CMS Manual System

Pub. 100-07 State Operations Provider Certification

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

Transmittal 199 **Date: January 17, 2020**

NOTE: Transmittal 195, dated November 15, 2019 is being Rescinded and Replaced by Transmittal 199, dated January 17, 2020 to correct formatting and mistakenly omitted information from the Transmittal and Manual Instruction Pages. All other information remains the same.

SUBJECT: Revisions to State Operations Manual (SOM) Chapter 6 - Special Procedures for Laboratories and Chapter 9 Exhibits

I. SUMMARY OF CHANGES: Revisions have been made to the Guidance content of Chapter 6 - Special Procedures for Laboratories and Chapter 9 Exhibits.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 17, 2020
IMPLEMENTATION: January 17, 2020

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

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

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III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

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

State Operations Manual

Chapter 6 - Special Procedures for Laboratories

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Program Background and Actions Related to Certification

6000 - Background

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

The Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100- 578, amended §353 of the Public Health Service Act (42 U.S.C. 263a), to extend jurisdiction of the Department of Health and Human Services (HHS) to regulate all laboratories that test human specimens for the purpose of providing information for diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. *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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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 §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 Public Law 100-578, §353, and subject to specified penalties. Such cases or suspected cases should be *forwarded* to the RO for referral to *the* OIG. (See §6036.)

6006 - Application and Certificate Process

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

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

CMS (directly or through its agents or contractors) is responsible for providing, collecting, and processing CLIA applications; *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 CLIA data system.

6006.1 - Certificate of Registration

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

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* laborator*y* appl*ies* 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 a*n 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. *L*aboratories 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

data system by the approving AO along with the AO inspection date and inspection specialties information.

6006.2 - Certificate of Waiver

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

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 t*ests approved for CoW status *are listed at 42 CFR Part 493.15, however, the list has been extended and* can be viewed at https://www.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.

6006.3 - Certificate for Provider-*p*erformed Microscopy (PPM) Procedures

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

A Certificate for Provider-*p*erformed Microscopy (PPM) procedures is issued to a laboratory in which a 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 a*n inspection* sample of non-waived laboratories *or a complaint inspection*.

6006.4 - Certificate of Compliance

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

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

If a Certificate of Compliance is due to expire prior to a hearing date, it may be reissued if CMS finds that conditions in the laboratory do not pose immediate jeopardy. *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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

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 data system.

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

Laboratories applying for a Certificate of PPM procedures, Certificate of Compliance or Certificate of Accreditation must meet the qualifications of Laboratory Director as found in Sections 493.1357, 493.1405, 493.1406 and 493.1443. *T*he 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 Medical Education (CME) 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. Refer to S&C 16-18 CLIA.

6008 - *Assignmentof CLIA Identification Numbers*

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

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 data system.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.

6010 - *Regulatory Exceptions for a Multiple Site Certificate Location*

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

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).*

6010.1 - Mobile Laboratory Units and Temporary Testing Sites

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

Exception (b)(1): *Laboratories that are not at a fixed location, that is, laboratories that move from testing*

site to testing site, such as mobile units providing laboratory testing, health screening fairs, or other temporary testing locations may be covered under the CLIA certificate and address of the designated primary site or home base. (42 CFR 493.35(b)(1), 493.43(b)(1), or 493.55(b)(1)).

Primary Site or Home Base:

The regulations do not specify the types of facility that may be designated as the primary site or home base. The primary site or home base is the location where the staff is based and records, equipment, supplies, etc. are maintained. For example, the main office for an ambulance service.

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

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

- *The regulation specifies no restrictions on the number of visits to a particular site, the type of testing performed, or scheduling.*
- *Records, files, etc. for temporary testing sites may be kept at the primary site or home base. The personnel, equipment, supplies, and reagents, etc. are not kept at a temporary testing site on a permanent basis.*

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

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 the RO 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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 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 terrorismtesting 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 the CLIA Regional Offices. 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Certificate of Waiver or Certificate of 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 §6006. A fee coupon will be system generated once the data is entered into the CLIA data system. The certificate is issued once the appropriate fees are paid.

