV option must maintain either paper or electronic reports from the PSV company.

- **NOTE: Not all personnel qualifications will be verifiable by a PSV company.** Based on our current understanding, PSV companies do not verify transcripts. Laboratories need to be aware that, even if they choose to use PSV, personnel may still need to produce documentation that cannot be verified by PSV companies for those positions in which a transcript is necessary to qualify the individual. Ultimately, the LD is responsible for making sure that personnel qualifications are met for each position and that there is available evidence of the qualifications.

Additional Qualification Guidance

- **Professional Certification and State Licensure Requirements -** An individual's professional certification, such as medical technology certification or nursing licenses, as the only type of documentation to meet the CLIA personnel requirements, documentation **IS NOT** necessarily considered sufficient evidence of meeting all applicable personnel qualifications. More detailed information, such as degrees, transcripts, or PSV documents verifying degrees and transcripts, are required.

  One exception to this exists where professional certification is required by the CLIA regulations: for example, CT and cytology CGS positions may require American Society of Clinical Pathology (ASCP) certification**, in addition** to documentation of their highest level of academic achievement in education, training, and experiential requirements.

  When the CLIA regulations specify that the individual must possess a license for any personnel in Subpart M (e.g., laboratory director, testing personnel), **if required by the State**, such as a physician (M.D., D.O., DDS) Midlevel practitioner (as defined at 42 CFR 493.2), testing personnel or otherwise, the laboratory need only produce a copy of the individual's State license or a report from a PSV company verifying the State license. No further academic documentation, such as diploma or transcripts, is required.

- **Nursing *Degrees* -** A bachelor's degree in nursing *from an accredited institution* meets the requirement *for moderate complexity testing personnel at §493.1423(b)(2).* The laboratory may show a PSV report verifying that a bachelor's degree in nursing was earned, a diploma with the type of degree earned, or transcripts as evidence of meeting the education personnel requirement.

  An associate degree in nursing *from an accredited institution* meets the requirement for moderate complexity testing personnel at *§493.1423(b)(4).* The laboratory may show a PSV report verifying that an associate degree in nursing was earned, a diploma with the type of degree earned, or transcripts as evidence of meeting the education personnel requirement.

- **Federal Laboratories -** The regulation at *42 CFR* 493.3(c) states that "laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate." Therefore, with respect to the employment of physicians and similar medical and scientific professionals in federal laboratories, the Secretary's noted discretion in applying CLIA

regulations to federal laboratories would offer other federal agencies a means for adopting hiring criteria that only require possession of a valid license in one state in order to work in any federally operated laboratory.

- **Home Schooling -** There is no standardized approach to home schooling across the country. Should a surveyor be presented with a home school diploma, in general, they would accept the home school diploma at face value and focus on the employee's training and competency. At this time, CMS is not aware of any primary source verification company that verifies home school programs.

- **Military Training -** Primary source verification companies are able to verify most military schooling and training. If the PSV company is unable to provide verification of the successful completion of an official U.S. Military medical laboratory procedures training course of at least 50 weeks duration and that the applicant has held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician), (42 CFR 493.1423(b)(5) for moderate complexity testing and 42 CFR 493.1489(b)(4) for high complexity testing), the laboratory must present documentation that the testing personnel has the qualifications to meet the CLIA personnel requirements.

- **Regents Bachelor's Degree (RBD) -** *The* RBD, *which* is a baccalaureate degree program designed for adult students, *is one example of a non-traditional degree which would be evaluated using the education algorithm.* The basic principle *of RBD* is that credit is awarded for what students know regardless of how that knowledge was obtained. In other words, students may earn college-equivalent credit for work and life experiences that can be equated to college courses. It is designed to provide students with a comprehensive general education. Many times, no specific courses are required for graduation, allowing students to design their own programs of study. This degree is usually awarded by a Board of Regents of an accredited institution. CLIA regulations require that a bachelor's degree be from an accredited institution. The RBD may meet this requirement. However, CLIA also requires that the bachelor's degree be in a "chemical, biological, clinical *or medical* laboratory science, or medical technology *from an accredited institution."*

Compliance with Personnel Requirements

If the surveyor identifies potentially serious isolated or pervasive test quality problems

that may be attributed to unqualified or untrained individuals performing or directing the laboratory's testing, the surveyor may request such documentation as may be necessary for the surveyor to confirm compliance with the personnel requirements.

Mandatory Citations

A laboratory is considered to be non-compliant if: a required position is not filled, if an individual does not meet the required qualifications for that position (such as education, training and experience).

Noncompliance with personnel regulations must be cited at the condition level if not met; i.e., the individual does not meet the required education, training, or experience, the position is not filled. The list of mandatory citations is at *section* 6130.5. As indicated in the list, **both the condition level AND standard level deficiencies must be cited.**

Practical Application of the Personnel Qualification Determinations

Surveyors are instructed to cite the most appropriate mandatory deficiency(s) if the laboratory does not meet the personnel requirements for the CLIA position categories which are included on *Form* CMS-209. Some examples are included here, though this is not an exhaustive list.

Example 1: A CLIA surveyor is evaluating a sample of TP qualifications in a moderate complexity laboratory and is presented with a home school diploma as evidence of compliance. What would the surveyor do?
Answer: Surveyor would accept the diploma at face value and focus on the testing personnel's training and competency.

Example 2: A CLIA surveyor is evaluating a sample of TP qualifications in a high complexity laboratory and is presented with proof of a medical technology degree from an accredited institution. Does this degree satisfy the personnel requirement or are transcripts needed?
Answer: Yes, a medical technology degree from an accredited institution is sufficient. A PSV report verifying a medical technology degree from an accredited institution would also meet the requirement.

Example 3: If a laboratory is applying for a CLIA certificate and the LD is not board certified, but is board eligible, what evidence is needed for CMS to issue a Certificate of Registration?
Answer: If an LD is only eligible to be board certified, the PSV Company may not be able to verify eligibility status. The LD would need to provide the documentation of training and experience required by the board to be eligible to take such examinations.

Example 4: A laboratory is hiring a military trained medical laboratory technician. What evidence is needed for the laboratory to maintain compliance with CLIA personnel qualifications? Answer: Primary source verification companies are able to verify most military schooling and training. If the PSV company cannot verify the

successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and that the applicant has held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician), the laboratory must present documentation that the testing personnel has the qualifications to meet the requirement.

Example 5: A CLIA surveyor evaluating qualifications of a nurse performing moderate complexity laboratory testing is presented with a nursing license as evidence of compliance. What would the surveyor do?
Answer: CLIA surveyors **do not** accept nursing licenses as evidence of compliance. The laboratory must provide the surveyor with a PSV report verifying the type of degree earned, a diploma showing the type of degree earned, or transcripts as evidence of meeting the personnel requirement.

Example 6: A CLIA surveyor is evaluating a sample of TP qualifications in a high complexity laboratory and is presented with a report from a primary source verification company. The report verifies that the TP has a degree in Medical Technology from an accredited university and that the TP has worked for 3 years as a medical technologist at a hospital. Does this report satisfy the personnel requirement or are transcripts needed?
Answer: Yes, the PSV company report is sufficient; no further evidence is needed.

Example 7: A CLIA surveyor is evaluating a sample of TP qualifications in a high complexity laboratory located in a state that requires licensure for medical technologists. The surveyor is presented with a PSV company report that verifies the TP's State license as evidence of meeting the personnel requirement. Does the surveyor also need to see further evidence of education, such as degrees or transcripts?
Answer: No. It is acceptable for the laboratory to present the surveyor with a PSV report verifying State licensure. The State license would also be acceptable. For laboratories in states that require licensure, no further academic documentation, such as diploma or transcripts, is required.

Example 8a: A CLIA surveyor is evaluating LD qualifications in a high complexity laboratory located in a state that requires licensure. The surveyor is presented with a PSV report verifying the LD's State license as evidence of meeting the personnel requirement. Does the surveyor also need to see further evidence of education, such as degrees or transcripts?
Answer: No. It is acceptable for the laboratory to present the surveyor with only a PSV report verifying State licensure. The State license would also meet the requirement. For laboratories in states that require licensure, no further academic documentation, such as diploma or transcripts, is required.

Example 8b: A CLIA surveyor is evaluating LD qualifications in a high complexity laboratory located in a state that requires licensure. The LD is a foreign trained physician. The surveyor is presented with a PSV company report verifying the LD's State medical license as evidence of meeting the personnel requirement. Does the LD also need to produce foreign educational equivalencies?

Answer: No. It is acceptable for the laboratory to present the surveyor with only a PSV report verifying State medical licensure. The State medical license would also meet the requirement. Foreign trained physicians (MD, DO, DPM or DDS) who are licensed to practice medicine in the State in which the laboratory is located do not need to produce educational equivalencies. The state medical license is also sufficient proof of academic achievement.

Example *9:* A CLIA surveyor is evaluating TP qualifications in a high complexity laboratory. The surveyor is presented with a PSV report verifying that the TP received a bachelor's degree from an accredited university in 2008. Is this sufficient evidence of meeting the personnel requirement?
Answer: No. Regulation §493.1489(b)*(2)(i)* states that high complexity testing personnel will have earned a "…bachelor's degree in a chemical, biological, clinical *or medical* laboratory science, or medical technology…" The documentation in the PSV report did not state the type of *bachelor's* degree earned. The surveyor would need to look for additional evidence of the type of bachelor's degree earned, a diploma showing the type of degree earned, or transcripts. Just having evidence of a *bachelor's* degree does not meet the personnel requirement.

6116.5 - Credentialing of Foreign Trained Laboratory Personnel

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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.

Nationally recognized evaluation organizations and their affiliates should perform the academic credential evaluation on a course-by-course basis. Nationally recognized evaluation organizations include but are not limited to the National Association Credential Evaluation Services, Inc. (NACES) (http://www.naces.org) and the Association of International Credential Evaluators, Inc. (AICE) (http://www.aice-eval.org). Other organizations may be available and may be able to be confirmed through research on the Internet (See Appendix C).

The laboratory should maintain a copy of the course-by-course foreign-trained equivalency evaluation/determination in the laboratory records.

Laboratories may also choose to use a primary source verification company for verifying foreign trained personnel, so long as the PSV relies on the same type of course-by-course evaluation to confirm and document the foreign degree's equivalency to the personnel qualifications.

- Foreign trained personnel that have a PhD equivalent must hold current HHS-approved board certification or meet the regulation at 42 CFR §493.1405(b)(3) or 42 CFR §493.14*4*3(b)(3).

- Foreign trained physicians (M.D., D.O., DDS) who are licensed to practice medicine in the State in which the laboratory is located do not need to produce educational equivalencies. A valid State medical license is sufficient proof of academic achievement.

- With the exception of licensed physicians, other moderate and high complexity testing personnel who attended a foreign school still need to have foreign equivalencies done.

- Each person examining cytology slide preparations must meet the qualifications of 42 CFR §493.1449(b) or *(e)* or *42 CFR §493.1483(a) and (b)(1) or (b)(2) or (b)(3).*

6116.6 - During the Survey

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The surveyors should allow laboratory personnel to accompany them during the tour of the facility. The tour of the facility should include observation, record review and interviews with personnel involved in preanalytic, analytic and postanalytic phases of testing. Managerial staff generally should not 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. Laboratory personnel should give the surveyors privacy as needed when the surveyors discuss their survey findings. Conversely, if the laboratory personnel harass surveyor(s), argue about observed problems, and make the survey more difficult, the surveyor should remove themselves from the difficult and or hostile environment.

6116.7 - Assessing Outcome or Potential Outcome

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If the information gathered indicates that the laboratory has established, implemented, and maintained appropriate ongoing mechanisms for ensuring quality test results by monitoring, evaluating, and resolving any problems in its practices, and findings do not warrant a more in-depth review, conclude the survey. However, if an assessment of the laboratory's performance cannot be made based on the cross-section of information collected, it may be necessary to expand the cross-section (e.g., number of sites, observations, or number of records). If the findings reveal potential problem areas with any test procedures, ensure the review is sufficient in breadth and depth to substantiate whether a negative or potentially negative outcome exists.

If a problem or potential problem related to patient test results is found, determine the

nature and seriousness of the problem.

The OOSP allows the freedom to increase or decrease the number and types of records reviewed, the personnel interviewed, and the observations made as individual needs are identified.

Analyze the findings for the degree of severity, pervasiveness, comparison with historical survey results, frequency of occurrence, and impact on delivery of services, i.e., accuracy, reliability, and timeliness of test results. A single occurrence of a deficiency directly related to a potential adverse impact on patient testing may be cited. On the other hand, some preliminary findings may have so slight an impact on outcome that they do not warrant a citation. However, there are four CLIA *c*ondition-level requirements the surveyor must cite if non-compliance is found, regardless of the presence or absence of any negative outcome or potential harm (see *section* 6130.5 "Mandatory Citations").

Figure 4-1, steps one through four, presents the decision process for whether or not to cite deficiencies during a survey. After a preliminary finding is established by the surveyor, the first step is to determine whether or not it is a mandatory citation. If yes, go to step #5; if no, go to step #2. Step 2 is to determine if the problem or potential problem is related to laboratory testing. If the answer is no, then no deficiency is cited. On the other hand, if the answer to this question is yes, then the third step is to determine if the identified problem does or could potentially impact patient test results. If the surveyor determines there is no impact or potential impact to patient test results, then the surveyor uses the OOSP to determine whether deficiencies should be cited. If the surveyor concludes that there is an impact or potential impact to patient test results, then the fourth step is to determine if the problem may be the result of, or otherwise related to, noncompliance with CLIA regulatory requirements. If yes, then the surveyor must cite a deficiency. If no, then consult with *CMS* on whether other Federal regulations are applicable. If the laboratory is subject to a State Licensure Program, consult with the *SA* supervisor for further instruction.

NOTE: Any condition-level deficiency is an actionable deficiency. Any standard-level deficiency that has an impact or potential impact on patient test results is also an actionable deficiency.

6120.1 - Regulatory Compliance Decision

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

After all necessary information has been collected and the surveyor determines whether any identified laboratory testing-related problems do (or could) negatively impact patient test outcomes, and, if so, whether such problems are due to non-compliance with CLIA, the surveyor will need to determine whether CLIA-related non-compliance driven issues constitute a condition-level deficiency. Review the findings and decide if additional information and/or documentation are necessary to substantiate and

document a standard- or condition-level deficient practice. The number of deficiencies generally does not correlate to whether a laboratory should be found out of compliance with a standard or condition. Standard-level deficiencies require: (1) the documentation of the nature and extent of the deficiencies, if any, with respect to a particular function, i.e., the creation of a list of the deficient practices; and (2) the surveyor to assess the need for improvement in relation to the prescribed conditions, i.e., review standard-level deficiencies to determine condition-level non-compliance. With the exception of the four mandatory condition-level citations discussed in subsection VII.D. below, consider a condition out of compliance as a result of one or more deficiencies if, in your judgment, the deficiency(ies) constitutes a significant or a serious problem that adversely affects patient test results/patient care, or has the potential for adversely affecting patient test results/patient care.

Determining Immediate Jeopardy

Immediate Jeopardy (IJ) represents a situation in which laboratory noncompliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment or death. These situations must be accurately identified by surveyors, thoroughly investigated, and resolved by the entity as quickly as possible. In addition, noncompliance cited at IJ is the most serious deficiency type, and carries the most serious sanctions for laboratories. An immediate jeopardy situation is one that is clearly identifiable due to the severity of its harm or likelihood for serious harm and the immediate need for it to be corrected to avoid further or future serious harm.

Immediate jeopardy is defined in 42 CFR §493.2 as "a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition-level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public".

The regulatory definitions form the basis for identifying three key components that are essential for surveyors to use in determining the presence of IJ. These components include:

- **Noncompliance:** An entity has failed to meet one or more federal health, safety, and/or quality regulations;

  AND

- **Serious Adverse Outcome or Likely Serious Adverse Outcome:** As a **result** of the identified noncompliance, serious injury, serious harm, serious impairment or death has occurred, is occurring, or is likely to occur to one or more identified recipients at risk;

  AND

- **Need for Immediate Action:** The noncompliance creates a need for immediate corrective action by the provider/supplier to prevent serious injury, serious harm, serious impairment or death from occurring or recurring.

(See 42 CFR §493.1812 providing the enforcement actions to be taken when deficiencies pose immediate jeopardy.) Refer to Figure 4-1 for guidance in determining whether to issue condition (and/or standard) citations and what enforcement actions to pursue.

The number of deficiencies does not necessarily relate to whether or not a *c*ondition is found out of compliance, but rather the impact or potential impact the deficiency(ies) has (have) on the quality of laboratory services and the results reported.

Figure 4-1, steps four through six, presents the decision steps for citing deficiencies in relation to patient outcome. In step four, the surveyor cites applicable CLIA *c*onditions, Mandatory CLIA Citations and/or supporting CLIA *s*tandards that are not met by the laboratory. Upon citing *c*ondition(s), step five is to determine whether the situation already caused, is causing, or likely to cause serious injury, harm or death. If yes, step 6 is to proceed with citing Immediate Jeopardy (IJ) along with the *c*ondition-level non-compliance. If the surveyor concludes no IJ is present, proceed with citing *c*ondition(s) as identified under *s*tep four.

When determining if the *c*ondition-level noncompliance reaches the level of immediate jeopardy. The surveyors should ask themselves:

Do the deficient practices result in inaccurate or the high probability of inaccurate, unreliable, or untimely test results?

- Is the situation one in which immediate corrective action is necessary because the laboratory's noncompliance has already caused or is likely to cause serious injury, harm, or death to individuals served by the laboratory?

- Does the laboratory's continued activity(ies) constitute a significant hazard to individuals served by the laboratory or to the public health or safety of the general public?

- Do the deficiencies warrant immediate limitation or suspension of the laboratory's CLIA certificate?

- Is there information or data not available at the time of the survey, or within a reasonable time frame, that must be provided by the laboratory in order to

determine if the deficient practice has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death?

In summary, the steps for regulatory considerations include:

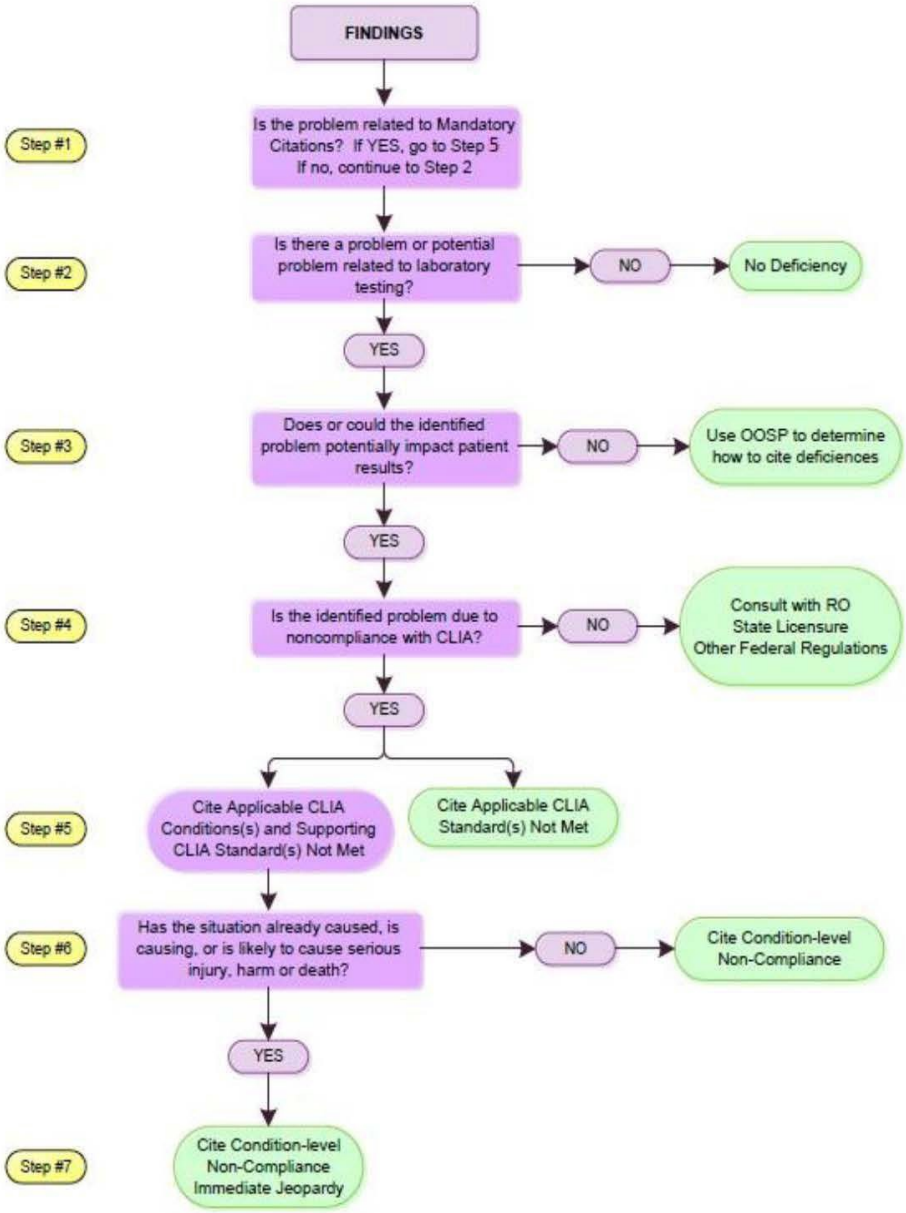
1. Are CLIA regulatory deficiencies identified?

2. Does the deficiency(ies) constitute(s) *c*ondition-level non-compliance?
    - Do the deficiencies prevent certification?

3. Does the *c*ondition-level non-compliance pose an immediate jeopardy to patient health and safety?
    - Is there an option for other enforcement remedies?

Refer to Revisions to Appendix Q, Guidance on Immediate Jeopardy, for further information.

Figure #4-1 Decision Algorithm for Laboratory Citations



6124 - Preparation for Exit Conference

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Prior to the exit conference, the surveyor(s) review *the* findings and come to a consensus on the seriousness and extent of the deficiencies and whether the number, character, or combination interferes with accurate and reliable laboratory test results. Deficiencies found in more than one *c*ondition or standard may be cumulative and interrelated and result in general, pervasive inadequacies in determining test results.

6126 - Exit Conference

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The purpose of the exit conference is to provide an overview of your findings with the laboratory. It is not meant to be an exhaustive discussion of your findings. It is the continuation of the survey process and is the first opportunity for the laboratory to present additional information in response to the findings. Acknowledge staff cooperation and operational support, as appropriate, before addressing the non-compliance issues. The exit conference is also the beginning of the period during which corrective action can be taken if the laboratory is to be subject to a corrective or an enforcement action.

If immediate jeopardy or condition-level deficiencies are identified, inform the laboratory of the seriousness of the problem(s)/finding(s) and indicate that they are not final until receipt of the written statement of deficiencies Form (CMS-2567). 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.

If the surveyor(s) calls IJ at the time of the onsite survey, the IJ Template in Appendix Q must be used. If the surveyor(s) determines that IJ exists after leaving the onsite survey, upon review of the information and evidence collected at the onsite survey, the completed template must be given to the laboratory at the time IJ is determined. This may be done electronically. CLIA surveyors are not required to return to the laboratory to deliver the completed template (see CLIA subpart of Appendix Q for sections that do not apply to CLIA). The laboratory will still be notified of the IJ, via written notice, when the Form CMS-2567 is sent to the laboratory requesting an Allegation of Compliance (AoC).

Refer to Revisions to Appendix Q, Guidance on Immediate Jeopardy, for further information.

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 *CMS*/SA with a credible AoC, no revisit will be made and the adverse action process will continue. Consider the following when conducting an exit conference:

- Conduct the exit conference with the facility's administrator, director, consultant, or supervisor, and/or other invited staff;

- Describe the laboratory practices that fail to be in compliance with the regulatory requirements and the findings that substantiate these potential deficiencies. 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;

- Provide the laboratory an opportunity to discuss and provide additional information regarding potential deficiencies. It is the laboratory's responsibility to determine the corrective action(s) necessary to remedy the problem(s);

- Inform the laboratory that they will receive a written statement of deficiencies (Form CMS-2567) with the final deficiencies cited;

- A team member should indicate that the official findings are presented in writing on the Form CMS-2567 and will be forwarded to the laboratory within 10 *working* days. The laboratory must also be informed they are to return the PoC or credible AoC in 10 calendar days *of receiving the Form CMS-2567 Statement of Deficiencies;*

- Given the complexity of the regulations and nature of the survey, the surveyors must indicate to the laboratory that the specific regulatory reference will be found in the Form CMS-2567 report that will be issued to them. The laboratory is informed that the information discussed in the exit interview is preliminary and the lab management will have an opportunity at the exit

interview to talk in general about the issues that were found;

- Inform the facility of your intended recommendation to *CMS* to certify, recertify, or deny certification of the laboratory. 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; and

- At the exit interview, inform the laboratory (director/administrator/supervisor) of changes in test volumes which may result in fee changes.