Certificate of Compliance to Certificate of 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 §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 data system; 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 of 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 §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 Condition-level compliance. Once a credible AoC is received, and compliance is verified, the certificate change data may be entered into the CLIA data system. A laboratory can elect to retain the Certificate of Compliance until the certificate expiration date and subsequently change the certificate status. If the laboratory elects to change its certificate status prior to the expiration date of the current CLIA certificate, the data system must be updated. The laboratory must submit a new CLIA application (Form CMS- 116). For specific instructions on the application process, see §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 State Agency. For specific instructions on the application process, see §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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

When a laboratory provides written notification or, as necessary, a new Form CMS-116 concerning changes listed in 6016.1, the SA enters the information into the CLIA data system 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

For information concerning change of ownership see Chapter 2, §2005. A *new Form CMS-116 must be obtained when any of the following laboratory changes or events take place:*

- *Initial Application*
- *Survey, Initial or Recertification*
- *Certificate Status Change other than to a Certificate of Waiver*
- *Reinstatement of CLIA Certificate with a Gap in Certification*
- *Laboratory Director Change (Provider-performed Microscopy (PPM); Certificate of Compliance)*

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

- *Certificate Status change to Certificate of Waiver*
- *Name of Laboratory*
- *Location (Physical Location)*
- *Location (Mailing Address)*
- *Location (Corporate Address)*
- *Ownership*
- *Tax ID (EIN)*
- *Specialty or Subspecialty change (Certificate of Compliance)*
- *Telephone and Fax Numbers*
- *Reinstatement - Activate without a Gap*
- *Multiple Site*
- *Change in Accreditation Organization*
- *Voluntary Closure/Termination*
- *Personnel-Technical Supervisor*

Written notification includes email, fax or hard copy. The written notification must include the laboratory's name, CLIA number, the name of Laboratory Director and Owner, the change(s) being made, and the signature of the Laboratory Director or his/her designee. In lieu of written notification, a new Form CMS-116 is also acceptable. Please note, the Form CMS-116 must be completed in its entirety. A revised certificate is reissued based on the requested changes.

6016.1.1 - Change in Laboratory Director for Certificate of Accreditation Laboratories

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

Once a laboratory becomes accredited by an Accreditation Organization (AO) (as indicated by the confirmation checkmark in the ASPEN Web 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 data system. The system has been programmed to automatically generate a replacement certificate showing the new laboratory director name to the CoA laboratory.

Example 1: *A State Agency 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 State Agency (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 State Agency, is the Form CMS-116 forwarded to the AO or the Regional Office (RO)?*

Response: *Neither. The State Agency 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 replacement 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 data system 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. The SA should send a replacement certificate after making the changes.*

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.*

6016.2 - Retention Requirements

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

According to Section XI of the CMS Records Schedule, Form CMS-116 needs to be kept by the SA/RO 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 - *Revised Certificates*

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

There is currently no fee for re-issuing lost certificates, or certificates with demographic revisions.

6020 - *Fee Adjustments*

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

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

6022 - *CLIA Data System*

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

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

Standard or user defined reports that provide general information are available through the CLIA data system reporting functions. Consult with your supervisor or Regional Office to obtain specific instructions/training on how to use the CLIA data system, or any of the current available CLIA data system Users' Guide(s).

State Agency and Regional Office Roles and Relationships with other Federal Agencies

6024 - *Consultative CLIA* Activities

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

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 Public Health Service Act, as amended. This committee provides scientific and technical advice and guidance to HHS regarding the need for, and the nature of:*

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

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

expertise.

6026 - *Regional Office* (*RO*) Role

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

The CMS ROs are responsible for ensuring that CLIA laboratories provide appropriate quality services and the SAs operate in accordance with the §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/RO 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 CO 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;*
- *Notifying CO of training and policy needs, PT referrals and circumstances with significant impact to the public health, media coverage, Federal/State Congressional or political concerns;*
- *Performing State Agency 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 RO Jurisdiction*

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

The following facilities may fall under the direct jurisdiction of the RO 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 RO 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 Federal jurisdiction, the RO determines whether the RO 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 the RO. (See SOM Chapter 1, §1018A)

The RO is also responsible for designating all federal jurisdictional laboratories as such in the CLIA data system.

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

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

CLIA has a single set of regulations applicable to all types of laboratories or entities performing laboratory tests based on test complexity. The RO is responsible for reviewing certification activity of the SA. The primary objective of this review is to ensure that the certification decision is supported by appropriate documentation that serves as sufficient evidence of the laboratory's compliance with the laws and regulations governing program participation. (See §6230)

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

6032 - *State Agency (SA) Role*

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

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 data system.

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 ROs according to standard operating procedures (SOPs).*
- *Managing the CLIA data base using CLIA system applications according to procedure.*
- *Responding timely to complaints, as per RO direction.*
- *Attending CO/RO 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 State agency 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 the RO 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 With Civil Rights Requirement*

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

CLIA laboratories are required to comply with certain requirements enforced by the Office for Civil Rights (OCR), including the Americans with Disabilities Act, but are not subject to traditional pre-certification assurance investigations. These requirements are enforced only on the basis of complaints. The OCR makes any necessary investigations and determinations related to compliance with civil rights requirements. The SA forwards complaints concerning a CLIA laboratory's noncompliance with Federal civil rights requirements to the RO. The RO 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. The RO does not investigate Federal civil rights complaints under any circumstances. OCR or the DOJ is responsible for investigating Federal civil rights complaints. CMS is not authorized to bill the laboratory for the cost of a complaint survey for noncompliance with civil rights as part of the laboratory's user fee obligation.

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

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

If a laboratory is operating without a CLIA certificate, the SA or RO 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, the RO will notify the OIG of the violation. If applicable, the SA forwards documentation to the RO within 20 days of the date the violation notice was sent to the laboratory. In addition, the RO also refers to the OIG:

- *Cases of misrepresentation in obtaining a CLIA certificate;*
- *Laboratories that perform or represent 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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.

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)*

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.

6038.1 - Inspections of Transfusion Services

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

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.

The following table summarizes the different types of facilities:

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

6040 - Transfusion-Related Fatalities

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

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 http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/TransfusionDonationFatalities/.*

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

The investigation should also include a review of other transfusion reaction reports to ensure that proper procedures were followed and corrective actions implemented. The RO 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 Complaint*s/Incidents* Tracking System (ACTS). When performing investigations in accredited laboratories or laboratories in exempt states, follow standard policies and procedures for RO authorization, review of deficiencies, and communication with the laboratory, the accreditation organization, and the exempt state.

The RO or SA will conduct the survey within 45 days of the notice from CO, with *notification to CO when the survey is complete*. *T*he information entered in ACTS is sufficient for reporting to CO. Investigations of transfusion-related fatalities are generally *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 RO conducts an unannounced survey.

The RO or SA will assess the facility's compliance with applicable CLIA conditions and standards during the onsite review. If condition-level deficiencies are found, a full CLIA inspection is conducted. The survey may uncover problems that warrant investigation of departments outside the laboratory, e.g., Operating Room, Emergency Room, nursing services, or medical records, to follow up on problems that may have led to the fatality. Since CLIA is specific only to laboratory testing, the RO forwards relevant information to other programs, e.g., hospital, for follow up as necessary. (**NOTE:** When citing

deficiencies related to a CLIA survey, only D-tags should be used on the 2567. A-tags *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.*

The RO 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

42 CFR Part 493 Subpart H, Participation in Proficiency Testing for Laboratories Performing Non-waived Testing, provides laboratories with the PT requirements they must follow to comply with CLIA. The subpart specifies requirements for PT enrollment, testing, PT sample handling, and documentation. The prohibition of referral of PT samples to another laboratory is found at 42 CFR Part 493.801(b)(4) and, if identified, carries one of the most severe sanctions in the CLIA law and regulations. The subpart also identifies successful participation in a CMS-approved PT program and how a laboratory may be reinstated when it has performed unsuccessfully. (Please see 42 CFR Part 493.2, Definitions, for unsatisfactory participation and unsuccessful participation.)