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. *Please document the reason if no exit conference is conducted.*

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, the surveyor should refuse to continue the conference unless the laboratory agrees to 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.

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.

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

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

- Documents that specific deficiencies were found. If there are no citations, the surveyor(s) 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.

6130.1 - Development of the Statement of Deficiencies

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Choose the most appropriate regulatory citation and corresponding D-tag when documenting a deficiency. For example, if deficient practices are a result of failure of the laboratory to properly perform quality assessment, cite the deficiency using the quality assessment requirements. Note, however, where a laboratory does not have a quality assessment program, one should cite the quality assessment requirements and the laboratory director for not ensuring that the quality assessment programs are established and maintained to ensure the quality of laboratory services provided. If deficient practices are the result of a laboratory's failure to perform (or perform correctly) certain specific tasks or requirements, then cite the deficiency in the specific area of the regulation such as personnel, general laboratory systems, preanalytic systems, analytic systems or postanalytic systems. Supporting information for documenting deficiencies should be complete, clear, and concise. Write deficiency statements in terms that allow a reasonably knowledgeable person to understand the aspects of the requirements that are not met. Avoid writing the same deficiency in several places. Write your statement of evidence following the format described in the Principles of Documentation

Guidelines *https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/principles-of-documentation-oct-2018.pdf*

For some cited deficiencies, the *CLIA Data System* may require that you list the appropriate specialty or subspecialty identifier code(s) and test complexity (moderate, high or both) for each D-tag. **This is applicable to standard and condition-level deficiencies**.

6130.2 - Citing Standard-Level Deficiencies
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

If standard-level noncompliance has been identified, cite the most specific standard available. For instance, if the deficient practice(s) is related to control procedures:

- Cite the appropriate D-tag (D5501 - D5773) for the specialty/subspecialty standards under 42 CFR §§493.1261 through 493.1278, which are Bacteriology,Mycobacteriology, Mycology, Parasitology, Virology, Routine Chemistry, Hematology, Immunohematology, Histopathology, Cytology, Clinical Cytogenetics, and Histocompatibility if such standard is available; OR

- Use the appropriate D-tag (D5401 - D5485; D5775 - D5793) for 42 CFR §§493.1251 through 493.1256 and 42 CFR §§493.1281 through 493.1289, if an appropriate D-tag is NOT available in the specialty/subspecialty standards.

EXAMPLE: A laboratory performs fluid cell counts using a hemocytometer. Use D5543.

EXAMPLE: A rheumatologist performs rheumatoid factor (RF) titers. Use D5451. Where there are underlying standards, condition-level deficiencies can only be cited when standard-level deficiencies have been identified. Remember to cite to standard-level deficiencies when such deficiencies support a finding of condition-level deficiencies.

6130.3 - Citing Condition-Level Deficiencies
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

When the deficient practice is of such a serious nature that correction is a condition for allowing the laboratory to continue with patient testing, cite the most appropriate condition and document the finding using the format in the Principles of Documentation. As stated in the Principles of Documentation, the laboratory must correct all standard-level deficiencies that are used to support the condition-level noncompliance finding before the laboratory can be found back in compliance with the condition.

Options within Subpart K

- Specialty and Subspecialty conditions--Use these conditions when serious deficiencies are identified within the specialty or subspecialty. D5002 - D5042.

- General Laboratory Systems--Use this condition when serious deficiencies are identified within general laboratory systems. D5200.

- Preanalytic--Use this condition when serious deficiencies are identified within the preanalytic phase of testing. D5300.

- Analytic--Use this condition when serious deficiencies are identified within the analytic phase of testing. D5400.

- Postanalytic--Use this condition when serious deficiencies are identified within the postanalytic phase of testing. D5800.

NOTE: A serious deficiency is based on the nature and extent of the deficient practice.

6130.4 - Choosing the Appropriate Condition
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Review the regulatory language at each of the conditions, noting the requirements that must be met for the condition to be in compliance. For example: The condition of Bacteriology at 42 CFR §493.1201 (D5002) states the laboratory must meet the requirements at 42 CFR §§493.1230 (D5200) through 493.1256 (D5485), 493.1261 (D5501 - D5507) and 493.1281 (D5775) through 493.1299 (D5893) (covering General Laboratory Systems, Preanalytic Systems, Analytic Systems, and Postanalytic Systems). Serious problems in one or more of these areas can cause the condition of Bacteriology to be out of compliance.

In comparison, the condition statement for Preanalytic Systems at 42 CFR §493.1240 (D5300) states the laboratory must meet the requirements at 42 CFR §§493.1241 (D5301 - D5309), 493.1242 (D5311 - D5317), and 493.1249 (D5393) for each specialty or subspecialty of testing. Serious preanalytic deficiencies that are pervasive throughout the laboratory (not related to specific specialties or subspecialties) could cause the condition of Preanalytic Systems to be out of compliance. Caution: An enforcement action based on noncompliance with the condition of General Laboratory Systems, Preanalytic Systems, Analytic Systems or Postanalytic Systems could be a revocation or a suspension of the CLIA certificate and would not necessarily be a limitation of the CLIA certificate for one or more specialties.

Standard-level deficiencies written in one subpart cannot be the basis for a condition in another subpart. Deficiencies in Proficiency Testing or Personnel would not be the basis for the condition of Bacteriology to be out of compliance. It is not uncommon for a

surveyor to identify issues that crossover between subparts of the regulations. Cite deficiencies at the appropriate area of the regulations that describes the problem. For example, failures in proficiency testing may be caused by an error in specimen identification, test system malfunction, or lack of training for staff. Consider citing the most appropriate citation for the laboratory to come into compliance. Avoid citing multiple citations for the same deficiency unless each citation focuses on a different aspect of the deficiency (instrument malfunction vs. staff training, or quality system vs. laboratory director responsibilities, as discussed above).

The surveyor must consider the deficiencies cited when determining the conditions out of compliance, and also the potential enforcement actions should the laboratory not correct the deficiencies. The organization of the regulations and conditions allows the surveyor to write a condition out of compliance according to specialty/subspecialty or to the Systems of testing (General Laboratory Systems, Preanalytic Systems, Analytic Systems, or Postanalytic Systems).

EXAMPLE 1:

A laboratory has one or more standard-level deficiencies related to Bacteriology testing in Preanalytic Systems 42 CFR §493.1241 through 493.1249 (D5301-D5393), Quality Control Procedures 42 CFR § 493.1256 (D5441-D5485) and the Bacteriology subspecialty
42 CFR § 493.1261 (D5501-D5507). The surveyor may determine the condition of Bacteriology 42 CFR § 493.1201 (D5002) is out of compliance based on the deficiencies written under all three systems, Preanalytic, Analytic and Postanalytic. Even though the laboratory conducts testing in other specialty or subspecialty areas, by citing the deficiencies under the condition of Bacteriology, the certificate could be limited for the subspecialty of Bacteriology instead of the entire CLIA certificate being affected.

EXAMPLE 2:

A laboratory is cited for one or more standard-level deficiencies in Preanalytic Systems 42 CFR §493.1241 through 493.1249 (D5301-D5393) and the deficiencies are related to practices in all the specialties and subspecialties offered by the laboratory. The surveyor determines the condition of Preanalytic Systems is out of compliance. If the laboratory does not correct the condition-level deficiency in Preanalytic Systems, the enforcement action is against the certificate and not a limitation of a specialty or subspecialty.

EXAMPLE 3:

A laboratory has deficiencies in Bacteriology in the Control Procedures 42 CFR §493.1256 (D5441-D5485), the Bacteriology subspecialty 42 CFR §493.1261 (D5501-D5507), and Routine Chemistry deficiencies in the Control Procedures 42 CFR §493.1256 (D5441- D5485). All deficiencies are within the Analytic System.

The surveyor may determine the condition of Bacteriology 42 CFR §493.1201 (D5002)

is out of compliance based on the deficiencies cited in Control Procedures 42 CFR §493.1256 (D5441-D5485) and also deficiencies in subspecialty areas for Bacteriology 42 CFR §493.1261 (D5501-D5507).

And the surveyor may determine the condition of Routine Chemistry 42 CFR §493.1210 (D5016) is out of compliance based on deficiencies cited related to Control Procedures 42 CFR §493.1256 (D5441-D5485). Even though the D-tags used to determine condition- level noncompliance in Routine Chemistry are cited in the Control Procedures area, the appropriate condition to mark out of compliance is the applicable subspecialty of Routine Chemistry.

If the laboratory performs testing in only the subspecialties of Bacteriology and Routine Chemistry, and if the deficient practices are pervasive, the surveyor may write the condition of Analytic Systems 42 CFR §493.1250 (D5400) out of compliance.

When a specialty or subspecialty condition is out of compliance, the enforcement action chosen may be a limitation to the certificate for the specialty or subspecialty out of compliance. This approach allows the laboratory to continue testing in those specialties and subspecialties in which compliance was determined. A condition-level deficiency in one of the Systems (General Laboratory Systems, Preanalytic Systems, Analytic Systems, or Postanalytic Systems) indicates a pervasive situation through all specialties and subspecialties offered by the laboratory.

6130.5 - Mandatory Citations

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

There are four CLIA *c*ondition-level requirements the surveyor must cite if non-compliance is found, regardless of the presence or absence of any negative outcome or potential harm. The four CLIA *c*ondition-level requirements are: proficiency testing enrollment, proficiency testing referral, unsuccessful proficiency testing participation and issues related to personnel qualifications.

The Mandatory Citations table provides guidance to surveyors for citing the four mandatory CLIA *c*ondition-level citations. Citations should include the *c*ondition citation and the corresponding D-tag. Where appropriate, surveyors should also provide any Standard -level citations under the condition as well as the standard-level D-tag for those standard-level citations.

The mandatory *c*ondition-level citations and D-tags and the *s*tandard-level citations and D-tags that correspond to the three mandatory PT conditions are:

1. Enrollment in Proficiency Testing (D2000) (42 CFR §493.801)

    - No minimum standard-level D-tag required. This is the ONLY mandatory *c*ondition-level citation where no *s*tandard-level D-tag is cited in conjunction

with the *c*ondition-level D- tag.

2. Proficiency Testing Referral (D2000) (42 CFR §493.801)

   - At a minimum cite the Standard at D2013 (42 CFR §493.801(b)(4))

3. Successful Participation in Proficiency Testing (D2016) (42 CFR §493.803)

   - At a minimum cite the Standard at any of the following as applicable: D2028, D2037, D2046, D2055, D2064, D2074, D2084, D2085, D2096, D2097, D2107, D2108, D2118, D2119, D2130, D2131, D2162, D2163, D2172, D2181, D2190 or D2191.

The mandatory *c*ondition-level citations and D-tags, and the potential standard-level citations and D-tags that correspond to the *c*ondition-level personnel qualifications, are:

1. Laboratory Director PPM (D5980) (42 CFR §493.1355)
   - At a minimum cite the Standard at D5981(42 CFR §493.1357)

2. Testing Personnel PPM (D5990) (42 CFR §493.1361)
   - At a minimum cite the Standard at D5991 (42 CFR §493.1363)

3. Laboratory Director Moderate Complexity Testing (D6000) (42 CFR §493.1403)
   - At a minimum cite the Standard at D6003 (42 CFR §493.1405)

4. Technical consultant Moderate Complexity Testing (D6033) (42 CFR §493.1409)
   - At a minimum cite the Standard at D6035 (42 CFR §493.1411)

5. Clinical Consultant Moderate Complexity Testing (D6056) (42 CFR §493.1415)
   - At a minimum cite the Standard at D6057 (42 CFR §493.1417)

6. Testing Personnel Moderate Complexity Testing (D6063) (42 CFR §493.1421)
   - At a minimum cite the Standard at D6065 (42 CFR §493.1423)

7. Laboratory Director High Complexity Testing (D6076) (42 CFR §493.1441)
   - At a minimum cite the Standard at D6078 (42 CFR §493.1443)

8. Technical Supervisor High Complexity Testing (D6108) (42 CFR §493.1447)
   - At a minimum cite the Standard at D6111 (42 CFR §493.1449)

9. Clinical Consultant High Complexity Testing (D6134) (42 CFR §493.1453)
   - At a minimum cite the Standard at D6135 (42 CFR §493.1455)

10. General Supervisor High Complexity Testing (D6141) (42 CFR §493.1459)
    - At a minimum cite the Standard at D6143 (42 CFR §493.1461)

11. Cytology General Supervisor (D6153) (42 CFR §493.1467)
    - At a minimum cite the Standard at D6155 (42 CFR §493.1469)

12. Cytotechnologist (D6162) (42 CFR §493.1481)
    - At a minimum cite the Standard at D6164 (42 CFR §493.1483)

13. Testing Personnel High Complexity Testing (D6168) (42 CFR §493.1487)
    - At a minimum cite the Standard at D6171 (42 CFR §493.1489(b))

MANDATORY CITATIONS

IF YOU FIND NON-COMPLIANCE WITH. . .		YOU MUST AT LEAST CITE THE STANDARD AT D-TAG. . .	YOU MUST AT LEAST CITE THE CONDITION AT D-TAG. . .
Non-enrollment in Proficiency Testing 42 CFR § 493.801			D2000
Proficiency Testing Referral 42 CFR § 493.801(b)(4) *§ 493.801(b)(5)*		*D2012* D2013	D2000
Unsuccessful Participation in Proficiency Testing 42 CFR § 493.803		D2028, D2037, D2046, D2055, D2064, D2074, D2084, D2085, D2096, D2097, D2107, D2108, D2118, D2119, D2130, D2131, D2162, D2163, D2172, D2181, D2190, OR D2191	D2016
Personnel Qualifications - Subpart M	Laboratory Director PPMP	D5981	D5980
	Testing Personnel PPMP	D5991	D5990
	Laboratory Director Moderate Complexity Testing	D6003	D6000
	Technical Consultant Moderate Complexity Testing	D6035	D6033
	Clinical Consultant Moderate Complexity Testing	D6057	D6056
	Testing Personnel Moderate Complexity Testing	D6065	D6063
	Laboratory Director High Complexity Testing	D6078	D6076
	Technical Supervisor High Complexity Testing	D6111	D6108
	Clinical Consultant High Complexity Testing	D6135	D6134
	General Supervisor High Complexity Testing	D6143	D6141
	Cytology General Supervisor	D6155	D6153

	Cytotechnologist	D6164	D6162
	Testing Personnel High Complexity Testing	D6171	D6168

6132 - Certification Actions Performed After the Survey

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The post-survey certification processes are summarized as follows:

- The surveyor completes survey documents. (*S*ee *section* 6136.4 "Survey Report Documentation and Data Entry"); and
- The Form CMS-2567 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.

The SA sends (e.g. emails, mails, fax) the laboratory a copy of the Form CMS-2567 within 10 *working* 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 *after receipt of the Form CMS-2567 Statement of Deficiencies*. If immediate jeopardy is identified, the SA follows the time frames in *section* 6284.

The Form CMS-2567 may be disclosed to the public in accordance with the instructions in Chapter 3, "**Additional Program Activities**." Refer to the SOM Chapter 3 *sections* 3304, 3308, 3308A, 3310, 3312, 3314, 3316 and 3318 for information on disclosure.

Information that may be disclosed to the Public by the SA:

1. Whether a facility participates in the Medicare/Medicaid/CLIA program;
2. The official CLIA report *(Form CMS-2567)* of a survey with the following redactions:
   - The name of any patient;
   - Medical information about any identifiable patient;
   - The identity of a complainant;
   - The address of anyone other than an owner of the facility; or

- Information which could be defamatory toward any identifiable person.

NOTE: The SA reviews the report of survey, and if it contains any of the above elements, it deletes the information from the report by blocking it out fully prior to release of the report. (See 42 CFR 401.118)

NOTE: Prior to release, the laboratory must have had an opportunity to review the report (not exceeding 60 days) and offer comments. The disclosure must be made within 90 days following completion of the survey by the SA.

3. Citations of deficiencies that have been conveyed to the provider following a survey, except to the extent the report contains any of the identifiable information listed above. The SA blocks this information out prior to release of the statement of deficiencies;

4. PoC and pertinent comments submitted by the provider relating to CLIA deficiencies cited following a survey, except to the extent the PoC or comments contain any of the identifiable information listed above. The SA blocks this information out prior to release of the PoC;

5. Official notices of involuntary provider termination;

6. Reports and information about a laboratory's performance in proficiency testing programs (**NOTE**: information about any individual person's performance may **not** be released);

7. Information contained within the CMS manuals distributed to the SAs, intermediaries, carriers, providers, or suppliers; and

8. Statistical data on provider characteristics that do not identify any specific provider or individual.

9. Form CMS-116, CLIA Application for Certification; however, the tax ID must be blocked prior to the release of the application.

10. Form CMS-209, Laboratory Personnel Report (CLIA), may not be released.

Paper or electronic copies of these Federal electronic documents may be released by the SA. Again, any individual identifiers (other than patient/resident or staff alphanumeric identifiers) must be deleted from the information prior to release.

See *section* 6318 for further information on the Freedom of Information Act (FOIA).

NOTE: Standard and User-Defined CASPER reports may also be released by the SA.

6132.1 - Generating the Statement of Deficiencies
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The Form CMS-2567 can be generated using the appropriate module in the ASPEN suite (e.g., ACO, ARO, ACTS, ASE-Q). 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. The SA must always obtain and maintain thorough and comprehensive documentation to support the survey findings and certification decisions to sustain the action in the event of a hearing or judicial review. The SA must use all available sources of information to assist with completing the Form CMS-2567.

6132.2 - Plan of Correction (PoC)
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The laboratory enters its planned action to correct the deficiency and the expected completion date opposite the appropriate data tag on Form CMS-2567. 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 PoC is a "plan" which contains records (documentary materials) that outlines how the laboratory is going to fix the standard-level deficiency(s) therefore, the PoC may have future dates (i.e., after the date of submission). A record includes all recorded information, regardless of form or characteristics, made or received by a federal agency under federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the US Government or because of the informational value of data in them. 44 U.S.C Chapter 33, Section 3301." All records must be kept the period defined by the federal requirements at DAA-0440-2015-0008, which is 7 years, or by State requirements, if more stringent than federal requirements.

There are four elements that are required to be submitted with a PoC. Those four elements are:

1. Documentation describing the corrective actions that have been taken for patients that were identified by the survey and subsequent analysis as having

been affected by the deficient practice(s);

2. An explanation as to how the laboratory has identified other patients who may have been affected by the deficient practice(s);

3. A description of the correction(s) that have been put into place and/or the systemic changes that have been made to ensure that the deficient practice does not recur; and

4. A description of how the corrective actions are being monitored to ensure the deficient practice does not recur.

All deficiencies may not be corrected at the time the plan of correction is submitted to the SA or *CMS*, but it must have corrected dates that are within 12 months after the "date survey completed" listed on the *Form* CMS-2567 and must be reasonable in timeframe and content.

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, (i.e. owner, operator and/or laboratory director) 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 an acceptable PoC.

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 *CMS*/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.

6132.3 - Allegation of Compliance (AoC)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When *c*ondition-level noncompliance is determined by *CMS* or *SA* surveyor, an AoC is requested.

An AoC is an assertion (i.e., allegation) from the laboratory that they are in compliance; hence, no future dates of correction are acceptable for any condition-level deficiency as well as standard-level deficiencies included in the condition on the Form CMS-2567. For any standard-level deficiencies that are not included in the condition, future dates are acceptable. The AoC contains records (documentary materials) that describe or support the laboratory's compliance. A record includes all recorded information, regardless of form or characteristics, made or received by a federal agency under federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the US Government or because of the informational value of data in them. 44 U.S.C Chapter 33, Section 3301." All records must be kept the period defined by the federal requirements at DAA-0440-2015-0008, which is 7 years, or by State requirements, if more stringent than federal requirements.

There are four elements that are required to be submitted with an AoC. Those four elements are:

1. Documentation describing the corrective actions that have been taken for patients that were identified by the survey and subsequent analysis as having been affected by the deficient practice(s);

2. An explanation as to how the laboratory has identified other patients who may have been affected by the deficient practice(s);

3. A description of the correction(s) that have been put into place and/or the systemic changes that have been made to ensure that the deficient practice does not recur; and

4. A description of how the corrective actions are being monitored to ensure the deficient practice does not recur.

In addition to the above four elements, the AoC is a statement or documentation that is:

1. Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;

2. Realistic in terms of the possibility of the corrective action being accomplished between the date of the survey and the date of the allegation: and,

3. Indicates resolution of the problem(s).

6134 - Review of Plan of Correction or Allegation of Compliance by State Agency

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The SA reviews the laboratory's PoC or AoC and accompanying documentation for appropriateness, legibility, completeness, and timeliness.

The SA verifies the evidence contains:

1. Corrective action(s) have been taken for patients found to have been affected by the deficient practice.
2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) have been taken.
3. Measures has been put into place or systemic changes have been made to ensure that the deficient practice does not recur.
4. Corrective action(s) are being monitored to ensure the deficient practice does not recur.
5. Identify the signature of the laboratory director or designee.

If not properly completed or there is a question about the PoC or AoC, the SA contacts the laboratory representative to obtain clarification or appropriate modification of the plan or allegation. The SA retains a copy of the Form CMS-2567, the laboratory's written PoC or AoC and the laboratory's accompanying documentation in the SA's file with the certification packet.

All records must be kept the period defined by the CMS Records Schedule at DAA-0440-2015-0008, which is 7 years, or by State requirements, if more stringent than CMS Records Schedule.

6134.1 - Strategy for Repeat *Deficiencies*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 *CMS* for possible enforcement action. (This strategy may not be applicable to certain repeat deficiencies, e.g., the laboratory's failure to have appropriately qualified laboratory personnel in rural areas.)

Strategy for Repeat Deficiencies:

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

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

3.Review the submitted plan of correction or allegation of compliance and determine whether the laboratory's submission meets the criteria for an acceptable plan of correction or a credible allegation of compliance. Based on established criteria, if the plan of correction is not acceptable or the allegation of compliance is not credible, give the laboratory no more than one additional opportunity to provide an acceptable or credible submission, or forward the case to CMS 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

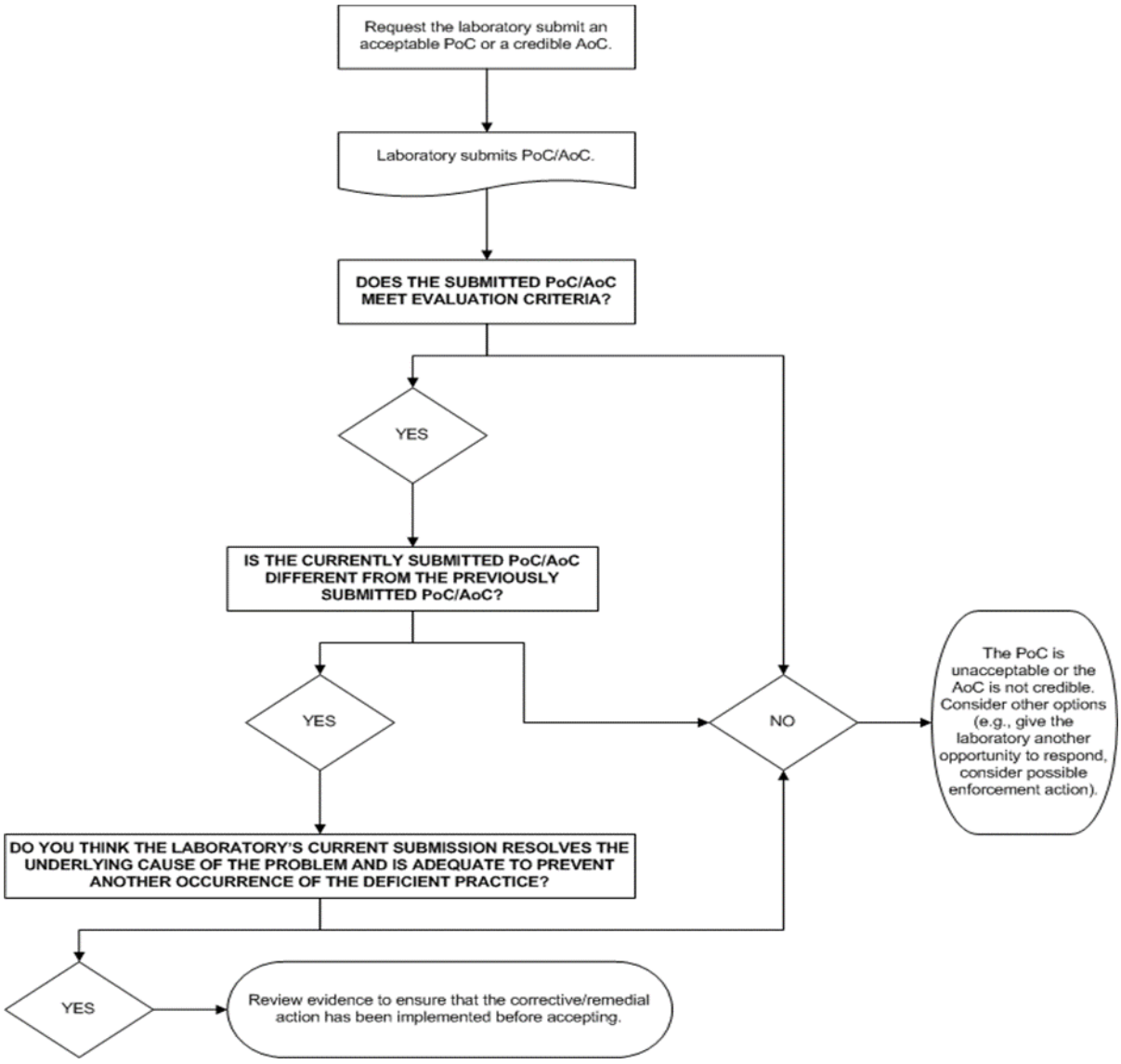
established criteria.

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 CMS 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 CMS 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:



6134.2 - Follow-Up on *AoC/*PoCs and Revisit *Survey*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If possible, the *follow-up/revisit s*urvey is to be conducted by a member of the survey team that made the findings. When a laboratory has failed to comply with one or more CLIA *condition-level deficiencies,* the SA *performs an onsite follow-up/revisit survey after the laboratory makes a credible AoC. When conducting an onsite follow-up/revisit survey, the SA verifies compliance with the federal regulations.*

In some cases, the condition-level deficiencies may allow for electronic transmission mail (e-mail), mail, or telephone contact in place of an onsite visit, (e.g., the laboratory agreed to amend its written policies). An onsite follow-up/revisit survey is ***not*** *required*

for mandatory condition-level deficiencies related to PT enrollment 42 CFR § 493.801, unsuccessful participation in PT 42 CFR § 493.803, and ***personnel qualifications*** *in subpart M – Personnel for Nonwaived Testing, 42 CFR §493.1351 through 42 CFR §493.1495. An onsite follow-up/revisit survey* ***is*** *performed for condition-level deficiencies related to* ***personnel responsibilities*** *in subpart M – Personnel for Nonwaived Testing, 42 CFR §493.1351 through 42 CFR §493.1495.*

If the condition-level deficiencies indicate a potential risk to the quality of patient test results, an onsite follow-up/revisit survey ***must*** *be performed. If the laboratory does not give the SA a credible AoC for outstanding condition-level deficiencies, an onsite follow-up/revisit is required prior to the imposition of principal sanctions.*

Within 12 months of the original survey, the SA conducts an offsite follow-up/revisit survey for any standard-level deficiencies not associated with a condition-level deficiency. This offsite follow-up/revisit survey is normally conducted by e-mail, mail, or telephone. An onsite follow-up/revisit survey of standard-level deficiencies is warranted in rare circumstances such as when the laboratory-provided evidence of correction does not verify correction of the deficiency and/or the documentation provided indicates potential risk to the quality of patient test results.

An offsite follow-up/revisit survey is performed following citation of mandatory condition-level deficiencies related to PT enrollment 42 CFR § 493.801, unsuccessful participation in PT 42 CFR § 493.803, and ***personnel qualifications*** *in subpart M – Personnel for Nonwaived Testing, 42 CFR §493.1351 through 42 CFR §493.1495.*

The SA may consult with CMS for a determination regarding the appropriate type of follow-up/revisit. Any additional onsite follow-up/revisit surveys must be approved by CMS.

The SA may consult with CMS for a determination regarding cases that are unclear. The SA obtains appropriate documentary verification (or onsite verification if warranted) before reporting a citation as corrected *in the CLIA Data System.*

If, at the time of the revisit, some deficiencies have not been corrected, the SA completes another Form CMS-2567 *for the revisit survey* summarizing the deficiencies not corrected by using the appropriate data prefix tag number. The SA must ask the laboratory to provide a revised PoC or AoC with a new completion date. The SA sends a copy of the Form CMS-2567 and allows the laboratory 10 calendar days to complete and return a PoC or AoC for any remaining deficiency(ies). The SA inputs the revised data into the ASPEN 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 *CMS*.

- *The SA is required to complete a Form CMS-2567 for every revisit survey. The CMS-2567 will document new deficiencies, uncorrected deficiencies with new findings of noncompliance, or a statement that the laboratory is in compliance.*

- *For example, a deficiency statement for no deficiencies on a revisit survey:*

  A (onsite/offsite) revisit survey was completed on XXX (date) for all previous deficiencies cited on XXX (date of original survey). All deficiencies have been corrected, and no new noncompliance was found. The facility is in compliance with 42 CFR Part 493, Requirements for Laboratories.

- *For example, a deficiency statement for new deficiencies on a revisit survey:*

  A (onsite/offsite) revisit survey was completed on XXX (date) for all previous deficiencies cited at the (initial/recertification/validation/complaint/focused complaint) survey performed on XXX (date of original survey). All deficiencies related to the (initial/recertification/validation/ complaint/focused complaint) survey have been corrected. New noncompliance was found.

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

6134.3 - Form CMS-2567B

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Form CMS-2567B is an electronic document within the CLIA Data System. The printed version of CMS-2567B is no longer required to document laboratory compliance.

6136 - Evaluation of Compliance

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The CLIA requirements establish a single set of *c*onditions and standards for all laboratories. CLIA certification is required for payment for laboratory services under the 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 *the* Form CMS-1539 are entered into the CLIA *D*ata *S*ystem, an official determination of CLIA compliance is made.

6136.1 - Compliance With all CLIA Conditions With No Deficiencies Identified

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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. It is optional for the laboratory director to sign the Form CMS-2567 when no deficiencies were cited. The laboratory is issued the appropriate CLIA certificate and is eligible to participate in the Medicare and Medicaid programs.

6136.2 - Compliance Based on an Acceptable *AoC*/PoC

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Compliance based on an acceptable *AoC or* PoC reflects the findings that all applicable *standards and c*onditions are met. The surveyor is certifying that the laboratory is able to *provide* 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 after the date survey *is* completed).

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 *after two submissions,* the laboratory does not submit an acceptable PoC or if it fails to correct its deficiencies, the SA *notifies CMS*.

6136.3 – Noncompliance *Based on an Unacceptable AoC*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

In situations where it is determined that a laboratory has failed to comply with one or more CLIA conditions (condition-level deficiencies), the SA requests an AoC and acceptable evidence of correction. If *after two submissions*, the laboratory fails to submit a credible AoC and acceptable evidence of correction, the SA notifies *CMS.*

6136.4 - Survey Report Documentation and Data Entry

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Following the survey, enter into the CLIA *Data System* any revisions, additions, or deletions to the application (Form CMS-116) information. Refer to the CLIA Systems Users Guide for specific information and instruction. Enter into the data system the Certification Kit, which consists of:

- Form CMS-1539, Certification and Transmittal;
- Form CMS-2567, Statement of Deficiencies and Plan of Correction; and
- Form CMS-670, Survey Team Composition and Workload Report *(see section 6428)*.

6137 - Data Management

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The following CLIA data entry actions:

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

- Form CMS-2567, Form CMS-670, and *the Survey Specialty section* are entered up to 45 days after the survey.

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

6138 - Retention of CLIA Certification Records

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Essential data from all CLIA forms can be captured electronically in the CMS mainframe data system, and will maintain the data for 7 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 *Section* 1864 agreement). The *Section* 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 *Section* 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, only the state actor is bound by the State law.

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

6138.1 - No Deficiencies Cited

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

6138.2 - Deficiencies Cited

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Upon completion of a survey where deficiencies are cited, the SA enters all forms into the CLIA *D*ata *S*ystem in the time frame specified above, regardless of whether the PoC or AoC are yet verified.

6138.3 - Exception

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Form CMS-209 is completed at the time of the survey. This form is currently not available in electronic form in *the CLIA Data System*. The SA either retains a hard copy or scans a 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

All Media-related inquiries must be forwarded to CMS.

6140 - Additional Information

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6140.1 - Counting Tests

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Total annual volume for waived tests, if any, should be recorded on the CLIA application (Form CMS-116) in the waived testing section. The total annual volume for nonwaived tests, including PPM procedures, should be reported on the form in the Nonwaived Testing section by specialty and subspecialty. Only tests that are **ordered** and **reported** should be included in the laboratory's test volume(s). Calculations (e.g., A/G ratio, MCH, MCHC, HCT, and T7), QC tests, and PT assays should not be counted.

- For chemistry tests, each non-calculated analyte is counted separately (e.g., Lipid Panel consisting of a total cholesterol, HDL cholesterol, LDL cholesterol and triglycerides equals 4 tests).

- For complete blood counts, each measured individual analyte that is ordered and reported is counted separately. Differentials count as one

test.

- For urinalysis, microscopic and macroscopic examinations each count as one test. Macroscopics (dipsticks) are counted as one test regardless of the number of reagent pads on the strip. For screening drug tests (e.g. dipsticks, cups, cards) count as one test regardless of the number of drugs tested.
- For microbiology, susceptibility testing is counted as one test per group of antibiotics used to determine sensitivity for one organism. Cultures are counted as one per test request from each specimen regardless of the extent of identification, number of organisms isolated, and number of tests/procedures required for identification. Each gram stain or acid-fast bacteria (AFB) smear requested from the primary source is counted as one. For example, if a sputum specimen has a routine bacteriology culture and gram stain, a mycology test, and an AFB smear and culture ordered, this would be counted as five tests. For parasitology, the direct smear and the concentration and prepared slide are counted as one test.
- For allergy testing, each allergen is counted as one test.
- For flow cytometry, each measured individual analyte (e.g. T cells, B cells, CD4, etc.) that is ordered and reported should be counted separately.
- For manual gynecologic and nongynecologic cytology, each slide (not case) is counted as one test. Refer to D5643 for counting non-gynecological slide preparations using liquid-based slide preparatory techniques. Refer to D5665 for counting gynecologic cytology slide preparations when using automated and semi-automated screening devices.
- For immunohematology, each ABO, Rh, antibody screen, cross match, or antibody identification is counted as one test.
- For histocompatibility, each HLA typing (including disease associated antigens) is counted as one test, each HLA antibody screen is counted as one test and each HLA cross match is counted as one test. For example, a B-cell, a T-cell, and an auto-crossmatch between the same donor and recipient pair would be counted as 3 tests.
- For histopathology, each block (not slide) is counted as one test. Autopsy services are not included. For those laboratories that perform special stains on histology slides, the test volume is determined by adding the number of special stains, including immunohistochemistry, performed on slides to the total number of specimen blocks prepared by the laboratory.
- For cytogenetics, the number of tests is determined by the number of specimen types processed on each patient (e.g., a bone marrow and a venous blood specimen received on one patient are counted as two tests).

NOTE: For all other genetic tests, the number of tests is determined by the number of results reported in the final report.

- Genetics tests should be placed in the specialty or subspecialty where they fit best, according to the methodology of the test.

6140.2 - Conducting Surveys of Multiple Testing Sites under One Certificate

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

1. Multiple sites are permitted to operate under a single certificate when the sites meet one of the multiple site exceptions at 42 CFR §§ 493.35(b), 493.43(b), or 493.55(b). Each site performing testing under a single certificate must meet all applicable requirements of 42 CFR Part 493. Each site is subject to a survey; however, the primary site or home base, as applicable, should be one of the locations included in the initial CLIA certification survey. Select a representative portion of the remaining locations for onsite survey.

   When choosing the representative sample for multiple site surveys, consider the following:

   a. Types of testing performed;

   b. Types of clients and/or facilities served, e.g., pediatric, geriatric, residential/emergency care, or health assessment screens;

   c. Location(s) participating in PT; and

   d. Problems or complaints identified either at the primary or other testing sites.

2. Temporary testing sites, including mobile units, should be inspected using the criteria listed above. Refer to the SOM Chapter 6, §6010.1 to assist with determining what constitutes a mobile unit and for temporary testing sites. Every effort should be made to schedule the survey to coincide with testing at temporary locations. (Refer to 42 CFR §§493.35(b)(1), 493.43(b)(1), 493.55(b)(1))

   a. Home Health and Hospice laboratory testing with multiple sites should generally be inspected using the criteria listed above (Refer to

CFR §§493.35(b)(1), 493.43(b)(1), 493.55(b)(1)) Refer to SOM Chapter 6 § 6010.1.2.1.

Many Home Health Agencies (HHAs) may be certified with multiple sites under one certificate. A parent HHA may apply for one CLIA certificate as long as these sites meet the applicable requirements. Medicare designates these multiple locations using the term "parent location" for the main location and the term "branches" for the additional sites. Hospices may also be certified with one certificate for multiple sites. Refer to the SOM Chapter 6, §6010.1.2.1 for additional information on HHAs and hospices.

3. Refer to the SOM Chapter 6, §6010.2 for additional information on laboratories performing limited public health testing. These entities should be inspected using the above criteria (Refer to 42 CFR §§ 493.35(b)(2), 493.43(b)(2), 493.55(b)(2))

4. In a hospital laboratory, multiple test sites under one certificate should generally be inspected using the criteria listed above. (Refer to 42 CFR §§ 493.35(b)(3), 493.43(b)(3), 493.55(b)(3)). Refer to SOM Chapter 6 §6010.3.

A laboratory having multiple sites under one certificate is required to enroll in only one PT program(s) for the primary test system/procedure for each specialty, subspecialty, analyte or test used under that certificate even though the same specialty, subspecialty, analyte or test may be used at multiple locations using different test systems or procedures and different personnel. Ensure that PT records indicate the location at which the tests were performed, and that all other locations have been compared with the system selected for PT, as specified in 42 CFR §493.1281(a).

A condition may be considered out of compliance even if deficiencies are only found at a subset of the sites operating under the single certificate.

6140.3 - Conducting Surveys of Laboratories Performing Waived Tests

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

In **any** laboratory holding a CLIA certificate, waived tests **are generally not** subject to routine survey. If the SA is surveying a CoC or CoA and finds cause that points towards problems in waived testing, the SA should investigate the problem(s).

6140.4 - Conducting Surveys of Laboratories with a Certificate of Waiver (CoW) or a Certificate for PPM Procedures

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

As provided at 42 CFR §493.1775 of Subpart Q Inspection, a laboratory that has been issued a CoW or a PPM certificate is not subject to biennial inspections. However, a survey may be conducted as specified in Subpart Q (i.e., randomly) during its hours of operation on authorization by *CMS* for any or all of the following to:

- Determine if the laboratory is testing outside its certificate;
- Collect information regarding the appropriateness of tests specified as waived or PPM;
- Investigate a complaint from the public; and
- Determine if the laboratory is operating and if testing is performed in a manner that does not constitute an imminent and serious risk to public health.

Please note that in those instances in which you are performing a survey on a laboratory with a certificate for PPM procedures, the appropriate requirements in 42 CFR Part 493 Subparts H, J, K, M and Q will apply. Furthermore, regardless of the certificate held, in instances in which a survey is occurring in a laboratory with a Certificate of Compliance or a Certificate of Accreditation, which has conducted PPM procedures, that PPM testing may be included in the sample for the patient testing review portion of the survey.

6140.5 - Complaints Involving Laboratories

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The SA/*CMS* investigates allegations of non-compliance that are related to CLIA requirements in laboratories. A complaint about a laboratory should be reported to the appropriate SA or *CMS* contact. The complete list of SA/*CMS* contacts can be found on the CLIA website at: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html. *CMS* is responsible for coordinating the responses to all complaints. (See SOM Chapter 5, *sections* 5500-5590, "Complaint Procedures" for guidance regarding complaint investigations).

Sample Validation Surveys of Accredited Laboratories

6150 - Background - CMS Approval of Accreditation Organizations (AO)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 *(AO)* are deemed to meet CLIA requirements. An *AO* may be approved for a maximum of 6 years and must re-apply for each succeeding approval. When CMS approves an *AO*, 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 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 *AOs* are:

- *Association for the Advancement of Blood and Biotherapies (*AABB*);*
- *American Association for Laboratory Accreditation (A2LA);*
- Accreditation *Commission for Health Care, Inc (ACHC)*
- American Society for Histocompatibility and Immunogenetics (ASHI)*;*
- COLA;
- College of American Pathologists (CAP); and
- The Joint Commission (TJC).

6151 - Accredited Laboratories - Deemed Status

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

An accredited laboratory is a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization *(AO)* approved by CMS. By virtue of its accreditation, an accredited laboratory that meets the requirements of §493.61 is deemed to meet CLIA condition-level requirements.

6152 - Accreditation Validation Surveys - Citations and General Description

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 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 *CMS*. The SA and *CMS* 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 *AO* programs. Validation surveys cover all CLIA conditions in the specialties and subspecialties listed on the CLIA certificate for which the *AO* is approved. Sample validation surveys are performed no later than 90 calendar days after *AO's* inspection. As part of the validation review process, CMS may conduct onsite visits at the *AO*'s headquarters to verify administrative integrity.

6154 - Objective of Validation Surveys of Accredited Laboratories

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The *v*alidation program is designed to evaluate the premise that a laboratory that receives accreditation is in fact meeting CLIA requirements. By comparing the CLIA findings of each validation survey to the *AO's* inspection results, calculating the disparity rate as prescribed by the regulations, and reporting the results to Congress annually, *CMS* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 total number of validation target numbers. (See *section* 6156.3).

6156.1 - Number of Validation Surveys

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Each fiscal year the number of validation surveys to be performed is specified in the annual budget. Monies are allocated in the CLIA annual budget call letter and proportionately in the SA budgets for this purpose, as outlined below.

NOTE: *Validation surveys performed by CMS are not included in the annual SA budgets.*

6156.2 - Criteria for Validation Selection

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS forwards annual inspection schedules for each *AO* to *the SAs. In addition, each month, the accreditation organizations submit a 3-month "rolling schedule" with updated inspection schedules for the previous, current and future month. CMS and the SA work together to select* laboratories to receive validation surveys using the following criteria:

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

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

- Select laboratories from each *AO* proportionate to the total number of accredited laboratories in the State*; and*

- *Select laboratories that have not received a CLIA validation survey during the previous survey cycle.*

CMS and *the* SA confirm validation selections and survey schedules using the monthly inspection schedules sent directly from each of the accreditation organizations to *CMS.*

6156.3 - Complaint *Surveys* Accepted for Validation Survey Target

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A complaint *survey* 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 calendar days after the accreditation inspection; and

- Covers the entire laboratory, i.e., all specialties and subspecialties listed on the CLIA certificate, even if the complaint is limited to particular areas or practices of the laboratory.

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

NOTE: Complaint surveys of laboratories' practices in *the subspecialty of* Cytology, are not counted toward the validation survey target or included in the validation review. In the *Cytology* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A validation survey is initiated when *CMS* approves the survey in the CLIA *D*ata *S*ystem and notifies the SA. When scheduling the survey, the SA verifies the *AO's* inspection date to ensure that the validation survey takes place no later than 90 calendar days after the inspection. If the survey cannot be performed, the SA should notify *CMS* immediately.

Validation surveys may be performed simultaneously with *AO* inspections. (See *sections* 6226-6228 for pre-survey arrangements and simultaneous survey procedures.)

Validation surveys are *generally* announced unless performed simultaneously with an AO survey, which may be unannounced (See *section* 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.

In States with more than one *CLIA* 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 survey types.

At its discretion, *CMS* may plan to accompany the SA on the validation survey in order to assist in the survey process or as part of an observational or participatory Federal Monitoring Survey (FMS).

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

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If a laboratory selected for validation fails to permit a survey, *CMS* notifies the laboratory, by letter, informing that:

- It will be subject to a full review and survey,
- It no longer meets the CLIA requirements by virtue of its accreditation in an approved accreditation program, and
- Is subject to suspension, revocation or limitation of its CLIA certificate of accreditation.

CMS will send a copy of the letter to the *AO and* SA. An accredited laboratory will be considered deemed to meet the CLIA *c*onditions when:

- It withdraws any prior refusal to authorize its *AO* to release to CMS or a CMS agent, a copy of the laboratory's current accreditation inspection, 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 condition-level requirements.

6164 - Conducting Validation Surveys of Accredited Laboratories

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The SA *and CMS* performs validation surveys according to established survey procedures. (See *section* 6100.) The *CLIA* surveyor refrains from reviewing any inspection results of the *AO* 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 *AO*. 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- *Requests CMS approval to survey prior to performing the survey;*

- Upon receipt of approval from *CMS*, *schedules* validation survey(s) to take place no later than 90 calendar days after the *AO's* survey;

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

- Perform*s* 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;

- Perform*s* an exit conference which outlines the survey findings and informs the laboratory of any follow-up actions or correspondence;

- Upon completion of the *validation* survey, document~~s~~ all required information in the CLIA *D*ata *S*ystem.

Any additional information/forms pertinent to the survey should be forwarded to *CMS* by attaching them to the survey in the CLIA *D*ata *S*ystem or by other means acceptable to *CMS,* e.g., *the surveyor's notes,* CMS-209 - Laboratory Personnel Report; Form CMS-116 CLIA Application for Certification; correspondence with the laboratory. *Once all documents have been uploaded the SA notifies CMS that the survey is complete for CMS to close.*

6164.2 - Discrepancy With CLIA Data Information

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If, during the course of a validation survey of an accredited laboratory, the laboratory is found to be performing more or less tests and/or specialties than *those* reflected in the CLIA *D*ata *S*ystem, i.e., the laboratory is in a higher or lower survey specialty test volume schedule, the discrepancy must be noted in the *v*alidation survey kit. (See Appendix C.)

The *CLIA surveyor* ensures the laboratory completes the Form CMS-116 to include test volumes and signature of the laboratory director or designee. The *CLIA surveyor*

completes the *Survey Specialties tab* in the validation kit designating whether there are discrepancies in the specialties, test volumes, or both.

A notation is made on the new Form CMS-116 clearly indicating it is for a change in test volume only. The SA notifies *CMS* of *changes in* test volume information.

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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- At the exit conference, the SA CLIA surveyor informs the laboratory of its noncompliance status; its recommendation to *CMS* that the laboratory no longer meets the CLIA *c*ondition-level requirements by virtue of accreditation; and that the laboratory is subject to the same enforcement actions as non-accredited laboratories; (See *section* 6126)

- Prepares a Statement of Deficiencies, Form CMS-2567 (Exhibit 7) and clearly documents the nature of the jeopardy and notifies *CMS* (within 2 days) of the recommended action.

- Within three working days of the survey exit date, completes all required information in the CLIA *D*ata *S*ystem and attaches any additional information pertinent to the survey for *CMS* review. (See *section* 6164)

6166.1.2 - *CMS*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

NOTE: For accredited laboratories, *CMS* rather than the SA is responsible for processing the enforcement actions listed in *section* 6290.

- Receives the SA recommendations and determines the appropriate actions according to the policies outlined in *section* 6284. *CMS* 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.

- Promptly notifies the laboratory by written communication (e.g., overnight mail, facsimile, e-mail) of the immediate jeopardy situation and of the actions being initiated (Exhibit 237). A copy of this communication is sent to the SA, *CMS*, and the applicable accreditation organization.

- On or before the 23rd day, *CMS* assures that the immediate jeopardy has been removed and follows procedures for *c*ondition-level deficiencies with no immediate jeopardy. If the immediate jeopardy has not been removed, *CMS* follows the procedure for immediate jeopardy enforcement actions in *section* 6284. *CMS* also updates the AO regarding the immediate jeopardy situation and/or findings.

- Ensures copies of selected documents and correspondence are available to *CMS* in the data system for performing the validation review. (See *section* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- At the exit conference, informs the laboratory of its *c*ondition-level noncompliance status and its recommendation to *CMS* that the laboratory no longer meets the applicable CLIA *c*ondition-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 *c*ondition-level compliance or until its certificate of accreditation is revoked.

- Explains that the Form CMS-2567 (Exhibit 7) will be sent by *CMS* to the laboratory in 10 *working* days. A plan of correction *(PoC), evidence of correction (EoC),* or allegation of compliance *(AoC)* is due within 10 calendar days of receiving the Form CMS-2567. Also explains that the accreditation organization will receive copies of all correspondence to the laboratory. In addition, the laboratory may wish to consult with the organization regarding its efforts to correct the deficiencies.

- Prepares a Form CMS-2567, completes all required information in the CLIA *D*ata *S*ystem, and attaches any additional information pertinent to the survey for *CMS* review within 10 *working* days from the survey exit

date. (See *section* 6164.)

6166.2.2 - *CMS*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

NOTE: For accredited laboratories, *CMS* rather than the SA is responsible for processing the enforcement actions listed in *section* 6290.

- 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 *section* 6290.

- Notifies the laboratory that it is not in *c*ondition-level compliance, and it is no longer deemed to meet the CLIA conditions by virtue of its accreditation within 10 *working* days of receipt of the Form CMS-2567 and any additional information pertinent to the validation survey from the *SA*.