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 the RO if PT referral is identified. *For additional information on PT Referral, see §6061.*

PT Program Approval: Not-for-profit organizations or States may apply to CO to become a CMS-approved PT program for specific subspecialties and analytes. CO PT specialists perform an in-depth review of 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 r*e-approval reviews are also conducted by CO specialists. Approved PT programs and the subspecialties and analytes for which they are approved are listed on the CMS CLIA Web site each year.

6044 - *PT* Enrollment *and CASPER System Reports*

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

The SA or RO 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 Part 493.841(c)(1)-(3)).

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

6046 - PT *Enrollment Information*

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

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 Part 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, the RO 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 Part 493.801 is found, but instead the SA may recommend to the RO appropriate sanctions if the non-enrollment isn't corrected in a timely manner.

Each calendar year the PT programs transmit enrollment records to the PT Monitoring System within the CLIA data system 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 on-site survey. If the SA or RO 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 RO should call the laboratory to ask for proof of enrollment for the missing tests or ask for a written statement from the laboratory director that it has discontinued performing the missing tests.

6048 - PT Participation and Testing Requirements

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

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

If 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*, the RO must be notified immediately. The RO will instruct and advise the SA surveyor of the appropriate actions the surveyor must take. The RO may contact CO with any questions.

All documentation to support the finding of any PT referral is forwarded to CO for review by the PT Referral Team who will recommend appropriate sanctions in accordance with Subpart R. (See §6061.)

6050 - Monitoring of PT Scores

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

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 their RO.

PT must also be reviewed during the on-site survey. Prior to the on-site 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 Part 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 the RO for failure to meet PT requirements for successful participation. This may only be done after the SA has verified the PT results from the PT program or from the laboratory. Specifically, SA follow-up action for unsuccessful PT performance should consist of:

- Obtaining the results for each unsatisfactory analyte, subspecialty, or specialty that contributed to the laboratory's unsuccessful performance from the laboratory or from the PT program; and

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

6054 - Unsuccessful Performance in Proficiency Testing

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

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

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

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 the RO that the laboratory undertake additional training, obtain technical assistance, or both, rather than recommending the imposition of alternative or principal sanctions. No on-site 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 Part 493.803(c) for regulatory specifications.*

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

- *The SA must first verify that the PT scores are 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 RO 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 Condition-level deficiency. The letter should also include the consequences of another PT failure.*

- *The laboratory may continue testing during this period.*

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

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

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

For a non-initial 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, the RO has the option, based on the laboratory's compliance history, SA recommendation, and the specific circumstances that caused the failure, to impose another T&TA rather than impose a sanction as specified in subpart R. If the RO determines that another T&TA is warranted, follow the procedure noted above for an initial unsuccessful 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 Condition-level noncompliance to the RO.*

- *The RO then sends a letter along with the Form CMS-2567 citing the Condition-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 data base 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

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

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

6060 - Reinstatement After Failure to Successfully Participate in Proficiency Testing

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

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 the RO 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 the RO and utilize the same procedure as indicated for all unsuccessful PT performance.

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

If a laboratory voluntarily stops testing in the area of failure, it may resume testing when it has demonstrated sustained satisfactory performance for two consecutive testing events; the PT samples may be tested as soon as the laboratory has identified and corrected the cause of theoriginal 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. The RO will make the final determination whether reinstatement requirements are met.

6061 - PT Referral

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

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 the RO immediately. If the RO directs the SA to investigate the potential PT referral, collect all information related to the PT referral including all records, interviews and observations and send the information to the RO immediately. The RO will notify CO of the potential PT referral and send all documents to CO for review by the PT referral team. The CO PT referral team will provide a recommendation for sanctions in accordance with Subpart R for all PT referral cases. See §6276.2 for enforcement and sanction information related to PT referral.