- Requests the laboratory to submit an allegation of compliance (AoC) within 10 calendar days of receiving the letter and informs the laboratory that there will be follow-up with the laboratory to determine whether *c*ondition-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 *5*5 calendar days of the laboratory's receipt of the letter, *CMS* has not received acceptable evidence of correction, or *CMS* has determined that the laboratory has failed to provide a credible AoC, *CMS* follows the established enforcement actions. (See *section* 6290.)

- If, in *5*5 calendar days, *CMS* has received acceptable evidence of correction and *CMS* has determined the laboratory provided a credible AoC, *CMS* notifies the laboratory that it continues to meet CLIA *c*ondition-level requirements by virtue of its accreditation.

- Ensures copies of selected documents and correspondence are available to *CMS* in the data system for performing the validation review. (See *section* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- At the exit conference, *the SA* informs the laboratory that it is in *c*ondition-level compliance.

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

- *The SA* explains to the laboratory that the accreditation organization will receive a copy of the Form CMS-2567 and the correspondence.

- *The SA p*repares a Form CMS-2567 and notifies *CMS* when the validation survey documentation is available in the CLIA *D*ata *S*ystem. (See *section* 6164)

6166.3.2 - *CMS*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- Forwards the CMS-2567 to the laboratory.

- Notifies the laboratory that the CMS-2567 is disclosable to the public within 90 calendar days along with any PoC the laboratory provides.

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

- Ensures copies of selected documents and correspondence are available to *CMS* in the data system for performing the validation review. (See *section* 6170)

6170 - Completing Validation Survey Information in the CLIA Data System
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When the validation survey of an accredited laboratory and the follow-up activities have been completed, *CMS* will ensure the following forms and other survey information are complete and available in the CLIA *D*ata *S*ystem for use by *CMS* in the annual validation review:

- Form CMS-2802A (Exhibit 242);

- Form CMS-2567 (Exhibit 7) - include AoC when there are *c*ondition-level deficiencies;

- 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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. *CMS* will record the date of receipt of the accreditation organization's notification.

The following describes those situations that should be communicated to *CMS*:

- 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 *CMS* removes the certificate of accreditation due to *c*ondition-level noncompliance that has not been corrected. *(*See §493.569(a)*)*.

6174 - Basis for Validation Surveys of Accredited Laboratories in Response to Substantial Allegations of Noncompliance *(Complaints)*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

42 CFR 493.563 provides that validation surveys may be conducted in response to a *complaint of* substantial allegation*s* 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 *State Laboratory Licensure Programs*

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

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 *licensure* program *(SLLP)*, 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 *SLLP* 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.

NOTE: *State laboratory licensure program is also referred to as exempt state (ES) or CLIA-exempt laboratory.*

6202 - Validation Surveys of State Laboratory Licensure Program Laboratories - Citations and Objectives

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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.

CMS conducts CLIA-exempt laboratory validation surveys to ensure that *the SLLP and the* laboratories under the jurisdiction of the approved *SLLP* 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 *section* 6214.)

6204 - Number and Criteria for Selection of *State Laboratory Licensure Program Laboratories for Validation Surveys*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

6204.1 - Number of Validation Surveys

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The number of CLIA-exempt laboratories to be validated is approximately 5 percent of State-licensed laboratories *that are not accredited*. (Refer to the annual budget call letter.)

6204.2 - Selection of Validation Surveys

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS obtains the *SLLP* survey schedule and verifies the date that the *SLLP* completed the inspection, so that the validation survey can be simultaneous or be conducted no later than 90 calendar days after the *SLLP* inspection. *CMS* 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 *State Laboratory Licensure Program Laboratories*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Validation surveys are *generally* announced. (See *section* 6227.3.1 for complete guidance on when to refrain from announcing CLIA validation surveys.) *CMS* surveyors should conduct validation surveys, to the extent possible, on a rotating basis so that no one surveyor conducts all the validation surveys.

CMS 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, *CMS* does not obtain a copy of the *SLLP* survey findings until the validation survey is completed.

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

6208 - Conducting Validation Surveys of *State Laboratory Licensure Program* Laboratories

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS has direct responsibility for the entire validation survey process for *SLLP* laboratories, unless *CMS* utilizes a CMS designated contractor, e.g., survey of cytology. The *CMS* surveyor conducts the survey according to established procedures for certification surveys (See *section* 6100). At the exit conference, the *CMS* surveyor informs the laboratory of any *c*ondition-level findings and the CLIA compliance determination. The validation survey may be conducted simultaneously with the *SLLP* inspection, however, the *CMS* surveyor makes an independent CLIA compliance determination and completes all necessary documentation and survey forms. *CMS* sends to the *SLLP* a notification of determination (letter) with Form CMS-2567 (Exhibit 7), and a copy of both to the laboratory. See, *sections* 6210.2.1 and 6210.3.1 for specifics related to the type of deficiencies.

NOTE: A *SLLP* organization may recognize a CMS-approved accreditation organization in lieu of State licensure. If so, a laboratory accredited by an approved accreditation organization may be subject to validation by the *SLLP* 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 *SLLP* uses State licensure requirements to validate the accredited laboratory. At *CMS'* discretion, *CMS* may accompany the *SLLP* on these surveys to observe the *SLLP's* validation activities.

6210 - Results of the *Validation Survey - CMS and State Laboratory Licensure Program* Responsibilities

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

6210.1 - Condition-Level Deficiencies *w*ith Immediate Jeopardy

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If the deficiencies identified are *c*ondition-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 - *CMS*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- At the exit conference, *CMS* informs the laboratory of its *c*ondition-level noncompliance status, explains to the laboratory that it does not meet the CLIA *c*ondition-level requirements and is subject to sanctions imposed by the *SLLP*.

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

- Within 2 working days of the survey, *CMS* sends to the *SLLP* a notification of determination (letter) that clearly explains the nature of the jeopardy and directs the *SLLP* 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. *CMS* sends to the laboratory a copy of the letter, including the Form CMS-2567 enclosure.

6210.1.2 - The *State Laboratory Licensure* Program
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- *The SLLP t*akes the appropriate enforcement actions based on the enforcement policies of its approved licensure program.
- Within 10 *working* days of the survey, *the SLLP* notifies *CMS* of the action taken.

6210.1.3 - *CMS*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

*CMS f*ollows up with the *SLLP* within 15 calendar days if not notified of the action taken or notified that the *immediate* jeopardy situation has been *removed*. If the *SLLP* is unwilling or unable to take enforcement action appropriate (as determined by *CMS*) to the *immediate* jeopardy situation, *CMS may* either contact the *SLLP* 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 - *CMS*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- At the exit conference*, CMS* informs the laboratory of its *c*ondition-level noncompliance and explains to the laboratory that it does not meet the CLIA *c*ondition-level requirements and is subject to sanctions and follow-up by the *SLLP*;

NOTE: If onsite simultaneously with the *SLLP* inspection, *CMS* assures that the laboratory is fully aware of the *c*ondition-level deficiencies and follow-up by the *SLLP*.

- Within 10 *working* days of completing the survey, *CMS* sends to the *SLLP* a notification of determination (letter) that explains the *c*ondition-level deficiencies and directs the *SLLP* to take appropriate action under its approved licensure program. A Form CMS-2567 (Exhibit 7) with *a* summary of the findings is *sent* with the notification letter *to the SLLP and the laboratory*. (See Exhibit 232.)

6210.2.2 - The State *Laboratory Licensure* Program
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

*The SLLP t*akes the appropriate enforcement actions based on the policies of its licensure program. Within 30 calendar days, the State program notifies *CMS* of the action taken.

6210.2.3 - *CMS*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- *CMS f*ollows up with the *SLLP* within 45 calendar days if not notified of the action taken.

- If the *SLLP* has not taken appropriate enforcement action, (as determined by *CMS* and/or the condition-level noncompliance remains, *CMS* contacts the *SLLP* to seek resolution/take action so that the laboratory comes into *c*ondition-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 - *CMS*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

- *CMS p*repares a Form CMS-2567 (Exhibit 7) and sends it to the *SLLP* 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 *Laboratory Licensure* Program
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Monitors the correction of the cited deficiencies based on the policies of its *SLLP*.

6212 - Processing Validation Survey Records

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- *CMS* inputs the survey information into the CLIA *D*ata *S*ystem within 45 calendar days of completing the survey.
- The applicable documents should be completed and processed (see *section* 6100).

6214 - Evaluation of Approved State Laboratory Licensure Program

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS not only performs the validation surveys as described above, but also prepares an annual evaluation of the *SLLPs* operations. The report includes a comparison of the *SLLPs* findings with validation survey findings at the *c*ondition-level. It also includes summary information about the *SLLPs* 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 *Licensure* Program

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Title 42 CFR 493.563(d)(2) *authorizes* CMS to conduct *onsite inspections of SLLP* offices. The purpose of the visits is to gather information about the *SLLP* operations, including any verifications needed about the representations made by the *SLLP* in their application for CLIA exemption.

Additionally, *CMS* may assess the *SLLPs* 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 *SLLP* to allow an onsite visit or poor performance in the management of the above activities may jeopardize the renewal of a *SLLP's* CLIA exemption.

6218 - Notification Responsibilities of Approved State *Laboratory* Licensure Program

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Responsibilities of each approved *SLLP* include notifying CMS, on an ongoing basis, when certain situations occur, as listed below. This information must be communicated in writing by the *SLLP* 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. *CMS* records the date of the State's notification of the information.

The following describes those situations that the approved *SLLP* communicates to *CMS*:

1. Immediate jeopardy situations (within 10 calendar days);
2. Newly licensed laboratories, including specialty and subspecialty information (within 30 calendar days);
3. Data related to unsuccessful PT performance and actions taken (within 30 calendar days);
4. Any sanctions taken by the *SLLP,* i.e., denial, withdrawal, or revocation of State licensure, limitation of specialty/subspecialty, etc. (within 30 calendar days); and
5. Revision in specialty/subspecialty testing (additions, deletions) in existing CLIA- exempt laboratories (within 30 calendar days).

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

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

6226 - Simultaneous Validation Surveys - General
(Rev. 1, 05-21-04)

6226.1 - Simultaneous Validation Survey - Definition
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A validation survey of an accredited or CLIA-exempt laboratory in which the CLIA surveyor accompanies the *AO* or approved *SLLP* inspector during the inspector's fact-gathering and uses the outcome-oriented survey principles (see *section* 6100) to determine whether the laboratory meets the CLIA *c*ondition-level requirements.

6226.2 - Purpose
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The main purpose of the simultaneous validation survey is the same as any CLIA validation survey: to verify that the *AO or SLLP* meets all applicable CLIA conditions. While determining the laboratory's *c*ondition-level compliance status, the CLIA surveyor gains insight into *the AO* or *SLLP* processes.

6226.3 - Relationship to Comparative Validation Surveys
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The simultaneous survey offers an additional approach for conducting validation surveys. Like the validation survey performed after the AO or *SLLP* inspection date, the simultaneous focuses on the laboratory's compliance status; however, the timing is different. Instead of performing the validation survey up to 90 calendar days after the *AO* or approved *SLLP* inspection, the *CLIA* surveyor performs the survey while accompanying the AO or *SLLP* inspector.

6226.5 - Team Size
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The SA *or CMS* may increase the number of CLIA surveyors when the accreditation inspection is performed by a team. Additional surveyors may be from the SA or *CMS*,

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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Well-coordinated pre-survey arrangements, open communication and flexibility are key to promoting a successful survey experience by all parties - the *AO* or *SLLP* 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 *compliance* of the laboratory practices and testing outcomes; and
- The laboratory operations can continue, minimally impacted by the survey.

6227.2 - *CLIA* Surveyor Responsibilities
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The CLIA surveyor promotes professional and collegial communication during pre-survey and onsite activities. Direct contact by the surveyor with the *AO* or *SLLP* representatives is necessary to enhance CLIA surveyor/AO inspector coordination, an essential element in a smooth-flowing survey.

6227.3 - Pre-Survey Arrangements for Accredited Laboratories
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When a laboratory is selected for a simultaneous validation survey, the special *pre-survey* tasks listed below are performed in addition to the usual survey scheduling tasks, in order to fully coordinate among all the parties.

6227.3.1 - Coordinating With Accreditation Organization (AO) Contact Person
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The CLIA surveyor contacts the *AO's* designated contact person (current names and contact information can be obtained from *CMS)*. The surveyor:

- Verifies the date of the organization's inspection; and

- Obtains contact information of the AO inspector.

NOTE: *Always verify with the AO contact person whether the AO inspection will be announced or unannounced. If unannounced, do not contact the laboratory.*

6227.3.2 - Arrangements With Laboratory

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The *CLIA* surveyor verifies that the laboratory received the SA *or CMS* notification about the validation survey and apprises the laboratory that it will be performed simultaneously with the *AO* inspection.

EXCEPTION: Do not have any pre-survey contact (written, electronic or oral) with a laboratory accredited by an AO with a policy of unannounced inspections. (See *section* 6227.3.1)

6227.3.3 - Coordinating With Accreditation Organization Inspector

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

- The CLIA surveyor contacts 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 smooth-flowing survey.

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

- Mutual agreement on the content of the opening conference (see *section* 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 *AO* 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 *AO* inspector or a comparison of the accreditation standards with the CLIA requirements.

6227.4 - Pre-Survey Arrangements for *State Laboratory Licensure Program*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

6228 - Onsite Activities - Simultaneous Validation Surveys

(Rev. 1, 05-21-04)

6228.1 - Entrance Conference

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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 conveys their 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The *AO/SLLP* inspector sets the flow of the fact-gathering. The *CLIA* surveyor accompanies the *AO/SLLP* inspector, and at the same time determines if sufficient information is obtained to evaluate compliance with CLIA *c*onditions, using the outcome-oriented survey *protocol*. (See *section* 6100.) The *CLIA* 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 *AO/SLLP* inspector do not result in sufficient information to make a CLIA compliance determination, the

CLIA surveyor and the *AO/SLLP* inspector mutually agree on the next course of action. The CLIA survey need not end at the same time as the *AO/SLLP* inspection, however, there may be blocks of time, such as the *AO/SLLP* inspector's period for administrative tasks, when the *CLIA* surveyor can gather sufficient additional information to make the compliance determination.

6228.3 - Pre-Exit Discussion

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The CLIA surveyor should plan to have a pre-exit meeting with the *AO/SLLP* 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 *CLIA* surveyor's conclusions differ from the *AO/SLLP* inspector's *findings*. Acknowledge this as you coordinate on the exit conference agenda. Should the *AO/SLLP* 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 *(CoA) or licensed under a SLLP* has an ongoing responsibility to meet the applicable CLIA *c*onditions, irrespective of the *AO/SLLP* inspection findings or the laboratory's agreement with the *AO*/SLLP.

NOTE: The CLIA surveyor should be mindful that each set of *AO* and *SLLP* requirements was approved by CMS as being equivalent (not necessarily identical) to the CLIA *c*onditions, 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 *AO/SLLP* inspection findings.

6228.4 - Exit Conference

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

As coordinated with the *AO/SLLP* inspector, the surveyor presents the CLIA findings. The *CLIA* 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 *CLIA* 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 *AO/SLLP* inspection and CLIA survey *findings*, or apparent dissimilarities in requirements, refer to the guidance in section *6228.3* above, as appropriate.

After the survey is completed, follow the procedures in *section* 6166.

Other Activities

6230 - CLIA State Agency Performance Review (SAPR)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The CLIA SAPR is *a mandated* evaluation *performed* by *CMS* each fiscal year *to review the* SAs performance of its survey and certification responsibilities under the CLIA Program, as specified in the Section 1864 Agreement. *The goals of CMS are to determine the SA's ability to perform CLIA activities, as well as provide educational and administrative support by evaluating and working with the SA to promote optimal performance and sustained proficiency by the SA and implement improvements where the need for improvements has been identified.*

The CLIA SAPR consists of review criteria based on the SAs responsibilities as outlined in the CLIA Budget Call Letter and the Section 1864 Agreement. CMS will make the determination which criteria are evaluated each year. The CLIA SAPR is structured to evaluate and report SA performance in an objective and consistent manner.

SA Responsibilities

The SA has the following responsibilities:

- Implement internal systems to organize, complete and track survey and certification responsibilities.

- *Maintain quality assessment activities to monitor, and assess, and when indicated, correct problems identified in their survey and certification activities.*

- Hire *and retain* qualified staff to implement the CLIA program *activities.*

- *Generate quarterly reports to identify issues and monitor the progress of its survey and certification responsibilities.*

- *Submit* a Corrective Action Plan (CAP) or Quality Improvement Plan (QIP) when required to *describe how the SA will improve performance.*

CMS **Responsibilities**

SAPRs are conducted either onsite or remotely via document review, or a combination of both, in collaboration with the SA. *CMS* will ask the SA to submit documentation on

how the SA has fulfilled each criterion. *CMS* has the following responsibilities in the SAPR process:

- Overall program oversight of the SA.
- Educational and supportive role to the SA.
- *Generate and evaluate mandatory quarterly reports.*
- Issue the Administrative Info Memo.
- *Review a SA's performance related to any aspect of CLIA SA responsibility not specifically evaluated by the standard SAPR protocol.*
- Review SAPR drafts submitted by *CMS* prior to *review and sign-off by the Branch Manager and* issuing to SAs.
- Track receipt and *retain* all *documents for SAPR* drafts, finals, CAPs, QIPs.
- Utilize the data to update and clarify policy and to determine national training needs.

6232 - CLIA Federal Monitoring Surveys (FMS) *- Identification of the Number and Type*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS is responsible for the SA's performance and compliance with the Section 1864 Agreement. Part of this oversight involves CMS conducting an FMS to review survey performance using a standardized process.

An FMS assessment is performed by CMS to evaluate all SA surveyors use and performance of the CLIA OOSP and adherence to CLIA policies and procedures. FMS targets and allocation requirements will be established at the beginning of each fiscal year using the CLIA Budget Call Letter. Identify the required numbers of total FMS for each state based on a 1% target per fiscal year established from the CLIA Budget Call Letter. All states with partial Full-Time Employees (FTE) will be rounded up to a whole FTE. Based on the 1% annual FMS numbers for the upcoming fiscal year, identify the numbers of Observational, Participatory (90%), and Comparative (10%) rounded to the

nearest whole number.

The following laboratory survey categories are eligible for an FMS:

- *Initial;*
- *Recertification;*
- *Validation; and*
- *Complaint Investigations (Full Survey).*

As a basic rule, CMS does not schedule a Comparative FMS for any facility against which adverse action has been initiated by the State survey agency. The CLIA FMS is distinguished from the CLIA SAPR (see section 6230) by its scope. The FMS focuses on individual surveyors while the SAPR focuses on the SA activities, in aggregate, related to its survey and certification responsibilities.

6234 - Performance of FMS on CLIA Surveyors

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

6234.1 - Definition

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

An FMS assessment includes all the activities performed by CMS to evaluate all SA surveyors use and performance of the CLIA OOSP and adherence to CLIA policies and procedures. The SA surveyor is assessed based upon a standardized list of technical skills. A summary report is prepared and sent to the SA supervisor with a courtesy copy to the SA surveyor.

6234.2 - Purpose

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS is responsible for validating each SA surveyor's use and performance of the CLIA OOSP and adherence to CLIA policies and procedures.

CMS performs the *FMS* for the following reasons:

- *Evaluate the effectiveness of existing SA training;*
- *Provide timely feedback to the SA and SA surveyor;*
- *Identify gaps in understanding;*

- *To design future training to support and improve survey process performance, and*

- *Make future policy decisions.*

6234.*3* – *CLIA FMS Types*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

- The **Observational** CLIA FMS is a *CLIA survey in which the CMS surveyor accompanies the SA surveyor and acts as an observer of the OOSP. The CMS surveyor interacts as necessary during the survey process to provide guidance and education at the appropriate times during the survey process. The CMS surveyor serves as a resource to enable the SA surveyor to strengthen skills, knowledge base, and adherence to the CLIA OOSP, CLIA regulations, and policies. CMS and SA surveyor communicate all findings, observations, decisions, and regulatory interpretations during the survey in a collaborative and cooperative environment.*

- The **Participatory** CLIA FMS is a *CLIA survey in which the CMS surveyor both observes and participates in the survey. The Participatory FMS encourages the development of a collaborative relationship between CMS and the SA. As in the Observational FMS, the CMS surveyor serves as a resource to enable the SA surveyor to strengthen skills, knowledge base, and adherence to the CLIA OOSP, regulations, and policies. CMS and SA surveyor communicate all findings, observations, decisions, and regulatory interpretations during the survey in a collaborative and cooperative environment.*

- The **Comparative** CLIA FMS is a *CLIA survey in which the CMS surveyor surveys the laboratory after the SA surveyor, preferably within 30 days but no later than 60 days from when the SA surveyor performs the survey. The deficiency citations of the CMS surveyor are compared to those of the SA surveyor.*

6234.*4 - SA Responsibilities for Survey Quality*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The FMS must focus on the SA responsibility for survey quality, and it is the SA's responsibility to ensure that all surveys are conducted by qualified and competent individuals.

The new employee is expected to complete these activities before an FMS is scheduled:

- *Quality, Safety & Education Portal (QSEP) CLIA modules, including the CLIA Orientation Program*

- *Performance of surveyor skills using the OOSP*
- *Applicable skill sets described below.*

Organization Skill:

Although organization lends itself to certain variables from person to person, the SA surveyor should make efficient use of costly survey time by demonstrating an ability to function in an orderly and structured fashion. For example, the surveyor's ability to organize his/her survey notes and survey information would facilitate his/her decision on the laboratory's compliance with a particular requirement.

Communication Skills:

The surveyor(s) should demonstrate the ability to communicate effectively to all appropriate parties throughout the entire OOSP. Surveyors should demonstrate effective communication skills in active listening, appropriate body language and diplomatically handling difficult people and/or situations. Communicating positive feedback on the laboratory's commendable practices also adds to the surveyor's credibility and serves as a foundation of success on which the laboratory can build. Communicate and clarify findings with the personnel directly involved in the issues being investigated. All interview questions should be clear, concise, open-ended, and non-threatening.

Information Gathering Skill:

This skill enables the surveyors to identify the information needed to determine the scope, pervasiveness, and seriousness of problems that may have an impact on the laboratory's compliance. A cross section of information is gathered, reviewed and verified in an orderly and logical manner. To maximize the use for costly onsite time, the surveyor limits his/her inquiry to issues that are pertinent and within the scope of the CLIA requirements. The preliminary findings are made from the information obtained by observation, interviews, facts, events, or documentation reviews. Sources of information may be observation of techniques or equipment, review of records (QC, PT, QA, calibration, etc.), interviews, etc. Effective interviews are conducted in a clear concise manner to obtain facts or specific and relevant information, not impressions, conclusions, judgments, etc.

Investigative Skills:

The investigative skills are techniques surveyors use to gather, preserve, or create various forms of information, in a manner that results in valid conclusions. The surveyor should make a systematic inquiry or examination into the laboratory's practices, conditions, and environment to either support or deny compliance determinations. The surveyor should remain focused on relevant monitors and information. The surveyor must carefully record the information obtained. Surveyors must have the knowledge of the regulations and how to apply them in order to relate deficient practice(s) to their findings to determine if the findings have identified a "true symptom" of a failed system. The surveyor is able to make decisions by evaluating findings in the context of public health responsibilities and recommend appropriate actions when patient health is at risk regarding laboratory test outcomes.

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.

The first FMS assessment for a new SA surveyor should occur after the SA training is complete, but no later than 12 months from the date of hire. If SA CLIA training is not completed within 12 months, documentation must be provided to CMS by the SA that explains the reasons for any delays in scheduling an FMS.

The SA must not replace the survey team or surveyor once the FMS has been scheduled with the SA unless there is an extenuating circumstance communicated to CMS.

6236 – CLIA FMS Procedures

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

6236.1 - *Pre-FMS Procedure -* Scheduling of Surveys

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A copy of the FMS assessment worksheet is provided to the SA prior to the FMS. All FMS documents are part of CMS' internal oversight processes for SAs.

The CMS surveyor confirms that all CLIA training is complete by reviewing all required documentation:

- *CLIA Virtual Basic training*
- *SA training. This activity may be completed by CMS in cases where CMS performs all of the training activities for the SA, i.e., a state where there is no Training Coordinator or SA supervisor who can perform these duties.*
- *Other CMS training requirements, as applicable.*

- *CMS and the SA agree that the SA surveyor is ready for an FMS assessment.*

The first FMS assessment for a new SA surveyor should occur after the SA training is complete, but no later than 12 months from the date of hire. If the SA is unable to complete training within 12 months, documentation must be provided to CMS by the SA that explains the reasons for any delays in scheduling an FMS. If no notification is received from the SA, the CMS surveyor must contact the SA for a status on the SA surveyor's training, including the expected completion date.

CLIA Survey Contractor

- *An FMS assessment must be performed on contracted surveyors as determined by CMS. When an FMS assessment is performed, all parts of this SOP must be followed.*

- *Active SA surveyors contracting with another state will have the FMS assessment process completed in their home state.*

- *Retired SA surveyors, contracted as CLIA surveyors must be up to date on all CLIA training requirements and must have at least one FMS assessment each year of contracted service.*

The FMS is to monitor the SA's performance, and it is not to recommend personnel or disciplinary action(s) based on the FMS. The FMS assessment is not a replacement for any individual staff performance evaluation(s). The FMS assessment should not be shared with parties external to CMS.

Scheduling of *FMS assessments* can occur as far in advance as *CMS requires* to organize its workload in consideration of survey priorities. In the case of an announced Observational or Participatory FMS, the SA notifies the laboratory of the upcoming survey with a maximum of 2 weeks advanced notice of the CLIA survey and that the *CMS* surveyor will accompany the SA surveyor. In the case of an announced Comparative FMS, *CMS* 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, "Complaint Procedures," for additional information about complaint investigations in a laboratory.

Observational or Participatory FMS

- *The SA surveyor and the CMS surveyor coordinate to select the type of laboratory (taking into consideration specialties/subspecialties, test complexity, and test volumes).*

- *The SA surveyor and CMS surveyor review the list of laboratories that are due for a survey using scheduling guidelines - geographic areas and timing, whether the survey is announced or unannounced, and agree on a specific laboratory(ies).*

- *The SA surveyor and the CMS surveyor review the laboratory survey history (CLIA database information: CMS-2567, CMS-116, Survey Specialty, CMS-209, CMS-670; fee status, complaints, enforcement actions, Proficiency Testing (PT) data, specialty and subspecialty services offered, and test volumes) prior to going into the laboratory.*

Comparative FMS

- *The CMS surveyor identifies a laboratory to be surveyed within 30 calendar days but no later than 60 calendar days from the date of the SA survey.*

NOTE: *Do not select a laboratory if you have prior knowledge of the laboratory's survey results/outcome.*

- *The CMS surveyor reviews the laboratory survey history (CLIA database information: previous survey cycle CMS-2567, CMS-116, Survey Specialty, CMS-209, CMS-670; fee status, complaints, enforcement actions, Proficiency Testing (PT) data, specialty and subspecialty services offered, and test volumes) prior to going into the laboratory.*

NOTE: *The CMS surveyor will NOT review the most current SA CMS-2567 prior to, or during, the Comparative FMS.*

- *The CMS surveyor notifies the laboratory following CLIA survey protocols and processes (e.g., email, phone call, letter, etc.).*

6236.2 - FMS Assessment Survey Activities

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Observational or Participatory FMS

- *The CMS surveyor provides verbal feedback during the onsite survey and/or immediately after the survey is completed.*

- *The CMS surveyor and SA surveyor discuss the findings, observations, decisions, and regulatory interpretations during the survey in a collaborative and cooperative environment.*

- *The Observational FMS may become a Participatory FMS based on the CMS surveyor's observations/assessment of SA surveyor skills.*

- *The CMS surveyor collects information from observations and verbal discussions to complete the FMS Assessment Worksheet.*

Comparative FMS

- *The CMS surveyor performs the onsite survey of the laboratory based on the OOSP.*

- *The CMS surveyor will refrain from asking questions about the SA survey.*

6236.3 - Post FMS Procedures - Survey Findings
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

See section 6126 - Exit Conference and section 6250 - Enforcement.

Observational or Participatory FMS

- *The CMS surveyor verifies that the SA certification kit has successfully been entered into the CLIA Data System and is available for review by CMS.*

- *No later than 45 days after the FMS, the CMS surveyor will review and evaluate the:*

    - *CMS-2567: adherence to requirements for writing SoDs and following the Principles of Documentation*

    - *CMS-209*

    - *Survey Specialty tab*

    - *CMS-670: correct documentation of survey hours*

    - *PoC/AoC: adherence to requirements for determining that the laboratory has provided an acceptable PoC/AoC.*

NOTE: *The process for performing a review of the PoC/AoC may fall out of the above timeframe if extensions have been granted to the laboratory or extenuating circumstances exist to prolong this review.*

Comparative FMS

- *The CMS surveyor prepares and issues the CMS-2567 and enters all survey information into the CLIA Data System.*

- *The CMS surveyor verifies that the SA survey kit has successfully uploaded into the CLIA Data System (e.g., timeliness).*

- *No later than 45 days after the FMS, the CMS surveyor will review and evaluate:*

  - *CMS-2567 citations from their survey with the SA surveyor's CMS-2567 citations;*

  - *The SA surveyor's adherence to requirements for writing SoDs and;*

  - *The SA surveyor's adherence to following the Principles of Documentation*

  ***NOTE:** Deficiencies may not have been present in the laboratory at the time the SA performed their survey. Special considerations should be employed if the CMS surveyor finds deficiencies previously cited by the SA during their comparative FMS survey. These special considerations may include but are not limited to whether the laboratory is on track in correcting those deficiencies cited.*

  - *CMS-209;*

  - *CMS-670: correct documentation of survey hours;*

  - *PoC/AoC: adherence to requirements for determining that the laboratory has provided an acceptable PoC/AoC.*

***NOTE:** The process for performing a review of the PoC/AoC may fall out of the above timeframe if extensions have been granted to the laboratory or extenuating circumstances exist to prolong this review.*

6236.4 - Feedback and Documentation of the FMS to the SA Surveyor and the SA Supervisor

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Feedback and documentation of all FMS must be provided to the SA surveyor and the SA Supervisor.

Observational or Participatory FMS

*The CMS surveyor **must** provide verbal feedback to the SA surveyor at the conclusion of the FMS.*

Verbal Feedback.

The CMS surveyor provides the SA surveyor with objective remarks on strengths and

areas for improvement noted in the comment section of the CLIA Federal Monitoring Survey Assessment (FMSA) Worksheet; i.e., effective use of OOSP, applicable skill sets, and Principles of Documentation (PoD).

Written Feedback.

No later than 60 calendar days after the survey, the CMS surveyor sends written feedback to the CLIA SA supervisor and a courtesy copy to the SA surveyor. The written feedback includes the CMS surveyor's assessment based on the FMSA Technical Skills Criteria, any recommendations to the SA and reflects the verbal feedback given to the surveyor following the survey.

- *The Cover Letter and Summary report **must** include specific comments regarding the surveyor's training needs and specific recommendations where appropriate in relationship to the minimum FMSA Technical Skills Criteria, PoD, and the CLIA OOSP.*

- *There is a section at the bottom of the Summary Report, Follow-up Action & Monitoring, for the CMS surveyor to request remedial training, the type of remedial training, and a due date for the SA to send documentation to CMS, as applicable.*

- *A preliminary Cover Letter and Summary report may be sent if circumstances identify that the CMS surveyor is unable to send a final report within 60 days.*

Comparative FMS

Verbal Feedback

At the discretion of the CMS surveyor, they may have a verbal or face to face discussion with the SA Manager, SA Training Coordinator/Preceptor and SA surveyor to discuss identified strengths and weaknesses (areas of concern) and the results of the FMS. Evidence of this conversation i.e. date, time, and notes, should be documented in the FMS Assessment Worksheet in the Additional Comments section.

Written Feedback

The Cover Letter and Summary report must include specificity about only those criteria that can be assessed without the SA surveyor present, as well as the results of the comparison of deficiency citations.

- *There is a section at the bottom of the Summary Report, follow-up Action & Monitoring, for the CMS surveyor to request remedial training, the type of remedial training, and a due date for the SA to send documentation to CMS, as applicable.*

- *A preliminary Cover Letter and Summary report may be sent if circumstances identify that the CMS surveyor is unable to send a final report within 60 days.*

6236.5 - FMS Assessment Follow Up by the SA and CMS Surveyor
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

New Surveyors (< 1 year)

1. ***The SA Surveyor demonstrates proficiency in all technical skills***

   No further action is required by CMS if the results of the FMS assessment(s) indicate(s) that the SA surveyor has an established understanding, and is able to apply the CLIA OOSP, and demonstrate adherence to CLIA policies and procedures in the field.

2. ***The SA surveyor requires remedial training***
   The SA manager/SA representative will address any areas of concern that are stated in the FMS Assessment Cover Letter & Summary Report.

   *A written response to the FMS Assessment Cover Letter & Summary Report from the SA manager/representative must be received by CMS within **30 calendar days** after the FMS Assessment Cover Letter & Summary Report are received by the SA.*

   All evidence and documentation of remedial training must be received in CMS within the timeframe provided in the FMS Assessment Cover Letter & Summary Report.

   A follow-up FMS should be performed within 3-6 months (from when the SA's response is received by CMS) to validate that all concerns identified in the FMS Assessment Cover Letter & Summary Report have been addressed.

New and Experienced Surveyors (All Surveyors) (> 1 year)

1. ***The SA surveyor demonstrates proficiency in all technical skills***

   No further action is required by CMS if the results of the FMS assessment(s) indicate(s) that the SA surveyor continues to demonstrate an understanding of the CLIA OOSP and adherence to CLIA policies and procedures in the field.

2. ***The FMS assessment indicates areas of concern***

   The SA manager/representative will address any areas of concern that are stated in the FMS Assessment Cover Letter & Summary Report.

*A written response to the FMS Assessment Cover Letter & Summary Report from the SA manager/representative must be received by CMS within **30 calendar days** after the FMS Assessment Cover Letter & Summary Report are received by the SA.*

All evidence and documentation of remedial training must be received in CMS within the timeframe provided in the FMS Assessment Cover Letter & Summary Report.

***Optional:** A follow-up FMS assessment should be performed within 3-6 months (from when the SA's response is received by CMS).*

6238 – Completion of FMS Workload and Time Expenditures

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The *CMS surveyor* hours are not included in the SA's CMS-670 in the SA's certification kit for the Observational and the Comparative surveys but are entered by the *CMS surveyor* into the ASPEN record for FMS Surveys. For the Participatory survey, the *CMS surveyor's* hours are included in the CMS-670 in the SA certification kit as well as any deficiency citations written by the *CMS* surveyor.

6240 - Other Special Purpose Federal Surveys - Definitions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- **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, *CMS* 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. *CMS* 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. *CMS* has regulatory oversight of CLIA certified international laboratories. Surveys of international laboratories are handled by *CMS.* SAs do not have jurisdiction over international laboratories and should refer all inquiries to *CMS.* *CMS* also has regulatory oversight over CLIA-accredited international laboratory-related complaints and validations.

- **Complaint survey** is a survey conducted to investigate an allegation of laboratory noncompliance with one or more CLIA requirements. The SA or *CMS* may conduct complaint surveys. Refer to Chapter 5, "Complaint

Procedures," for additional information about complaint investigations in a laboratory.

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

Adverse Actions

6250 - Purpose of and Basis for Enforcement Action

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Laboratories holding any type of CLIA certificate are subject to enforcement actions under the authority of §353 of the *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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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, PT referral, failure to comply with notification requirements); and
- Unsuccessful participation in PT.

6252 - Definitions/Terminology - Enforcement

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

- **Confirmatory testing** means testing performed by a second analytical procedure that could be used to substantiate or bring into question the result of an initial laboratory test.

  Example: Pos HIV screen or Pos Lyme → Western Blot

- **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.

- **Distributive testing** means laboratory testing performed on the same specimen, or an aliquot of it, that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test. When such testing occurs at multiple locations with different CLIA certificates, it is considered distributive testing.

  Example: Protein Electrophoresis - Lab A does electrophoresis, Lab B does Total Protein

- **International Laboratories** - CLIA-certified laboratories operating outside the United States or its territories.

  NOTE: All enforcement actions on international laboratories are handled by the CMS Central Office.

- **Lifting a sanction -** Generally, sanctions are not lifted until a

laboratory's compliance with all condition level requirements is verified; in other words, sanctions are imposed for a period of time and then *lifted* when condition-level compliance is confirmed.

- **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.

- **Reflex testing** means confirmatory or additional laboratory testing that is automatically requested by a laboratory under its standard operating procedures for patient specimens when the laboratory's findings indicate test results that are abnormal, are outside a predetermined range, or meet other pre-established criteria for additional testing.

  Examples: Pos Hep A screen → Total vs IgM, Pos E.coli → serotyping

- **Repeat proficiency testing referral** means a second instance in which a proficiency testing sample, or a portion of a sample, is referred, for any reason, to another laboratory for analysis prior to the laboratory's proficiency testing program event cut-off date within the period of time encompassing the two prior survey cycles (including initial certification, recertification, or the equivalent for laboratories surveyed by an approved accreditation organization).

- **Rescinding a sanction** - Generally, sanctions may be withdrawn if they have been imposed when information, which was not previously known to CMS, comes to CMS' attention that the sanction should not have been imposed.

- **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 *annually* except cytology.

6254 - Enforcement Options for All Laboratories

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 condition-level requirements.

6256 - Sanctions(s) - General

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6256.1 - Sanction*s* - Factors to Consider

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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. *CMS* 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 *c*ondition-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, to other CMS agents, and to CMS;
- 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; and

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

6256.2 - *Principal* Sanctions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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.

A limitation of the CLIA certificate means the laboratory is not permitted to perform *certain* testing *for an analyte, specialty, or subspecialty* and will *not receive reimbursement from* Medicare or Medicaid for the laboratory*'s* work in the applicable *analyte,* specialty*,* or subspecialty as a result of that limitation. The laboratory may continue to conduct all other testing permitted under the non-limited portions of its CLIA certificate.

A suspension of the CLIA certificate means that the laboratory cannot report out the results of testing of human specimens for diagnostic, treatment, or assessment purposes during the period of suspension. *A suspension may be imposed for no longer than 12 months, or until a revocation is effective.*

A revocation of the CLIA certificate means that the laboratory cannot report out the results of testing of human specimens for diagnostic, treatment or assessment purposes following during the period of the revocation. *A revocation is a loss of CLIA certificate for up to two years. Once the revocation period has ended, the laboratory must apply for a new CLIA certificate. The loss of a CLIA certificate may also result in a prohibition of the owner/operator/laboratory director from owning, operating, or directing a laboratory.*

6256.3 - *Alternative* Sanctions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

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

6256.4 - *Additional Sanctions – Medicare Payments*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

- Cancellation of the laboratory's approval to receive Medicare payment;
- Suspension of part of Medicare payment; or
- Suspension of all of Medicare payment.

6256.5 - *Civil Suit*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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, 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.

6256.6 - *Criminal Sanctions*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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. *CMS* refers suspected instances of intentional violations to the Office of Inspector General (OIG).

6256.7 - Criminal Sanctions
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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).

6258 - Denial of Form CMS-116 from Prospective Laboratory or Denial of Request to Test in New Specialties or Subspecialties
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If the Form CMS-116 for any CLIA certificate is denied, *CMS* 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 *file* for a reconsideration.

If a laboratory is requesting the addition of a new specialty or subspecialty, the laboratory may not report patient test results or receive payment under Medicare or Medicaid for those additions unless the denial is overturned. However, the laboratory may continue to report patient test results and bill for the already approved specialties and subspecialties.

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

6260 - Certificate Changes When Enforcement Action is Pending
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Once sanctions have been imposed, CMS should move forward with the imposition, regardless of changes in the CLIA certificate or the laboratory going out of business.

6260.1 - Laboratory Gives Notification of Going Out of Business
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 *CMS* 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 *CMS* in writing (e.g., email), including the projected date of closure. Any correspondence received from the laboratory and any other pertinent document(s) are submitted to *CMS*.

6260.2 - Laboratory Gives No Notification of Going Out of Business

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If a laboratory voluntarily withdraws from all testing *or* refuses new requests for testing, it voluntarily relinquishes its CLIA certificate. If the SA learns that a laboratory may be out of business, it verifies the *operational status* and notifies *CMS* in writing (e.g., email).

6260.3 - Voluntary Withdrawal When Enforcement Action Is Pending

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS should proceed with the enforcement action despite the laboratory's withdrawal, particularly if *CMS* 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 *CMS* 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. *CMS* will restate in the notice the laboratory's appeal rights mentioned in the notice of sanction.

If *CMS* decides to discontinue the revocation, it notifies the SA to process the withdrawal.

6260.4 - Requests to Change Certificate Type When Enforcement Action is Pending

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

If *CMS* proceeds with the enforcement action, *CMS* notifies the laboratory that its current 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, *CMS* or SA proceeds with the change of certificate type.

6260.5 - Request to Change Accreditation Organization When Enforcement Action is Pending

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS proceeds with the enforcement action proposed against a laboratory's existing certificate if the laboratory's deficiencies warrant it. *I*f *CMS* proceeds with the enforcement action, *CMS* notifies the laboratory that its current certificate will remain active until the enforcement action becomes effective, at which time the request may be acted upon. In addition, *CMS* notifies the laboratory that the laboratory may not change accreditation organizations during an enforcement action. If, during the enforcement action, the accreditation organization revokes the laboratory's accreditation, the laboratory will continue to hold a certificate of accreditation throughout the duration of the enforcement action.

If the enforcement action is discontinued, *CMS* or SA proceeds with the change of AO.

6262 - Reissuance of Certificates to Laboratories Found Out of Compliance

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A laboratory that has been found out of compliance with one or more CLIA *c*ondition(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 Certificate of Compliance or Certificate of Accreditation may also be administratively extended for a laboratory that has been found out of compliance if the laboratory's certificate 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 of these circumstances is subject to all principal and alternative sanctions.

6264 - Sanction Notification Requirements
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6264.1 - Notice of Proposed Sanction(s) - All Sanctions
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS provides written notice of the proposed sanction(s) and gives the laboratory at least 10 calendar days to respond.

6264.2 - Notice of Imposition of Sanction(s) - All Sanctions
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS 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.

6266 - CLIA Conditions Not Met - Additional Sanctions Related to Medicare Payments - Principal and Alternative Sanctions for Laboratories that Participate in Medicare
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

NOTE: This section and its subsections are Medicare Provisions enforced under the Medicare Program Authority, not CLIA.

CLIA certification is mandatory for all laboratories that report out test results on human specimens for diagnosis, treatment or assessment purposes. CLIA obligations are not dependent on the payment source for the testing. However, CLIA certification is required for payment under Medicare and Medicaid.

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 on the alleged CLIA infractions. CLIA also permits imposition of alternative sanctions other than a civil money penalty prior to a hearing on the alleged CLIA infractions, 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 *PHSA* and the Social Security Act apply to these facilities. These Medicare sanctions are described below.

6266.1 - Principal Sanction - Cancellation of Medicare Payments

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

6266.1.1 - Basis for Cancellation

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 *c*ondition including failure to meet PT requirements;

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

- The laboratory fails to correct all its deficiencies within the time frames specified in the PoC. For deficiencies not at the condition level, correction of deficiencies cannot extend beyond 12 months from the last date of survey that identified the deficiencies.

6266.1.2 - Effective Date of Cancellation

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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.

6266.1.3 - Effect of Cancellation on Other Medicare Payment Sanctions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

6266.1.4 - Effect of Cancellation of Medicare on Laboratory's Eligibility to Receive Medicaid Payments

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Except as otherwise 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 meets CLIA requirements or is licensed by a State whose licensure program has been approved for CLIA exemption by CMS.

6266.2 - Alternative Sanctions - Suspension of Part or All of Medicare Payments

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6266.2.1 - Suspension of Part of Medicare Payments

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS may impose this sanction in the following situations:

- The laboratory has *c*ondition-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, *CMS* will instruct 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 *c*ondition-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. In this situation, the SA and *CMS* should be in communication throughout the process so that any enforcement action can be timely.

If the laboratory corrects all *c*ondition-level deficiencies, *CMS* instructs the MAC to resume Medicare payment effective for all services furnished on or after the date the deficiencies are corrected. If all deficiencies are not corrected within the time frames specified in the AoC or PoC (corrections cannot exceed 12 months for a PoC), *CMS* cancels the laboratory's approval to receive Medicare payment for its services.

If the sanction of suspension of Medicare payment is recommended, *CMS* 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. *CMS* 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.

6268 - Adverse Action on Any Type of CLIA Certificate: Effect on Medicare Approval

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6268.1 - Suspension or Revocation of Any Type of CLIA Certificate

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When *CMS* suspends or revokes any type of CLIA certificate, the laboratory's approval to receive Medicare payment for its services is canceled. *The laboratory director or designee should sign an agreement not to bill Medicare for laboratory testing services. Additionally, the Medicare Administrative Contractor (MAC) should be notified of the laboratory's suspension or revocation by CMS.*

6268.2 - Limitation of Any Type of CLIA Certificate

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When *CMS* limits any type of CLIA certificate, it concurrently amends the laboratory's approval to receive Medicare payment to only those specialties or subspecialties that are authorized by the laboratory's limited certificate. *The MAC should be notified of the laboratory's limited certificate.*

6270 - Effect on Medicaid Participation

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Payment for laboratory services may be made under the State plan only if those services are furnished by a laboratory that has a CLIA certificate or is licensed by a State whose licensure program has been approved by the Secretary.

6272 - Failure to Furnish Notification of Changes

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If a laboratory fails to meet the notification of change requirements as outlined in the regulations (42 C.F.R §493.39(b), §493.51(a), §493.53(b), §493.63(a)), *CMS* may impose a principal sanction. (Refer to *section* 6256.3).

Refer to Notification sections for timelines earlier in the SOM.

6276 - Suspension, Limitation, or Revocation of Any Type of CLIA Certificate

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6276.1 - Adverse Actions Based on Actions of the Laboratory's Owner, Operator or Employees

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6276.1.1 - Basis for Action

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS may initiate adverse action to impose principal sanctions (i.e., suspension, limitation, revocation) on any CLIA certificate if CMS finds that a laboratory owner, operator or one of its employee*s* has:

- Been found (e.g., through findings during the survey process, or through documents submitted to CMS or the SA) to have potentially made a misrepresentation which was materially relevant to the laboratory having obtained or maintained 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 (e.g., failed to comply with notification of change requirements).

- Failed to comply with reasonable requests by *CMS* or CMS' agent for any information or work on materials that *CMS* 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 *CMS* 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.

- 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.)

If *CMS* determines that any of the above CLIA violations have occurred, *CMS* imposes a principal sanction.

Also, *CMS* notifies the OIG in cases of:

- Misrepresentation in obtaining a CLIA certificate;

- Performance, or representation by the laboratory as entitled to perform, an examination or other procedure that is not authorized by its CLIA certificate;

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

- Adverse action based on improper PT referral.

6276.2 – Adverse Actions Based on Improper Referrals in Proficiency Testing

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If CMS determines that a laboratory has intentionally referred its proficiency testing to another laboratory for analysis, CMS will categorize the PT referral. (see *sections* 6276.2.1-6276.3).

The PT referral regulations provide a specific framework for application of sanctions for PT referral cases taking into account circumstances of the referral. The process for review of PT referral cases is as follows - when a possible case of PT referral is found by *CMS* or the SA, it is forwarded to the PT Referral Team at *CMS*.

6276.2.1 – Category 1

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A laboratory that refers its proficiency testing samples to another laboratory for analysis, and reports out that other laboratory's proficiency testing results, or has a repeat PT referral regardless of category, will be considered Category 1 PT referral.

In these instances, *CMS*:

- Must impose - Revocation of the CLIA certificate and owner/operator/laboratory director prohibition for at least 1 year, and
- May impose - CMP.

NOTE: The owner may be exempt from the owner/operator ban if, after review, CMS finds that there is no evidence that patients would be put at risk by *the* owner being exempted from the ban, that the owner was not complicit in the PT referral, and that the laboratory has either not received PT samples from another laboratory in 2 previous survey cycles, or, if it did, it reported the receipt to CMS or to the CMS- approved AO. This determination is made on a lab-by-lab basis.

6276.2.2 - Category 2

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A laboratory that refers its proficiency testing samples to another laboratory for analysis and obtains test results for PT samples from that other lab on or before proficiency testing event cut-off date, but reports its own PT sample results, will be considered a Category 2 PT referral.

In these instances, *CMS*:

- Must impose - Suspension/limitation for less than 1 year and alternative sanctions, as appropriate, but will always impose a CMP and dPoC which includes training of staff.

6276.2.3 - Category 3

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A laboratory that refers its proficiency testing samples to another laboratory for analysis and obtains test results for PT samples from another laboratory after the cut-off, will be considered a Category 3 PT referral.

In these instances, *CMS*:

- Must impose - Alternative sanctions, as appropriate, but will always impose a CMP and dPoC which includes training of staff.

6276.2.4 - Carve-Out

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimen, and if the proficiency testing referral is not a repeat proficiency testing referral, CMS will consider the referral improper, but not intentional, and potentially subject the laboratory to alternative sanctions in accordance with §493.1804(c).

Reflex, distributive and confirmatory testing is prohibited for PT unless it is performed by the same laboratory that performed the initial testing, is included in that laboratory's standard operating procedure, and the results are reported as part of the proficiency testing program.

NOTE: Any CLIA-certified laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex, distributive or confirmatory testing, or any other reason.

6276.2.5 - *CMS* Actions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

6276.3 - Adverse Action Based on Exclusion from Medicare

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If the Inspector General excludes a laboratory from participation in Medicare, CMS will suspend the laboratory's CLIA certificate for the period of time the OIG excludes the laboratory.