Documentation forwarded to CO should include, at a minimum:

- *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*

If it is determined that PT samples or PT results have been referred to another laboratory, 'PT Referral' is *cited*. *The SA prepares a 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 cutoff 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 cut-off date.*

For example, a laboratory refers PT samples to a 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 includes the scenario in which the referring laboratory does not receive test results from another laboratory prior to the event cut-off date and reports their own results. This category includes referral of confirmatory, distributive, and reflex PT samples.*

   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.

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.

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 Accredit*ation* 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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 RO use the same survey protocol.

The SA/RO is responsible for conducting the on-site survey, and entering the information concerning the results of the survey into the Automated Survey Processing Environment (ASPEN), which includes ASPEN Central Office (ACO) and ASPEN Regional Office (ARO).

Survey protocols and interpretive guidelines are intended to provide guidance to personnel conducting surveys of laboratories. The protocols and guidelines clarify and/or explain the Federal requirements for laboratories

and are required for use by all surveyors assessing laboratory performance based on these Federal requirements. The same survey protocols are used by the Centers for Medicare & Medicaid Services (CMS) Regional Office (RO) and/or State Agency (SA) surveyors.
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 approach to 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 on-site survey, and analyzing, evaluating, and documenting survey findings, the surveyor's professional judgment is the most critical element in the survey process.

CMS's 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 initial laboratory inspection, to help laboratoriesunderstand 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, whether it is producing quality test results (i.e., accurate, reliable, and timely). Specifically, the primary objective of the survey process is to determine whether or not the laboratory meets the CLIA requirements. The surveyor meets this objective by employing an outcome-oriented survey process or approach, the intent of which is to focus the surveyor on the overall performance of the laboratory and the way it monitors itself, rather than on a methodical evaluation of each standard-level regulatory requirement.

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

The principal focus of the outcome-oriented survey is the effect (outcome) of the laboratory's practices on patient test results and/or patient care. The 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 test results.

In the outcome-oriented survey process, 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 outcome-oriented survey process, 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 §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.*

6102.1 - Scheduling Priorities

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

When scheduling surveys use the following priorities:

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

Scheduling surveys - There are three activities associated with scheduling surveys:

- *The intention to survey which is the in-office formulation of a workplan,*
- *Announcing the surveys which is notifying the laboratory (when applicable) of the survey date and time, and*
- *Performing the survey which is the actual on-site inspection.*

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

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

1. Initial Surveys: In order to permit observation of actual testing during the initial survey,

schedule the initial survey to occur at least 90 days after the data entry date of the 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,* 20*15*. Initial survey should be conducted between August *10,* 20*15* (90th day after May *12,* 20*15*) and May *11*, 20*16* (365th day after May *12,* 20*15). If after the 90 days a representative from the laboratory states that laboratory testing is not being performed because equipment is not ready, etc., advise the laboratory that the CLIA certificate will be terminated until such time testing is being performed. If there is suspicion that the laboratory is being operated in a manner that constitutes a risk to human health, schedule an unannounced survey. An unannounced survey could be an option for either case.*

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, 20*14*. Recertification survey should be conducted between December 31, 20*13* and July *4*, 20*14*.

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

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

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

- *Laboratory Personnel Report (CLIA), Form CMS-209 (required) with directions for completing or updating information, adding new personnel or changes in positions or status; and*

- *Clinical Laboratory Improvement Amendments (CLIA) Application for Certification, Form CMS-116 (required) printed from the CLIA data system with all the current values filed in by the system. The laboratory should be asked to write changes on the form and once the survey begins the testing volumes should be corrected and the current owner/operator/director should sign the updated form. (For counting test volumes, refer to SOM Appendix C, Survey Protocols, OOSP, Section IX: Additional Information.)*

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;

    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. Remedial 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. Remedial 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).

6102.3 - Change of Location of Laboratory

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

Changes in location of a laboratory within a State do not ordinarily require a special on- site survey. The laboratory is expected to continue to uphold the standards of operation detailed in its most recent survey. An on-site survey is to be performed only when the relocation raises significant questions as to the laboratory's ability to maintain standards.