The notice of suspension should be sent immediately after *CMS* learns that the exclusion was imposed. While subject to appeal, the effective date of the Medicare cancellation is not delayed pending the hearing decision. A change of laboratory ownership may not release a laboratory from its exclusion from Medicare and the suspension. (See *section* 6294.2)

6276.4 - Procedures for Suspension, Limitation, or *Revocation*: Exceptions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

6276.4.1 - Suspension or Limitation: Exceptions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If an appeal is requested, CMS does not finalize the suspension or limitation of a CLIA certificate until after the ALJ hearing decision that upholds the suspension or limitation. However, CMS may suspend or limit a CLIA certificate prior the ALJ hearing *decision* if any of the following circumstances exist:

- The laboratory's deficiencies pose immediate jeopardy;
- The laboratory has refused a reasonable request for information or work on materials; or
- The laboratory has refused permission for CMS or a CMS agent to inspect the laboratory or its operations.

6276.4.2 - Procedures for Revocation

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If an appeal is requested, CMS does not *finalize the revocation* of *a* CLIA certificate until after an ALJ hearing that upholds the revocation. CMS may revoke a CLIA certificate after the hearing decision even if it had not previously suspended or limited that certificate.

6276.5 - Notice to Office of the Inspector General (OIG)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

- The owner, operator, or one of the laboratory's employees is *proven* guilty *in a court of law* 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 any CLIA provisions and its implementing regulations; or

- The laboratory intentionally referred PT samples to another laboratory for analysis. (See *section* 6276.2.1, Category 1)

6278 - Unsuccessful Participation in PT

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6278.1 - Unsuccessful Participation in PT: Training and Technical Assistance Option

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

For a laboratory's initial unsuccessful participation in PT, *CMS* may require the laboratory to undertake special training of its personnel, or to obtain necessary technical assistance, or both. This 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 *CMS*. *CMS* may allow the SA to require the laboratory to obtain training and technical experience; however, in this instance, the SA must report this information to *CMS*.

This only applies to initial unsuccessful participation. Any non-initial (i.e., subsequent) unsuccessful participation for PT must be immediately forwarded to *CMS* by the SA.

Training and technical assistance is not an option in the following situations:

- Immediate jeopardy;

- Laboratory fails to provide satisfactory evidence that it has corrected the problem which caused the unsuccessful PT performance;

- Laboratory has *a* poor compliance history.

6278.2 - Subsequent (Non-Initial) Unsuccessful Participation in PT

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If a laboratory fails to successfully participate in PT for a specialty, subspecialty or analyte, *CMS* will suspend or limit the CLIA certificate *in the failed specialty, subspecialty, or analyte,* as well as cancel or suspend the laboratory's ability to receive Medicare payments for a period of no less than 6 months. However, if the laboratory agrees to stop testing in the failed specialty, subspecialty, or analyte prior to the written notification proposing sanctions and, the laboratory demonstrates satisfactory performance on two consecutive events (either regularly schedule*d* or off-cycle or a combination *of both), then CMS may make the determination not to impose a suspension or limitation of its CLIA certificate and the laboratory may be permitted to resume patient testing.*

6278.2.1 – Notice of Proposed Sanction(s)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS provides written notice of the proposed sanction(s) and gives the laboratory at least 10 days to respond.

6278.2.2 – Notice of Imposition of Sanction(s)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS 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.

6278.3 - Duration of Sanction

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Once imposed, onsite monitoring continues until the laboratory demonstrates that it is capable of ensuring compliance with all *c*ondition-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, *CMS* 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 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 Sanctions
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6280.1 - Alternative Sanctions: Directed Plan of Correction (dPoC) and Directed Portion of a Plan of Correction (dPPoC)
(Rev. 195, Issued: 11-15-19, Effective: 11-15-19, Implementation: 11-15-19

6280.1.1 - Basis for Action
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS may impose a directed PoC for a laboratory that has *c*ondition-level deficiencies. Under this sanction, the laboratory is directed to take specific corrective action within specific time frames in order to compel the laboratory to achieve compliance. The laboratory must correct every deficiency addressed in the directed PoC. If *CMS* does not impose a directed PoC as an alternative sanction, it at least imposes 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.

6280.1.2 - Procedures for Directed PoC (dPoC)
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When imposing this sanction, *CMS* takes the following action:

- **Specific Corrective Action and Time Frames** - Directs the laboratory to take specific corrective action within specified time frames.

- **Duration and Effect of Sanction -** If a revisit or other documentation confirms that the laboratory has not corrected its deficiencies within 12 months from the survey date, *CMS may* cancel the laboratory's approval to *receive* Medicare payment for its services *by sending notice to* 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.

6280.1.3 - Procedures for Directed Portion of PoC (dPPoC)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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, *CMS* directs the SA to notify the laboratory's clients. When *CMS* imposes this sanction, the following procedures apply:

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

- Within 30 days of the date the SA receives this information, *CMS* 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.

6280.2 - Alternative Sanction: Civil Money Penalty (CMP)

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6280.2.1 - Scope and Basis

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS determines if a CMP will be based on a "per day of noncompliance" or "per violation". When a laboratory has *c*ondition-level deficiencies, *CMS* may generally impose a civil money penalty in lieu of, or in addition to, imposing a principal sanction against the laboratory's CLIA certificate. Civil money penalties may only accrue, but may not be collected prior to a hearing (if one is requested). The penalty is collected according to the procedures outlined below. CMP fees are tracked by *CMS* in the Civil Money Penalty Tracking System (CMPTS) tab of the AEM system.

NOTE: See *section* 6276.2 for requirements related to CMPs in cases of PT referral.

6280.2.2 - Amount of Penalty

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

- The nature, scope, severity, and duration of the noncompliance;
- Whether the same *c*ondition-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 *CMS* or CMS' agent.

NOTE: Per the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, adjustments to the civil money penalties are expected to be published annually. These adjustments will be published in the Federal Register and located at 45 CFR Part 102. In addition, CMP amounts for laboratories will also be posted on the Survey and Certification website at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Civil-Monetary-Penalties-Annual-Adjustments.html.

Once the effective date of new CMP levels occurs, the new amounts shall be used to impose any CMPs, regardless of when noncompliance is identified. For example, if a survey identifies noncompliance prior to the effective date of new CMP levels, but the CMP is imposed after that effective date, the new CMP levels shall be used to calculate the CMP

imposed. These new amounts shall be used until the next effective date occurs.

6280.2.3 - Range of Penalty Amount

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The range of penalty amounts are broken into Immediate Jeopardy (maximum and minimum) and Not Immediate Jeopardy (maximum and minimum). These ranges are updated by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

The annual adjustment penalty amount is located at: https://www.cms.gov/medicare/health-safety-standards/civil-monetary-penalties.

Changes in Penalty Amounts*:*

- If a *CMP* is proposed for immediate jeopardy and the immediate jeopardy is subsequently removed, but the *c*ondition-level deficiency continues, the penalty amount may be shifted to the lower range.

- Conversely, if deficiencies cited during the survey did not pose immediate jeopardy and *CMS* proposed a penalty in the lower range, *CMS* may before the hearing, propose an increase in the penalty amount to the higher range when deficiencies become sufficiently serious to pose immediate jeopardy.

6280.2.4 - Notice of Intent

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS will notify the laboratory in writing of its intent to impose a civil money penalty at least five days before the effective date when immediate jeopardy exists and at least 15 days before the effective date of the sanction if there is no immediate jeopardy. The notice includes the following information:

- 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, *CMS* may reduce the proposed penalty amount by 35 percent.

6280.2.5 - Accrual of Penalty

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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.

6280.2.6 - Duration of Penalty

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 *c*onditions 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.

6280.2.7 - Computation and Notice of Total Penalty Amount

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

After the laboratory's compliance is verified or its CLIA certificate has been suspended, limited, or revoked, *CMS* computes the total penalty amount due. This computation occurs:

- **After** the 60-day period for requesting a hearing has expired and the laboratory has not requested a hearing*;* or

- If the laboratory has waived its right to a hearing; or

- When an ALJ issues a hearing decision that upholds imposition of the CMP.

NOTE: If the laboratory does not request a hearing, *CMS* may *choose to* reduce the proposed penalty amount by 35 percent.

CMS 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 *CMS'* 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. *CMS* computes interest in accordance with 42 CFR Part 405.378(d).

6280.2.8 - Collection of Penalty Amounts
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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).

6280.2.9 - Settlement
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

6280.3 - Alternative Sanction: State Onsite Monitoring
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6280.3.1 - Basis for Action Basis for Action
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Continuous or intermittent monitoring by the SA may be required to ensure the laboratory implements its AoC or PoC and makes the corrective actions necessary to bring it into compliance with the *c*ondition-level requirements. The monitor's responsibility is to oversee whether deficiencies are being corrected and whether compliance is achieved.
The State onsite 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 *CMS* 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 *CMS* and the State. Form CMS-670 is used to collect this data.

6280.3.2 - Duration of Sanction

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

6280.4 - Duration of Alternative Sanctions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

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

If an alternative sanction is imposed for *c*ondition-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, *CMS* takes the following action:

- Cancels the laboratory's approval to receive Medicare payment for its services;
- 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.

6280.4.1 - Notice of Intent
(Rev. 45, Issued: 05-08-09, Effective: 05-08-09, Implementation: 05-08-09)

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

- The statutory basis for the penalty;
- The proposed daily or per violation amount of the penalty;
- The factors considered in determining the penalty amount;
- The laboratory's opportunity to respond within ten days of receipt of the notification, which includes the opportunity to submit additional information or a credible allegation of compliance; and
- The laboratory's appeal rights, including the criterion that, if the laboratory does not request a hearing, RO may reduce the proposed penalty amount by 35 percent.

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-Lifting of Alternative Sanctions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Alternative sanctions are not lifted until compliance with all *c*ondition-level requirements is verified.

6280.6 - *Settlement*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

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.

6284 - Noncompliance With One or More Conditions - Immediate Jeopardy Exists

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When a laboratory's deficiencies pose immediate jeopardy, *CMS* 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 *CMS* 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 agrees to voluntarily cease testing in the area related to the IJ, then the laboratory may be able to abate the IJ; however, IJ cannot be removed until the laboratory provides the evidence and documentation to show that they are in condition-level compliance.

If the laboratory has not removed the immediate jeopardy, *CMS* 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.

6284.1 - Processing Immediate Jeopardy Enforcement Actions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When immediate jeopardy is documented, *CMS* completes enforcement procedures within 23 calendar days. ***CMS* does not postpone or stop the procedure unless the removal of the immediate jeopardy is achieved and verified**. *When the SA determines the laboratory's noncompliance has caused a serious adverse outcome, or has made a serious adverse outcome likely, and immediate action is needed to prevent serious harm from occurring or recurring, the surveyor/survey team consults with CMS as directed.*

1. **Survey Date*/Day One* -** The survey date is the date on which the survey process is completed. *When IJ is determined, the SA sends the IJ templates, one for each condition-level deficiency, to the laboratory.*

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

   The SA sends written notice (e.g., overnight mail, facsimile followed by mail, email) notifying the laboratory of the IJ *on Form CMS-2567 using the D0000 statement and request an AoC.*

   - *If the AoC is unacceptable:*

     - *The SA sends the 1st AoC unacceptable letter to the laboratory and prepare to perform an unannounced onsite revisit by the 15th calendar day.*

     - *CMS (and SA if able) will contact the laboratory director (LD) before the unannounced onsite revisit to ensure that the LD understands the noncompliance, what they must do to fix it, and what will happen if the noncompliance is not fixed.*

   - *If the AoC is acceptable AND the IJ is removed:*

     - *The SA must perform an onsite revisit by the 15th calendar*

day to confirm the IJ has been removed and the laboratory is in compliance with all CLIA regulations.

3. ***Fifteenth Working Day*** *– the SA performs the unannounced onsite revisit. During the revisit, the LD must be notified.*

    - *If based on the onsite revisit the laboratory is in compliance:*

        - *The SA releases the revisit no deficiency Form CMS-2567 and the AoC acceptable letter.*

    - *If based on the onsite revisit the laboratory is not in compliance:*

        - *The SA notifies CMS within 1 business day and CMS composes the Proposed Sanction letter to be sent with the revisit Form CMS-2567,* ***no later than the 18th calendar day.***

        - *The SA may perform one more unannounced onsite revisit prior to CMS imposing sanctions.*

        - *CMS will send the Imposition notice* ***on the 23rd day.***

6286 - Noncompliance With One or More Conditions - No Immediate Jeopardy Exists

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When condition-level deficiencies are identified, but immediate jeopardy does not exist, and an enforcement action is warranted, *CMS* completes enforcement procedures within 90 calendar days. *CMS* 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 survey process is completed.

2. **Tenth *Working* Day -** No later than ten *working* days following the survey date,
   the SA will notify (e.g., overnight mail, facsimile, email) the laboratory in writing of the cited deficiencies, including *c*ondition-level noncompliance. 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.

3. **Twenty-*Fifth* Calendar Day -** The laboratory *should* submit a credible AoC to the SA *by the 10th calendar day after the laboratory has received the Form CMS-2567 Statement of Deficiency.*

4. ***No later than* the Fifty-Fifth *Calendar* Day -** If the laboratory has submitted a credible allegation of compliance, the SA will determine whether compliance *can* be verified by an onsite revisit or whether compliance can be verified based on evidence presented by the laboratory (e.g., paper revisit for PT enrollment and personnel qualifying documentation). If compliance can be verified without an onsite revisit, the SA will certify compliance, notify the laboratory, and will notify *CMS* to unflag (L32, L33) in the certification kit. If the SA determines that the AoC is credible and the evidence supports the AoC, but cannot verify compliance without an onsite review, the SA will conduct a revisit. *CMS will* approve subsequent SA onsite revisits which usually occur between the 45th and 55th day. *During the unannounced onsite revisit, the LD must be notified. The SA notifies CMS within 1 business day if the deficiencies are not corrected.*

   - *If the 1st AoC is acceptable:*
     - *The SA performs the onsite/offsite revisit.*
     - *If no deficiencies are found, the SA releases the revisit Form CMS-2567 and the AoC acceptable letter.*
   - *If the 1st AoC is unacceptable:*
     - *The SA sends the 1st AoC unacceptable letter and prepares for an unannounced onsite revisit.*
     - *CMS (and SA if able) will contact the laboratory director (LD) before the unannounced onsite revisit to ensure that the LD understands the noncompliance, what they must do to fix it, and what will happen if the noncompliance is not fixed.*
   - *If no AoC received, send a 2nd request.*
   - *If the 2nd AoC is acceptable:*

- *The SA schedules the unannounced onsite/ offsite revisit.*

- *If no deficiencies are found, the SA releases the revisit Form CMS-2567 and the AoC acceptable letter.*

- *If the 2nd AoC is unacceptable:*

  - *The SA send the 2nd AoC unacceptable letter. No more AoCs are solicited or reviewed by the SA. Compliance is based on the onsite revisit.*

  - *The case is sent to CMS for enforcement actions.*

- *If no AoC received, send to CMS for enforcement actions.*

5. ***By the*** **Sixtieth Calendar Day -** The SA *completes the onsite revisit Form CMS-2567.*

   - *If the laboratory is in compliance:*

     - *The SA completes a no deficiency revisit on Form CMS-2567.*

   - *If the lab is* ***not*** *in compliance:*

     - *The SA completes the revisit Form CMS-2567 and send it to CMS for enforcement actions by the* ***5th working day following the revisit (this is calendar day 60).***

6. ***Ninetieth*** **Calendar Day -** *Sanctions are effective 15 days (when non-IJ) from the date of the imposed notice. This is the 90th day. CMS may wait until the 60-day appeal period is complete before sanctions are finalized.*

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 *c*ondition-level deficiencies, but never beyond 12 months from the last date of the survey which identified the deficiencies.

If the laboratory corrects all *c*ondition-level deficiencies and participates in Medicare, *if applicable, CMS lets the MAC know that the laboratory may* resume 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, *CMS may tell the MAC to* cancel the laboratory's approval to receive Medicare payment for its services. *CMS* may impose a principal sanction against the laboratory's CLIA certificate. *CMS* notifies the laboratory in writing of the sanction(s) that CMS is proposing to impose and its right to due process.

6286.1 - Monitoring of Corrective Action(s)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

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

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If a revisit verifies that the laboratory has not corrected its *c*ondition-level deficiencies within the period specified in the approved PoC, *CMS* 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, *CMS* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

At the end of the PoC period, if all *c*ondition-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, *CMS* 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 *c*ondition-level as well as deficiencies *not at the condition-level* remain uncorrected. If a hearing decision upholds the proposed principal sanction against the laboratory's CLIA certificate, *CMS* lifts the alternative sanction as of the day the principal sanction is effective.

6286.5 - Revocation of CLIA Certificate

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If *CMS* decides to revoke a noncompliant laboratory's CLIA certificate, it may do so within the time frames that *CMS* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS switches from the no immediate jeopardy procedures to the accelerated procedures of *section 6284* at any point that it determines immediate jeopardy to patient health or safety exists.

6288 - Condition-level Deficiencies Corrected but Other Deficiencies Remain -12-Month Maximum for Correction

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If all condition-level deficiencies have been corrected, and standard level deficiencies remain uncorrected at the end of 12 months from the date of the survey that originally identified the deficiencies, the SA will recommend to *CMS* that principal sanctions be imposed against the laboratory's CLIA certificate as well as cancelling the laboratory's approval to receive Medicare payments. This applies when the SA has received a PoC which was acceptable in content and time frame, but based on a revisit, the SA has determined that the laboratory has not corrected the Standard level deficiencies. The SA will not accept a revised PoC that extends beyond 12 months.

6289 - Deficiencies That Are Not *a*t Condition-*l*evel

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If a laboratory has deficiencies that are not at the *c*ondition-level, the following rules apply.

- The laboratory must submit a PoC that is acceptable in terms of both its contents and the time frames for correction. For the PoC to be acceptable, it must show that the laboratory can achieve compliance and that the 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, *CMS* may cancel the laboratory's approval to receive Medicare payment for its services in accordance with 42 CFR § 493.1842(a)(2)(ii). In addition, *CMS* 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 on the basis of this failure.

- If the laboratory has not corrected its deficiencies within 12 months after the

last date of the survey that identified the deficiencies, *CMS* cancels the laboratory's approval to receive Medicare payment for its services and imposes a principal sanction against the laboratory's CLIA certificate.

6290 - Laboratory Found Not in Compliance Following Validation Survey or Complaint Survey

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

NOTE: Refer to SOM Chapter 5, Complaint Procedures regarding additional information about complaint investigations/surveys.

If deficiencies identified are *c*ondition-level and pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public, *CMS* follows the adverse action procedures described in *section* 6284.

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, *CMS* follows the adverse action procedures described in *section* 6286. *CMS* notifies the laboratory that it has been found out of compliance with a *c*ondition(s) and is, therefore, placed under CMS jurisdiction.

The laboratory is placed under CMS jurisdiction, while continuing to retain its Certificate of Accreditation, until it reaches CLIA *c*ondition-level compliance or until such time as it loses its Certificate of Accreditation. Accredited laboratories found out of compliance at the *c*ondition-level on a validation or complaint survey, and do not provide a credible AoC, are subject to the same enforcement procedures applied to non-accredited laboratories.

For any cases that may have national media implications, *CMS* should also be notified of enforcement actions proposed and/or imposed against accredited laboratories.

NOTE: *CMS* should provide notices and documentation related to enforcement actions to the appropriate AOs.

6290.1 - Allegation of Compliance

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If *CMS*, in conjunction with the SA, determines that the AoC is credible, *CMS* sends written notification to the laboratory and to the accreditation organization.

If *CMS*, in conjunction with the SA, determines that the AoC is not credible, *CMS* sends written notification to the laboratory requesting an amended AoC, and also notifies the accreditation organization of their actions.

6290.2 - Compliance With All CLIA Conditions After Correction of Deficiencies

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When an accredited laboratory is determined to be in compliance with all CLIA conditions, *CMS* notifies the laboratory and the accrediting organization accordingly.

6290.2.1 - Plan of Correction

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If *CMS* concurs with the SAs recommendation of an acceptable PoC, *CMS* sends written notification to the laboratory and to the accreditation organization. Where the SA has found the PoC unacceptable and *CMS* concurs with the SAs recommendation, *CMS* notifies the laboratory accordingly and requests an amended acceptable PoC.

6290.2.2 - Compliance With All CLIA Conditions After Correction of Deficiencies

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When an accredited laboratory is determined to be in compliance with all CLIA conditions, *CMS* notifies the laboratory and the accrediting organization accordingly. *CMS* informs the SA in writing to cease monitoring activities. Revisits are never authorized after an accredited laboratory has been notified that it is in *c*ondition-level compliance with all CLIA conditions.

6290.2.3 - Notification of Accreditation Organization

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

6292 - Procedures for Noncompliant Federal and State Operated Laboratories

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If *CMS* surveys a Federal or State operated laboratory and finds *c*ondition-level noncompliance, *CMS* will function as both the SA and *CMS* and follow the

enforcement procedures outlined in the section.

6292.1 - Initial Action

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

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

If a laboratory fails to submit an acceptable PoC, and subsequent requests for an acceptable PoC are unsuccessful, *CMS* may cancel the laboratory's approval to receive Medicare payment for its services in accordance with 42 CFR 493.1842(a)(2)(ii). In addition, *CMS* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

6294 - Enforcement - Additional Information

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6294.1 - Ensuring Timely Correction of Condition-level Deficiencies

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

6294.1.1 - Monitoring of Corrective Action(s)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS 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.

6294.1.2 - Acceleration of Timetable

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS may switch from the no immediate jeopardy procedures to the accelerated procedures of *section* 6284 at any point that it determines immediate jeopardy to patient

health or safety exists.

6294.2 - Intervening Actions That Do Not Postpone or Delay Enforcement Timetable

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Only verified correction of noncompliance can stop an enforcement action.

A change in the laboratory director *or owner* does not affect completion of an enforcement action. *CMS* or SA does not solicit an AoC or PoC from the new laboratory director. *However, if the laboratory director or owner requests to submit a new AoC or PoC, CMS or SA may accept it.*

Changes in ownership *do* not affect completion of an enforcement action. Court-appointed receivership is not a basis for cessation of the sanction process.

6294.3 - Lifting of Sanctions - Compliance Achieved Before or During Date of Revisit

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If compliance can be verified on the basis of an AoC or PoC and supporting evidence submitted by the laboratory or by a revisit, *CMS* may lift the sanction(s) as of the date of compliance.

If a laboratory is in compliance at the time of the revisit and it produces credible evidence that it achieved compliance before the revisit, *CMS* may lift the sanction(s) 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, *CMS* may lift the sanction(s) as of the last day of the revisit.

6294.4 - Credible Allegation of Compliance Submitted During Adverse Action

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When a sanctioned laboratory submits a credible *AoC*, *CMS* 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, *CMS* lifts the sanction as of the date of compliance supported by the evidence.

6294.5 - Entering Enforcement Cases in ASPEN Enforcement Management (AEM)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

It is *CMS'* responsibility to enter all information related to enforcement cases in AEM.

6295 - Lifting of Alternative Sanctions

(Rev. 1, 05-21-04)

6295.1 - General Rule

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Alternative sanctions are not lifted until compliance with all *c*ondition-level requirements is verified.

6295.2 - Credible Allegation of Compliance

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When a sanctioned laboratory submits a credible allegation of compliance, *CMS* 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, *CMS* lifts the sanction as of the date of compliance supported by the evidence.

6295.3 - Compliance Achieved Before or During Date of Revisit

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If a laboratory is in compliance at the time of the revisit and it produces credible evidence that it achieved compliance before the revisit, *CMS* 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, *CMS* lifts the sanction as of the last day of the revisit.

6296 - Table 1 - Required Sanction(s) When Specific Action(s) are Taken by CMS

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If CMS…	CMS Must…	Regulatory Reference
Suspends or Revokes any type of CLIA certificate	Concurrently cancel the laboratory's approval to receive Medicare payments for its services	42 *CFR* §493.1808(a)
Limits any type of CLIA certificate	Concurrently limit Medicare approval to only those specialties or subspecialties that are authorized by the laboratory's limited certificate	42 *CFR* §493.1808(b)
Finds that deficiencies are not corrected within 12 months	Cancel the laboratory's approval to receive Medicare payments AND notify the laboratory of its intent to suspend, limit, or revoke the CLIA certificate and its appeal rights	42 *CFR* §493.1816
Does not impose a dPoC when a laboratory has condition level deficiencies	Impose a dPPoC when it imposes any of the following: State onsite monitoring, CMP, suspension of all or part of Medicare payments	42 *CFR* §493.1832(a)

6296.1 - Suspension or Revocation of Any Type of CLIA Certificate

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When *CMS* suspends or revokes any type of CLIA certificate, the laboratory's approval to receive Medicare payment for its services is *also* canceled.

6296.2 - Limitation of Any Type of CLIA Certificate

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

When *CMS* limits any type of CLIA certificate, *they let the MAC know to limit* the laboratory's approval to receive Medicare payment to only those specialties or subspecialties that are authorized by the laboratory's limited certificate.

6298 - Summary of *CMS* Responsibilities during the CLIA Adverse Action Process

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

- Notifies the laboratory of the exact enforcement action to be imposed

  against it, the authority for the action, and the effective dates;

- Generates revised CLIA certificates, if necessary;

- Suspends or limits the CLIA certificate if a laboratory's

  noncompliance poses immediate jeopardy;

- Assists in the collection of evidence and other information

  related to criminal actions by the laboratories;

- Notifies carriers and fiscal intermediaries or MACs of Medicare

  payment sanctions imposed against laboratories; and

- Provides appropriate notice to Medicaid State Agencies.

6299 - CLIA Violations - OIG Excludes Laboratory *f*rom Medicare Participation - Effect on CLIA Certificate

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

The notice of suspension should be sent immediately after *CMS* 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 Process

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 493.1844.

6302 - Reconsideration
(Rev. 1, 05-21-04)

6302.1 - Definition of Reconsideration
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A reconsideration is a thorough, independent review by CMS of a prior decision by CMS, *called an initial determination, which is defined in 42 CFR 493.1844(b).* The entire body of evidence, including any new information presented is reviewed.

6302.2 - Right to Reconsideration
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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. *CMS* reconsiders only initial determinations as outlined below and in 42 CFR. 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 *the CMS* 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 *CMS* 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 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.
Previously approved laboratories are not given reconsideration determinations.

6302.3 - Request for Reconsideration: Manner and Timing

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

A request for reconsideration is any written expression of dissatisfaction with *CMS'* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS or the SA will document the date that the request was received, and promptly acknowledge the request. A copy of the request and the letter of acknowledgment will be forwarded immediately to *CMS* 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 *CMS*. All reports of onsite visits and telephone contact with the prospective laboratory will also be sent to *CMS* from the SA.

6302.5 - Withdrawal Requests and Extensions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If the affected party files a written notice to withdraw its request for reconsideration, *CMS* 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 *CMS*, stating the reasons why the request was not filed timely. *CMS* 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, *CMS* 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 498.3.

6304 - *CMS* Notice of Reconsidered Determination

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If the initial reconsideration is denied, *CMS* 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 *CMS* in accordance with the Delegations of Authority. All information related to the reconsideration should be recorded in AEM on the specialty tab.

6304.1 - Determination Reversal (Approval)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If a reconsideration is requested and a laboratory's application is subsequently approved, *CMS* 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, *CMS* enters the application into the CMS-116 database and a CLIA ID number is assigned. The reconsideration decision should be documented and attached, along with the Form CMS-116, to the laboratory CLIA number in the CMS-116 database. The laboratory is then billed, and issued, a Certificate of Registration, Certificate of Waiver, or Certificate *for* PPM, as applicable.

6304.2 - Denial Affirmed - Denial of Form CMS-116 from Prospective Laboratory or Denial of Request to Test in New Specialties or Subspecialties

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS notifies the laboratory, via written notification, of the decision which includes a listing of each statutory and regulatory requirement with which the prospective laboratory is not in compliance and why.

6304.3 - Administrative Evidentiary Hearing

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 *a*re Appealable
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 - Actions Which are Not Appealable
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The following actions are not initial determinations and are, therefore, not subject to appeal in accordance with 42 CFR §493.1844:

- The finding that a laboratory accredited by a CMS-approved accreditation organization is no longer deemed to meet the conditions set forth in subparts H, J, K, M, and Q of this part. However, the suspension, limitation or revocation of a certificate of accreditation is an initial determination and is appealable.

- The finding that a laboratory determined to be in compliance with condition-level requirements but has deficiencies that are not at the condition level.

- The determination not to reinstate a suspended CLIA certificate because the reason for the suspension has not been removed or there is insufficient assurance that the reason will not recur.

- The determination as to which alternative sanction or sanctions to impose, including the amount of a civil money penalty to impose per day or per violation.

- The denial of approval for Medicare payment for the services of a laboratory that does not have in effect a valid CLIA certificate.

- The determination that a laboratory's deficiencies pose immediate jeopardy.

- The amount of the civil money penalty assessed per day or for each violation of Federal requirements.

If *CMS* decides to impose principal and/or alternative sanctions on laboratory's CLIA certificate, it may do so within the time frames that *CMS* communicates to the laboratory in the notice of sanction(s). If the laboratory does not request a hearing, *CMS* will *finalize* the sanctions after the appeal period has expired which is at least 60 days. If the laboratory requests a hearing, in general, principal sanctions and CMPs may not be finalized until the decision is rendered by the ALJ. However, in certain cases, the suspension or limitation of the laboratory's CLIA certificate may be imposed prior to the hearing (see 42 *CFR sections* 493.1840(d) and 493.1842(b)(2)).

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

6306.3 - Procedure for Requesting a Hearing

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Any laboratory or prospective laboratory dissatisfied with a request of reconsideration or an initial determination is entitled to an administrative hearing before an ALJ of the DAB.

If *the* laboratory does not believe the determination to impose sanctions against its CLIA certificate is correct, the laboratory may request a hearing before an ALJ of the DAB in accordance with 42 CFR Sections 493.1844 and 498.40 through 498.78. A request for hearing must be filed electronically no later than sixty (60) calendar days after the date that the laboratory is notified of the imposition of sanctions. Instructions for filing an appeal are outlined in the imposition of notification letters. In order to request a hearing, the laboratory, prospective laboratory or its legal representative must file a request for an appeal with the Civil Remedies Division

(CRD) of the DAB within 60 days of its receipt of the notice of initial, reconsidered, or revised determination. All requests for an appeal must be filed electronically unless an exemption is granted by the CRD.

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.

Hearings are conducted in accordance with Subpart D of 42 CFR Part 498. If the laboratory requests a hearing prior to receiving a notice of sanction or a notice of a reconsidered determination, *CMS* 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.

6306.4 - Content of the Request for Hearing

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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.

6306.5 - Relationship of Action on Laboratory's CLIA Certificate to Timing of Hearing

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 administratively extend the certificate in order for the laboratory to remain operational and the CLIA certificate to be active for the duration of the enforcement process except in cases of immediate jeopardy or when the criteria at 42 CFR *sections* 493.1840(a)(4) or (a)(5) are not met.

6308 - Processing of Hearing Requests

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Any laboratory or prospective laboratory dissatisfied with an initial, reconsidered or

revised determination may file an electronic 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(s). *CMS* sends all hearing requests that are sent to it, or received by the SA and forwarded to *CMS*, to the DAB (see *section* 6306.3).

If the laboratory requests a hearing prior to receiving a notice of sanction or a notice of reconsidered determination, *CMS* 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.

6310 - Timing of the Hearing

(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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.

6312 - Adverse Hearings Decisions by Administrative Law Judge (ALJ)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 498. The authority to change a decision rests solely with the DAB. If the SA receives the request, it transmits the request immediately to *CMS*. *CMS* 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.*1844*(f)(3).)

6314 - Readmission to CLIA Program

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

When a previously sanctioned laboratory seeks readmission or reinstatement, it may be

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

6316 - Laboratory Registry

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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

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

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

- A list of persons who have been convicted of violating CLIA requirements, as specified in *section* 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.

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

- *A list of laboratories that had corrections of any Erroneous Statements of Information that Appeared in a previous Registry.*

- *A list of laboratories with specific information that may be useful in evaluating the performance of laboratories, as specified in 42 CFR 493.1850(a) and information provided by CLIA exempt status.*

6318 - Freedom of Information Act (FOIA)

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

FOIA provides the public the right to request access to records from any federal agency and is often described as the law that keeps citizens in the know about their government. Requests can be made by any person, US citizen or not, for any agency record and federal agencies are required to disclose any information requested under the FOIA unless it falls under one of nine exemptions.

A request does not require agencies to create new records or to conduct research, analyze data, or answer questions when responding. The response format of records may be specified by requestor.

If the SA receives a FOIA request, the SA must determine if it is for federal documents or State documents. If the SA receives a FOIA request for federal documents, they must contact *CMS* for guidance. The SA must contact their FOIA office, or State equivalent, in order to determine requirements for releasing State documents to the public.

The following records are directly releasable by the *SA* WITHOUT a FOIA Request:

- Form CMS-2567

    - Prior to release, the lab must have had an opportunity to respond (not exceeding 60 days); if a credible AoC or acceptable PoC is received, immediately releasable (only applies for surveys

performed by the SA; surveys performed by *CMS* must go through FOIA process)

- Disclosure must be made within 90 days following completion of the survey

- Individual identifiers must be redacted prior to release (this does not include identifiers used by surveyors as part of their coding system)

- Standard enforcement notices, once agency confirms receipt by the laboratory (only applies for surveys performed by the SA; surveys performed by *CMS* must go through FOIA process)

- Whether a lab participates in the CLIA program

- Reports/information about a laboratory's performance in proficiency testing programs

- Statistical data on laboratory characteristics that do not identify a specific laboratory

NOTE: If a laboratory labels any CLIA documentation or record that it falls under FOIA and that it is confidential, the SA *or CMS* must contact the FOIA officer even if the document or record can be directly released per policy. All documents forwarded to the FOIA office must not be redacted - the FOIA office is responsible for redaction prior to release.

Budget and Administration

6400 - The CLIA Federal/State Relationship

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) establish a close and integrated relationship between the Federal government and State Agencies (SAs) responsible for implementing, maintaining, and enforcing federal requirements for clinical laboratories. The CLIA regulations at 42 CFR Part 493 set forth specific requirements and the applicable guidance serves as interpretive documentation for both State and Federal agencies, guiding their joint efforts to ensure proper initiation and effective fulfillment of Congress-mandated clinical laboratory improvements.

SAs play a pivotal role as the local interface and representative of the Centers for Medicare & Medicaid Services (CMS) to CLIA-certified clinical laboratories. While CLIA has expanded the Federal government's oversight to almost all laboratories conducting diagnostic testing nationwide, the primary oversight of non-Federal Jurisdictional laboratories is carried out by SAs or their agents such as a contractor. SAs are tasked with hiring, training, and managing personnel to comply with the Section 1864, and related provisions of the Social Security Act.

CLIA is a self-funded program, and fees for compliance determination and oversight must be established and collected exclusively from laboratories subject to CLIA requirements. Consequently, workload planning and budgeting become critical components of the CLIA Federal/State administrative partnership. This collaborative process involves negotiation between the SA, each SAs budgeting process, laboratory surveys, related workloads, and the cost required for the workload. The SA takes on the responsibility in this process, while CMS assists States in developing acceptable work plans and budgets.

For CLIA-exempt and accredited laboratories, the payment of initial fees and fees covering Federal oversight activities forms the primary exchange between the State and CMS in the budget process. CLIA-exempt States or accrediting bodies may impose additional charges on individual laboratories.

The budget process commences with the State's preparation of their budget submission forwarded to CMS. Subsequent steps involve budget approval, the release of CLIA funds, and the preparation and submission of Survey Team Composition and Workload Reports for completed surveys and related support activities. Quarterly reports detailing completed work contribute to Federal payments for SAs completed work on the CLIA workload.

6402 - Federal Administrative Responsibilities

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The responsibilities delegated to CMS include:

- 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) mandates that the CLIA program be self-funded. *The financial responsibility for implementing, operating, enforcing, and overseeing the program lies with CLIA laboratories. CLIA laboratory is defined at 42 CFR 493.2 as "a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings."*

Funds for running the CLIA program are generated through different mechanisms, including:

• Certificate of Registration fees, from the start-up period, that are to accompany the initial registration;

• Certificate fees for Federal administration of the program;

• Compliance determination and enforcement fees to cover the costs incurred by the State and Federal government to ensure program requirements are met*; and*

• State-exempt fees.

6404.2 - Laboratory Remitted Funds
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The process involves lock-box contractors receiving funds from laboratories, which are deposited into a CMS CLIA account for State advances and CLIA-related payments. States bill CMS using Forms CMS-670 and CMS-102 for various CLIA tasks. The Form CMS-670 captures the total time spent on a survey or CLIA workload. Payments to States are funded by user fees collected from laboratories,

covering administrative expenses. Actual expenditures are determined and reconciled at the end of the year between CMS and each State, forming the basis for future fee schedules for laboratories.

6406 - State Agency Administrative Responsibilities

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 *CMS* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

SAs play a crucial role in managing records and preparing operating reports, such as Form CMS-670 and Form CMS-102. These reports serve multiple purposes, including evaluating program effectiveness, analyzing workloads, identifying problem areas, justifying payments, and documenting CLIA fund expenditures for compliance surveys. SAs are responsible for maintaining relevant records and reports that align with agency operations and workload. The use of electronic formats and effective management practices is encouraged, and reasonable costs for implementing databases and information systems are eligible for CLIA funding. The CMS requirements aim to provide flexibility without limiting fiscal and administrative practices of SAs.

6410 - State Agency Responsibility for Staff Training and Development
(Rev. 1, 05-21-04)

6410.1 - Staff Training
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The SA is responsible for providing continuing education to employees. In conjunction with, and subject to, the approval of CMS, SAs must have a procedure for identifying the training needs of the surveyors. That procedure must *ensure* that *regulatory requirements,* SOM revisions, *CMS* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

In evaluating the appropriateness of any outside training activity for CLIA funding, SAs and *CMS* must consider *the cost of the training and* 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. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS is responsible for:

- Reviewing and recommending action on each budget *request*;
- 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.

6414 - CLIA Budget - *CMS* Procedures

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 - *CMS* Administrative Responsibilities

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS plays a crucial role in efficiently administering the CLIA program across states. CMS' responsibilities include, but are not limited to, issuing the CLIA Budget Call Letter, providing guidance on the annual budget process and leadership to SA, reviewing and recommending actions on SA budgets, consulting with SAs on program activities, making determinations on allowable State costs, and controlling fund payments for CLIA administration.

Before approving each State budget request, CMS considers key questions such as whether the Annual Activity Plan aligns with program priorities, if staffing estimates meet the emphasis outlined in the CLIA Budget Call Letter, whether all reasonable costs are approved and communicated, and if SA budgets adhere to programmatic, administrative, and fiscal principles outlined in the State Operations Manual (SOM) and the CLIA Budget Call Letter.

6416 - Budget Call *Letter - Annual Budget Process*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Each fiscal year, *CMS* issues a *CLIA 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.

A complete SA budget request includes the Annual Activity Plan, the Form CMS-102 "Budget/Expenditure Report," the Form CMS-105 "Planned Workload Report," the Form CMS-1465A "State Agency Budget List of Positions," and the Form CMS-1466 "State Agency Schedule for Equipment Purchases" for any equipment

purchases. Receipt of the SA budget request is the start of the negotiated budget process between the SAs and *CMS*.

Each budget submission requires close attention and proper scrutiny. It is imperative that *CMS* manage*s* the SAs CLIA activity, including budgets, aggressively for efficiency and productivity. Contracts and purchases planned by the SAs and approved by *CMS*, 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 *CMS* encounters any unusual plans or purchases, it assures they are supported by an adequate written justification and that *CMS* is convinced of the actual need to support efficiency and productivity.

It is important that *CMS* question*s* and challenge*s* unsupported spending levels or supported requests that *CMS* does not feel *sufficiently benefit the program or are not cost effective*. Aggressive monitoring throughout the year can help to lower the cost of managing the CLIA program.

In negotiating and approving the budgets, CMS limits the number of full-time equivalents chargeable to the CLIA program budget. With limits in place, an SA cannot exceed the approved full-time staff levels without prior consultation and authorization. This will enable CMS to monitor staffing (all disciplines), especially the actual number of on-board surveyors, and allow CMS better to analyze State requests and requirements for additional-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 - *Budget Awards*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CMS provides *state* specific budget *awards*. The *awards* reflect both the needs and special priorities of each program workload, as well as national and *state*-specific priorities. *CMS should* be aware of and apply these 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. *States* should communicate significant problems or changes to *CMS* as soon as they are identified.

6420 - The SA *Budget Request*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

By the due date established in the CLIA Budget Call Letter, the SA enters and certifies Form CMS-102, Form CMS-105, Form CMS-1465A, and Form CMS-1466 in the Survey and Certification/Clinical Laboratory Improvement Amendments

System (SC/CLIA system) and submits the Annual Activity Plan via email to CMS. Working with the SA, CMS 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 *SA, CMS* determine*s* the adequacy and appropriateness of the programs planned by each *SA* as they relate to the legislatively mandated goals and budget estimates. The information on the *Annual A*ctivity *P*lan should agree with the *Forms submitted in the SC/CLIA system*.

6420.1 - Form CMS-102, "Clinical Laboratory Improvement Amendments Program Budget/Expenditure Report"

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Form CMS-102 is required as part of the annual budget request. The Form CMS-102 is included with the SA budget request, to project the FY budget by categories of expenditure.

6420.2 - Form CMS-105, "Clinical Laboratory Improvement Amendments Program Accomplished/Planned Workload Report"

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Form CMS-105 is required as part of the annual budget request and is used in developing CLIA SA workload plans. The Form CMS-105 lays out the SA plan to conduct surveys and other related activities for the fiscal year by laboratory schedule related to workload volume and based on the annual CLIA Budget Call Letter. 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.

The workload reflected in the Form CMS-105 is to include initial surveys, re-visits, follow-up visits, and complaint visits for the various schedules of laboratories. Laboratories holding a Certificate of Accreditation are inspected at an administrative goal of five percent biannually. The number of validation surveys are assigned by CMS.

6420.3 - Form CMS-1465A, "State Agency Budget List of Positions for the Clinical Laboratory Improvement Amendments Program"

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Form CMS-1465A is required as part of the annual budget request. The Form CMS-1465A breaks out the salaries for all CLIA funded position approvals.

6420.4 - Form CMS-1466, "State Agency Schedule for Equipment Purchases for the Clinical Laboratory Improvement Amendments

Program"
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Form CMS-1466 must be submitted with the annual budget request if equipment costs are included in the budget request for the FY. Equipment costs included in the annual budget are entered on line 10 of the Form CMS-102. If an amount is included on this line, a Form CMS-1466 is required as part of the annual budget request. If no equipment is budgeted, then a Form CMS-1466 is not required.

6420.5 - Annual Activity Plan
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Annual Activity Plan is a written narrative submitted to CMS with the annual budget request. The narrative should include information and supporting documentation essential to support the annual budget. The information addressed in the Annual Activity Plan includes, but is not limited to, the following:

a. *Describe the SA CLIA program which permits survey and certification work to be done orderly throughout the year and with an even workload distribution over the 1- and 2-year cycle.*

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 workload areas, and geographic deployment).*

c. *Describe the methodology used to allocate partial FTEs to the CLIA program. For example, if the SA has employees that are partially funded by CLIA, explain in the Annual Activity Plan how the SA will determine the amount of time spent on CLIA activities and allocate the appropriate amount of the employee's salary to the quarterly Form CMS-102 expenditure reports.*

d. *Explain how the retirement and fringe benefits are calculated and allocated to the employees on line 4 and line 5 of the Form CMS-102. If a set percentage is used to allocate the fringe and retirement benefits, the SA provides an explanation of how this percentage is derived.*

e. *Describe how the Travel portion of the budget on line 6 of the Form CMS-102 was calculated. Indicate in the Annual Activity Plan 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.

f. *Explain costs included on the Communications line 7 of the Form CMS-102.*

g. *Describe the supplies included on the Supplies line 8 of the Form CMS-102*

h. *Provide a description and justification for all equipment budgeted on line 10 of Form CMS-102 and included on Form CMS-1465A. Provide the purchase date for all equipment that is being replaced by a newly budgeted equipment purchase. For example, if a new printer is included in the budget on line 10, the SA should include the original date of purchase of the printer that is being replaced.*

i. *An outline of program training planned and budgeted on line 11 of Form CMS-102 (staff training meetings, formal courses attended, seminars, in-service training program, and any mandatory CMS National Training).*

j. *Provide justification and details of the contracts for amounts budgeted on lines 12 and 13 of the Form CMS-102 for Consultants and Contractors.*

k. *Describe all miscellaneous expenditures budgeted on line 14.*

l. *Explanation of how indirect costs are allocated to the CLIA program on lines 17 and 18 of the Form CMS-102. If an indirect cost rate is used, confirm in the Annual Activity Plan that the SA has an approved Indirect Cost Rate Agreement with HHS. Describe the indirect cost base. If an indirect cost rate is not used, provide a description of the indirect cost allocation methodology.*

m. *If the SA is requesting an increase over the funding allocated in the Budget Call Letter, a detailed description of the types of costs and activities to be funded by the increase is required. Provide a breakout of the costs included in the increase. Justification and description of why the increase in funding is required and should be included. Provide any data or supporting documentation that supports the increase in funding. Without an adequate description of the additional costs and justification of the increase, CMS will not be able to approve the increased funding request. The SA should be prepared to respond timely to follow up questions and requests for additional documentation regarding budget increases.*

n. Any additional information requested in the Budget Call Letter.

6422 - *The SA Quarterly Expenditure Reports*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

States are required to submit quarterly expenditure reports, via the automated SC/CLIA system, no later than 45 days following the end of each fiscal quarter. Quarterly expenditure reporting consists of Form CMS-102, Form CMS-105, and, if equipment was purchased in the quarter, Form CMS-1466. Final adjustments, when necessary, to quarterly expenditure reports are due no later than 120 days following the end of each fiscal year. CMS will review both quarterly as well as year-end final adjustments to quarterly expenditure reports within 15 days following the submission of reports by the State.

6422.1 – Form CMS-102, "Clinical Laboratory Improvement Amendments Program Budget/Expenditure Report"
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Form CMS-102 is the CLIA statement of expenditures. The Form is used by the SA to enter and certify the amount expended in the quarter on CLIA related activities. In certifying the Form, the SA confirms that the costs entered only include allowable expenditures under the CLIA program.

6422.2 – Form CMS-105, "Clinical Laboratory Improvement Amendments Program Accomplished/Planned Workload Report"
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Form CMS-105 is submitted each quarter to enter the accomplished workload. The SA uses the Form to enter the number of surveys completed in the quarter.

6422.3 – Form CMS-1466, "State Agency Schedule for Equipment Purchases for the Clinical Laboratory Improvement Amendments Program"
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If equipment was purchased during the quarter, the Form CMS-1466, detailing the equipment purchased, must be submitted along with the Form CMS-102.

6424 - *State Budget Request/Quarterly Expenditure Report, Form CMS-102, "Budget/Expenditure Report"*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Form CMS-102 is a multipurpose form used for both budget and expenditure reporting. The Form when included with the annual budget request is a detailed estimate of CLIA survey program costs. The Form, when included with the quarterly reporting, is a detailed reporting of actual CLIA expenditures. The SA classifies costs on the Form CMS-102 according to the category of the expense. Justification and supporting documentation for the amounts entered under specific expense categories are essential in both budget preparation and the subsequent review of quarterly expenditures.

CMS personnel are available to assist in preparing budget requests. The SA should consult with appropriate CMS staff on any problem with the budget preparation process. Begin consultations as early as possible and submit the state budget request in accordance with the due date established in the CLIA Budget Call Letter provided by CMS. Timely submissions help ensure timely CMS completion of the budget approval process.

6424.1 – Description of Form Fields – Form CMS-102

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Heading, Agency/Location/State Code/Budget Period/ FY Quarter *– The SA will automatically populate. Enter the Location number and name of the State, the Federal period and the quarter for which the workload is submitted, and indicate if the submission is a budget request, a supplemental request, or a quarterly expenditure report.*

SALARIES

1 (A/B/C), 2, 3 – *Surveyor/Professional, Non-Surveyor/Professional, Supervisor, Clerical*

Enter the regular salaries and wages for the total work hours employed in the conduct of the CLIA workload, broken into four categories, "Surveyor/Professional" on line 1A, "Non- Surveyor/Professional" on line 1B, "Supervisor" on line 1C, and "Clerical" on line 2. The SA enters 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), "Staff Years," and the annual salary cost in column (B), "Amount." The SA totals the FTEs and salaries in columns (A) and (B) and enters the amounts on line 3, "Total Salaries." When submitted as an annual budget request, the totals on line 3 in Column (A) and Column (B) should match the totals on the Form CMS-1465A "State Agency Budget List of Positions" Column (D) "Staff Years" and Column (E) "Funds Required."

OTHER DIRECT COSTS

4, 5 – Rate %, Ret(Retirement)/Fringe Benefits

Enter 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.

6 - Travel

Enter the 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. Enter costs based on provisions of State law, regulation, and administrative procedures applicable to the travel of State employees.

7 - Communications

Enter the costs of technologies that allow people to make and place phone calls to share information across long distances (such as mobile phones, land lines, and the internet) and other communication-related expenses.

8 - Office Supplies

Enter the cost of office supplies to be used by CLIA personnel only. Include the costs of usual desk materials, books, and other required desk reference materials, photocopier supplies, FAX supplies, computer equipment-related supplies, and other reasonable supplies.

9 - Office Space

Enter the costs of office space utilized by CLIA personnel. The cost of office space essential for CLIA laboratory survey functions is a proper charge against CLIA funds. Describe in the Annual Activity Plan how office space costs are attributed to the CLIA program.

10 - Equipment

Enter the cost 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. A description and justification for all equipment purchase requests should be included in the Annual Activity Plan and a Form CMS-1466 "State Agency Schedule for Equipment Purchases" must be included with the budget request. All equipment expenditures entered on the quarterly Form CMS-102 expenditure report must be accompanied by a Form CMS-1466.

11 - Training

Enter the cost of surveyor training. Funds for training must be requested, in advance, in the annual budget request. 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 Annual Activity Plan should indicate the types of courses to be taken by employee type and by number of employees to be trained.

12 - Consultants

Enter the 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

Enter the cost of subcontracts employed in the conduct of CLIA-related work. Subcontract costs attributable to CLIA survey activities are allowable and payable. The Annual Activity Report should provide the reasons for, and approximate cost of each separate subcontract.

14 - Miscellaneous

Enter the 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 the Annual Activity Report to explain all proposed expenditures.

15 - Total Other Direct Costs

Enter the total of line 4 through line 14.

16 – Total Direct Costs

Enter the total of line 3 and line 15.

17 - Rate%

Enter 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. If an indirect cost rate is not used to allocate indirect costs, do not enter an amount on this line.

18 - Indirect Costs

Enter the amount of indirect costs.

19 - Total Costs

Enter the sum total of lines 16 and 17.

20 - Unliquidated Obligation

Unliquidated obligations are financial obligations incurred by the SA that have not been paid. This line should be left blank when the Form is used for budget requests. This line should only be utilized on the fourth quarter Form CMS-102 expenditure report. The SA enters an amount indicating to CMS the amount of unliquidated obligations as of the end of the fiscal year. The SA then has 120 days following the end of the fiscal year to pay the unliquidated obligations and adjust and recertify the fourth quarter Form CMS-102 by removing the unliquidated obligation amount on line 20 and entering the cost under the appropriate cost category.

HOURLY RATE

Divides the Total Costs by the Total Staff Years and divides again by the Hours Per Staff Years. to derive Hourly Rate, as in the example:

***Example**:*

Total Costs	*$100,000*
Divided by Total Staff Years	*2*
Equals	*$ 50,000*
Divided by Hrs. Per Staff Yrs.	*1,600*
Equals Hourly Rate	*$31.25*

***Signature, Title, Date** – Shows the name and title of the individual certifying the Form and the date of certification.*

6426 - *State Budget Request, Form CMS-105, "Accomplished/Planned Workload Report"*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Form CMS-105 is a multipurpose form used for both planned and accomplished

workload reporting. The Form when submitted with the budget request provides the State's estimate of the number of laboratory surveys for each laboratory schedule it expects to perform in the fiscal year. The Form when submitted with the quarterly expenditure reports provides a report of the surveys completed in the quarter. The Form lists by laboratory type the number of surveys planned or accomplished to be conducted in the fiscal year. (This Form also accompanies the States quarterly expenditure reports.)

6426.1 - Description of Form Fields – Form CMS-105

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Heading, Location/State Code/Fiscal Year/Agency *- Enter the Location number and name of the State, the Federal period for which the workload is submitted, and the official name of the SA.*

Column (A), Number of Sites *- Enter the number of separate laboratory sites for surveys, follow-up visits, and complaints.*

Column (B), Initial Visits *- Enter the number of initial compliance determination surveys (laboratory surveys) for each type of laboratory. A five percent sample biannually of those that hold a Certificate of Accreditation are to be inspected for compliance in accordance with the SA oversight role and responsibility.*

Column (C), Resurvey Visits *- Enter the total number of non-initial compliance surveys. This figure is to reflect the number of other than first time laboratory surveys.*

Column (D), Follow-up Visits *– Enter the number of follow-up surveys. 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 requires 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 *- Enter the number of complaint surveys.*

Column (F), Total Visits *- Provides the total for rows (B) through (E) in column (F) and computes the totals at the bottom of the form.*

Signature, Title, Date *– Shows the name and title of the individual certifying the Form and the date of certification.*

6428 - *State Budget Request/Quarterly Expenditure Report, Form CMS-1466, "State Agency Schedule for Equipment Purchases"*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Form CMS-1466 is a multipurpose form used for both budget and expenditure reporting. The Form when included with the annual budget request is used to provide detail for the equipment purchases included on line 10 of the Form CMS-102 budget request. The Form when included with the quarterly reporting is a detailed reporting of the equipment purchased in the quarter and claimed on line 10 of the Form CMS-102 quarterly expenditure report.

6428.1 - Description of Form Fields – Form CMS-1466

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Heading, Agency/State/Fiscal Year/Submitted With/From *– The SA will automatically populate. Enter the name of the State, indicate if the Form is submitted with a budget request, a supplemental request, or a quarterly expenditure report, and the Federal period for which the equipment is budgeted or claimed as an expenditure.*

Column (A), Description of Equipment *- Enter the items of equipment being requested or reported as purchased. Describe in the Annual Activity Report any items previously approved by CMS but which are being re-budgeted or requested again. Explain in the Annual Activity Report why the purchase was not completed in the prior budget period.*

Column (B), Number of Items on Hand *- Enter the number of similar items on hand in the SA at the time the form is prepared. If a new and different item is being shown, enter "None" in this column. 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.*

Columns (C), Additional - *Enter the number of units requested or purchased that are an addition to current equipment inventory.*

Column (D), Replacement *– Enter the number of units requested or purchased as replacements for current equipment inventory.*

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 - *Computes and enters the trade-in- value of item identified in column (D) if the requested or purchased equipment is replacing 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).*

Totals *- Enter the sum of column (H). Enter this amount on line 10 of the Form CMS-102.*

Signature, Title, Date *– Shows the name and title of the individual certifying the Form and the date of certification.*

6430 - *State Budget Request, Form CMS-1465A, "State Agency Budget List of Positions"*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The Form CMS-1465A is required as part of the annual budget request. The SA uses the Form CMS-1465A 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.

6430.1 - Description of Form Fields – Form CMS-1465A

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Heading Information, Name of Agency/State/Fiscal Year *– The SA will automatically populate. Enter the name of the State, and the Federal period for which program position approval is requested.*

Column (A), Position Title/Last Name/First Name/Initial *- Enter each position type (surveyor, non-surveyor professional, supervisor, or clerical) for which the SA is requesting funding and the name of each employee occupying each position type. If the SA is requesting funding for positions which are currently unfilled, enter "VACANT" under the Last Name and First Name columns. This will help the SA distinguish between the number of positions it has filled as opposed to the number approved. This information may prove useful when determining the number of employees that require training in each discipline. If an employee performs the duties of more than one position title (surveyor, non-surveyor professional, supervisor, or clerical), a line should be entered for that employee under each relevant position title. For example, a surveyor that performs both surveys and clerical work would be entered on two lines, one line would reflect the allocation of their FTE spent on survey work and one for clerical work.*

Column (B), City Where Located *- Enter this for all position types and employees.*

Column (C), No. of Pos. (Number of Positions) *- Enter the number of employees occupying that position title.*

Column (D), Staff Years *- Enter the FTE ratio reflecting the work years the*

employee is projected to spend on performing the duties of the position that are eligible for CLIA funding. The ratio should be calculated as the number of hours projected to be spent on the duties associated with the position divided by the total number of work hours during the fiscal year. For example, for a surveyor that will spend 800 hours on CLIA activities out of a total of 1600 work hours during the fiscal year, the state will enter .5 (800/1600) in the "Staff Years" field.

Column (E), Funds Required *- For each Position Title, compute the salary dollars required by multiplying the Staff Years, Column (D), for each Position Title by the Annual Salary, Column (F)*

Column (F), Annual Salary *– Enter the annual salary for each position. Do not include fringe, retirement, or other benefits.*

Totals *- Enter the sum of each column.*

Note: *The total Staff Years (Column (D)) by position title (surveyor, non-surveyor professional, supervisor, and clerical) should match the Staff Years (Column (A)), lines 1 A/B/C and 2, of the Form CMS-102 included with the budget request. The total Funds Required (Column (E)) by position title (surveyor, non-surveyor professional, supervisor, and clerical) should match the Amount (Column (B)) of the Form CMS-102, lines 1 A/B/C and line 2 included with the budget request.*

Signature, Title, Date *– Shows the name and title of the individual certifying the Form and the date of certification.*

6432-*Basis for Budget Approval*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

State budget requests must be submitted through the SC/CLIA system. CMS may approve State budget requests only after proper certification by the approved State certifying official. The basis for approving the line-item budget is the number of surveys to be completed and the amount of staff and money needed to complete them. The 1988 amendments to CLIA mandate that all laboratories be surveyed every two years. Thus, the budget plan should address the basic question of how the SA will accomplish this goal. It is important that CMS evaluate the accomplishments of the past performance period to determine the goals that need to be set for the next performance period. Budget constraints or unexpected events may affect hiring or any of the budget line items. Revised national and regional priorities may also impact workload plans and accomplishments, so CMS should be flexible and diplomatic in negotiations with the SA.

6432.1- Line Item Negotiation and Approval

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The budget approval is a detailed concurrence or revision to State estimated survey

program costs. CMS negotiates the budgets by line item, according to the category of the proposed expenditure. CMS should be able to explain any adjustments and the method used to compute each amount.

CMS should caution the State that funds provided agencies through the budget approval, must be used only for necessary expenses. 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.

6432.2- Payable Reasonable Costs

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If funding is available, the SAs are 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 SAs 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 SAs only for CLIA-related expenses, proper proration of expenses is mandatory.

Reasonable costs include all necessary expenses in accordance with the standards described in this 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.

6432.3 - Projected Workload

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The projected workload, program emphases, the SAs hiring and training plans, and the experience of the 12-month preceding period, if appropriate, are the primary factors for CMS to consider when approving the line-item budget. CMS uses these factors as a guide to negotiate the budget in a fashion that assures national and regional goals are

met. When CMS makes changes to the State's proposal, it provides the rationale for the proposed change. The CMS rationale should include:

- *The revised estimate;*
- *The rationale for the change; and*
- *The basis for computing the revised estimate.*

6434 - *Employee Salaries and Wages*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

6434.1 - Distribution of Staff Time for Program Purposes

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Salary and wage expenditures claimed on Form CMS-102 must be based on records that accurately reflect the work performed. The records must support the distribution of the employee's salary and wage among specific activities or cost objectives if the employee works on programs in addition to CLIA. Budget estimates of FTE attributed to the CLIA program do not qualify as support for the FTE salary and wage expenditures claimed on Form CMS-102. Expenditures on the Form CMS-102 must reflect actual employee time spent in support of the CLIA program.

An important administrative goal should be to ensure 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 support expenditure claiming on Form CMS-102.

In the event staff is shared and a cost proration study 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 CMS are a necessary and reasonable CLIA expense.

6434.2– Allocation of Administrative Costs

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Using a prorate method is acceptable when administrative costs cannot be directly 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 CMS. This method permits adjustments for circumstances a particular agency may encounter.
The following method may be used by the SA to determine a proper split of administrative costs between CLIA and other programs:

- *Determine the number of inspections and related staffing needed to fulfill the requirements of the CLIA laboratory inspection program.*

- *Determine the number of inspections and related staffing requirements needed to fulfill the requirements of other programs.*

- *The ratio of inspections and related staffing needed to fulfill the requirements of the CLIA program to the total of the inspections and related staffing activities of all programs can be applied to the cost of the total multi-program activity.*

It is possible that administrative costs not directly identifiable as CLIA expenses may already be accounted for in the indirect cost allocation rate and entered on line 18 of the Form CMS-102. Costs included in the SA indirect cost rate should not be claimed on other line of the Form CMS-102s. Indirect Cost Rate Agreements can be obtained by contacting Health and Human Services, Program Support Center, Cost Allocation Services. There are instances in which commonly shared personnel are included in the Indirect Cost Rate Agreement. If costs for commonly shared personnel were included in the Indirect Cost Rate Agreement, inclusion in another line item of the Form CMS-102 would create duplicate reporting of these costs. Since no two Indirect Cost Rate agreements are the same, CMS should not presume that costs included in each SA Indirect Cost Rate will be the same.

SA proposals to use sampling or prorate formulas to allocate administrative costs to the CLIA program must be approved by CMS before the costs can be claimed on a quarterly Form CMS-102. CMS may conduct studies, or direct that the SA conduct them to verify the accuracy of allocation methodologies.

6436 - *Retirement Contributions and Fringe Benefits*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 Rate. Indirect Cost Rate agreements can be obtained by contacting Health and Human Services, Program Support Center, Cost Allocation Services.

6436.1 - Retirement Contributions

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Retirement contributions include SA cost (not employees' share) of contributions to retirement funds such as State retirement or social security.

6436.2 - Prorating Costs

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Where SA prorate personal services costs of State survey personnel, it prorates the retirement costs for these personnel.

6438 - *Travel*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Travel costs are expenses for transportation, lodging, subsistence, and related items incurred by employees who are in travel status on official business of the SA. Travel charged to the CLIA program is allowable to the extent such charges do not exceed charges normally allowed by the State in its non-CLIA operations and should be in accordance with the State's established travel reimbursement policies.

6438.1 - CLIA Laboratory Survey and Administrative Travel

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Laboratory survey travel includes travel to and from a facility:

- *To conduct laboratory inspections;*
- *For revisits or to verify PoC/AoC;*
- *To perform laboratory complaint or oversight inspections; and*
- *For meetings with CMS personnel on CLIA-related activities.*

Administrative travel is defined, for budget requests, 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;*
- *For planning or liaison visits to other agencies concerning certification;*
- *To participate in sanction meetings or negotiations; and*
- *To appear before an ALJ in a hearing (to provide testimony or support for a sanction activity against an alleged non-compliant laboratory).*

6438.2 - Travel Involving Multiple Program Activities

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Travel expenses for an employee performing multiple program activities (for example, Medicare/Medicaid and CLIA) for the State should be charged to those programs in accordance with the work hours spent on each program. Alternatively, trip records may be accumulated for an accounting period and prorated accordingly. For example, if 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.

The method used to allocate travel expenses between programs must be applied to the entire trip and not to selected days of the trip and should result in charges consistent with those normally allowed for travel in the State's non-CLIA funded activities.

6438.3 - Travel Expenditures for Training Related Activities
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Travel expenditures for training related activities that are not directly related to the line operations of surveying laboratories, providing consultation, and conducting administration of the CLIA program should be entered on line 11, "Training" of the Form CMS-102. Training costs included in this category include expenditures for orientation and basic training of new employees, training needs of experienced employees, conferences, workshops, and seminars if the agenda material is directly related to the laboratory survey functions of the SA. Professional meetings for which attendance maybe justified and funded, subject to prior CMS 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 Clinical Laboratory Science (ASCLS), American Medical Technologists (AMT), American Clinical Laboratory Association (ACLA), American Society for Cytotechnology (ASC), College of American Pathologists (CAP), and the Clinical Laboratory Management Association (CLMA).

It is possible that some common charges may already be included in the Indirect Cost
Rate agreement and should not be included on line 11 of Form CMS-102. Indirect Cost
Rate agreements can be obtained by contacting Health and Human Services, Program
Support Center, Cost Allocation Services.

6438.4 - Requesting Approval
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Funds for conferences and short-term training activity must be requested, in advance, in the annual budget request. The SA submits any training that has not received prior CMS approval in the approved budget, in advance, to CMS for approval. Approval is to be on a case-by-case basis. Consult with CMS for guidance on submitting such requests.

6438.5 - Fiscal and Reporting Considerations - the Amount Requested for Travel Costs of Such Activity)
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The SA shows the total amount approved on the Form CMS-102 for the CLIA program (the "State Agency Budget Expenditure Report." 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.

6440 - *Communications and Supplies*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

6440.1 - Basis for Charges)
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 pro-rata basis if used for multiple program purposes. 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.

6440.2 - Communications
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Communications includes the costs of technologies that allow people to make and place phone calls and share information across long distances (such as mobile phones, land lines, and the internet).

For services such as satellite training or conferences, the SA has been advised to contact CMS to determine if the expense is a reasonable expense. CMS 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 and other communications related expenses. If CMS concurs that the circumstances do indeed substantiate such an expense, CMS may include it in the approved budget computations. It is incumbent upon the SA to be in close consultation to ensure that any planned unusual expenses are approved.

6440.3 - Supplies
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

CLIA is responsible for covering expenses related to supporting CLIA personnel and activities. This includes general office supplies, non-consumable items (up to $500 per item), printing/duplicating expenses, and transportation or shipment costs for these items. State-specified amounts take precedence, and if purchases are mixed with non-CLIA program items, documentation and justification are required on a pro rata basis.

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, Indirect Cost Rate Agreements can be obtained by contacting the Department of Health and Human Services, Program Support Center, Cost Allocation Services.

6442 - *Office Space*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

6442.1 - Cost of Office Space
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The cost of office space for CLIA laboratory survey functions is an appropriate use of CLIA funds. The rules governing office space rental and leases are the same for CLIA as for all other CMS rentals and leases. The rules cover expenses like rent, service, maintenance, and repairs for privately or publicly owned buildings. Payments are expected for the actual periods of occupancy.

6444 - *Identifiable (Direct) Costs*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 SAs rental cost apportionment plan each year as part of the budget documentation. Approval of the budget constitutes approval of the plan of apportionment.

6446 - *Office Maintenance*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

6446.1 - *Definition*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Office maintenance includes services such as light, heat, janitor service, and machine repair service prorated on the same basis as rent, provided such services are not already included in rental costs.

6446.2 - *Basis for Charges*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If associated office maintenance costs, in whole or in part, are included in the SAs 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.

6448 - Equipment
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Form CMS-1466 must be attached to the annual budget submission if equipment purchases are included in the budget. Planned purchases should adhere to CMS hardware and software acquisition guidelines. Permissible equipment purchases for CLIA-specific positions include computer systems, peripherals, office furniture, and other necessary machines. CMS will review the form for appropriate details and reasonable requirements. When purchasing computer systems, printers should be listed on Form CMS-1466, while software appears on Form CMS-102. CMS recommends reviewing software for compliance with guidelines. Equipment authorized but not purchased by the end of the fiscal year must be requested in the next fiscal year's budget if still needed. If hiring constraints impact staffing plans, CMS suggests reevaluating equipment purchase timing to align with future staffing needs.

6448.1 - Definition of Equipment
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Items considered tangible personal property 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 equipment if they have a unit cost more than $500. 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 equipment in general use in other SA offices.

6448.2 - Title to and Accountability
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Title to and accountability for 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 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.

6450 - *Purchase of Equipment*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

6450.1- *State Practice*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The SA follows established State law or regulations for procurement of equipment for the State survey program. The SA is responsible for tracking and maintaining records of equipment purchases and purchase dates.

6450.2 - Purchases Related to Budget Process
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 request. 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 total expended for equipment during the budget period cannot exceed the total funds allocated for equipment for that period without prior approval of CMS.

6450.3 - Items Deleted by CMS
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 wants 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 CLIA funds.

6450.4 - Purchase of Items Not Included in Budget Request
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 request. The SA must secure CMS' approval 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 CMS approval when the unit cost of the item is $500 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 on the Form CMS-1466 submitted at the end of the quarter in which purchased.

6450.5 - Reporting Equipment
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 CMS as soon as possible.

6452 - Rental of Equipment
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Situations may occur where it will be advisable to rent certain equipment instead of purchasing it. The rental of 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 CMS if the SA wishes to rent equipment for more than 90 days.

6454 - *Training*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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, Indirect Cost Rate Agreements can be obtained by contacting the Department of Health and Human Services, Program Support Center, Cost Allocation Services.

6456 - *Consultants*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Consultant services are furnished by persons who are State employees but who are used on a part-time, fee-for-service, or temporary basis to perform CLIA-related work and provide needed skills to the State survey program.

6458 - *Subcontracts*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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.

6460 - *Miscellaneous*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Reported in these spaces should be any unusual, budgeted items that have not been reported in any of the preceding classifications. Consult with CMS for guidance and approval of miscellaneous expenses. To facilitate decision making, the SA should include in the Annual Activity Plan a narrative justification that explains all proposed miscellaneous expenditures.

6462 - *Centralized State Services*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

In certain States, specialized service departments outside health departments provide administrative services such as accounting, printing, civil service, or central purchasing to various State agencies. When the services benefit the State CLIA program, the SA allocates a fair portion of the charge to the CLIA program. This allocation is contingent upon certain conditions, including excluding general state

government expenses, ensuring reasonable costs, and having identifiable and ascertainable costs related to the CLIA program. The SA must describe the basis of the service agency's charge, detailing the method of proration and the services provided, seeking prior approval and separately identifying these costs in the CLIA budget request.

6464 - *Indirect Cost Rates*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

Indirect Cost Rates are 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 funds are not used for any activities that are funded by another program or provision. Where doubt exists, CMS 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, Indirect Cost Rate Agreements can be obtained by contacting Health and Human Services, Program Support Center, Cost Allocation Services.

6466 - *Hourly Rate Requested*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The dollar amount of the hourly rate of payment requested by the State is usually computed by dividing the total budget cost by the projected total workload hours in the Budget Call Letter.

6468 - *Supplemental Budget Requests*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

If funding is available, supplemental awards can be issued by CMS to reimburse SAs for CLIA allowable expenditures exceeding the original approved annual budget. Due to the limited nature of funding for the CLIA program, it is important that SAs advise CMS as soon as possible if a budget shortfall is expected. The annual approved budget should not be exceeded without prior approval.

SAs should be aware of their rate of expenditure throughout the fiscal year and funding requirements for the balance of the fiscal year. If it appears that expenditures may exceed the annual budget, the SAs should contact CMS. Supplemental award requests should be submitted during the fiscal year for which the funds are requested but no later than 120 days after the end of the fiscal year. Office of Management and Budget regulations regarding grant closeouts at 2 CFR 200.344 require award recipients to submit final reporting for a grant year no later than 120 days following the end of the award period.

If the SA intends to request a supplemental award, the SA should provide the following information to CMS:

a. *Justification and description of why the increase in funding over the original approved budget is needed.*

b. *Detailed description of the types of costs and activities to be funded by the increase that were not funded in the original approved annual budget.*

c. *Breakout of the costs included in the supplemental request by line item on Form CMS-102.*

d. *Any data or documentation that supports the request. For example, if the supplemental request is for an increase in administrative costs related to CLIA application processing, provide data to support the increase in CLIA application processing. If the supplemental request is for an equipment purchase, provide a purchase order or other documentation showing the purchase price of the equipment.*

e. *The SA should be prepared to respond to follow up questions and requests for additional documentation regarding supplemental budget requests.*

After discussion with CMS, if it is determined that the supplemental funding request is allowable and CLIA funds are available, the SA will submit a Form CMS-102 supplemental budget request in the SC/CLIA system with the agreed upon supplemental funding under the FY for which the funding is requested.

6470 - State Agency Accounts and Reporting

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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.

6472 - *Support for Expenditures - SA Procedures*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 and assuring the validity of all data used for budgetary and other purposes.

6474 - *Cash Basis - SA Procedures*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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.

6476 - *Limit on Expenditures - SA Procedures*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

The total amount approved in the SA annual budget shall be the limit on expenditures for the fiscal year.

6478 - *Periodic Analysis of Accounts - SA Procedures*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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.

6480 - *Cash Balances and Expenditure Authority - SA Procedures*
(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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.

6482 - *Unliquidated Obligations - SA Procedures*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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 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 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.*

6484 - *Payment by Electronic Transfer of Funds - SA Procedures*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

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.

6486 - *Closeout of Annual Awards*

(Rev. 230; Issued: 07-11-25; Effective: 07-11-25; Implementation: 07-11-25)

State Agencies must finalize the accounting for each federal fiscal year no later than 120 days following the end of the fiscal year. CMS will close out each federal fiscal year award when it determines that all applicable administrative actions have been completed by the SA.

Unless CMS authorizes an extension, State Agencies are required to complete the following actions no later than 120 days after the end of the federal fiscal year:

- *Liquidate all obligations.*
- *Submit supplemental budget requests as needed.*
- *Finalize all quarterly Form CMS-102 expenditure reports for the fiscal year.*
- *Complete final draw down of funds from the Payment Management System (total funds drawn down for the fiscal year must equal the lessor of the total grant award or the total cumulative certified expenditures on the quarterly Form CMS-102s for the fiscal year).*

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R230SOM	07/11/2025	Revisions to State Operations Manual (SOM) Chapter 6 - Special Procedures for Laboratories.	07/11/2025	N/A
R199SOM	01/17/2020	Revisions to State Operations Manual (SOM) Chapter 6 - Special Procedures for Laboratories and Chapter 9 Exhibits	01/17/2020	N/A
R195SOM	11/15/2019	Revisions to State Operations Manual (SOM) Chapter 6 - Special Procedures for Laboratories and Chapter 9 Exhibits- **Rescinded and replaced by Transmittal 199**	11/15/2019	N/A
R45SOM	05/08/2009	Revisions to Chapter 6 - “Special Procedures for Laboratories	05/08/2009	N/A
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