In these situations, the SA considers when the last recertification survey was performed. If a recertification survey is due within the next six months, the SA advances the entire resurvey. If the recertification survey is not due, and an on- site visit is performed, the SA conducts a *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 on-site surveys and maintains this documentation in the laboratory's official file.

6102.4 - Change of Testing Performed by a Laboratory

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

If a laboratory, other than a laboratory with a Certificate of Waiver, 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 §60*14* and §60*18)* 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 - Announc*ed and/or Unannounced* Surveys

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

Section 353(g)(1) of the Public Health Service Act provides for either announced or unannounced surveys, but it is generally CMS's policy to use announced surveys. Complaint or 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.

*When applicable, the laboratory should be notified in writing (e.g. email, mail) and followed up by telephone. 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 RO or 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. If the laboratory has applied for a certificate of accreditation, ask the laboratory to provide documentation (e.g., written verification from the accreditation organization) of its accreditation status prior to going on-site, when possible.*

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

6106.1 - *Testing Outside the Certificate Type*

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

In accordance with 42 CFR §493.1775, if it is verified that the laboratory that has been issued a Certificate of Waiver or a Certificate for Provider-performed Microscopy 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 ACTS on the Medicare/Medicaid Certification and Transmittal (Form CMS-1539), and in Item 16 (State Survey Agency Remarks) recommends referral to the RO. 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 "Release for CMS Review." The SA notifies the RO that the RO needs to review the kit for enforcement. The SA refers to §6014 if the laboratory wants to add nonwaived tests.

6106.2 - *Accredited Laboratories*

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

Laboratories accredited by a CMS approved organization are deemed to meet the requirements of 42 CFR Part 493. When the RO/SA receives notification from a laboratory, which was previously inspected by the RO/SA, that it has been accredited, the SA verifies the laboratory's accreditation status by asking the laboratory for documentation of its application to the accreditation organization before removing the laboratory from the RO/SA's biennial survey schedule. A laboratory requesting a change from a Certificate of Compliance to a Certificate of Accreditation remains under CMS' jurisdiction until the Condition-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., Condition-level non-compliance exists, the matter is referred to the RO. A laboratory's

accreditation cannot be recognized until it has corrected its Condition-level deficiencies.

Withdrawal or Denial of Laboratory Accreditation

When an accreditation organization withdraws or denies a laboratory's accreditation, the RO will authorize the SA to conduct a complaint investigation to determine compliance with all CLIA requirements. (See SOM Chapter 5, "Complaint Procedures"). The RO takes appropriate enforcement action if deficiencies are found. If the laboratory is found to be in compliance with all CLIA requirements, the SA obtains an updated Form CMS-116 and processes the change in certification type.

6106.3 - *CLIA-Exempt Laboratories*

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

Laboratories exempt through an approved State licensure program are subject to validation surveys conducted by the RO or its designee. A validation survey of a CLIA-exempt laboratory is conducted to ensure that the exempt laboratory meets CLIA compliance. The RO laboratory surveyor applies the CLIA regulations during a validation survey. When Condition-level deficiencies are determined, CMS directs the State to take appropriate enforcement action. (See §6208)

6108 - *Laboratory Refuses to Allow* Survey

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

Section 353(g) of the PHSA permits authorized officials to make announced or unannounced surveys of laboratories holding any type of CLIA certificate, at any time during the laboratory's normal hours of operation. If access is refused, the SA documents the identity (name and title) of the individual refusing admission and the reasons given, and submits this documentation immediately to the RO, i.e., by email, telephone or fax. The CLIA regulations at 42 CFR §493.1771and §493.1773 permits the SA to cite the laboratory for refusal to allow a survey on a CMS Form 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. The RO will make the referral to the OIG. (See §6270.)

6112 - *Pre-Survey Preparation*

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

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*** *- Consult the annual laboratory registry to assist with determining whether the director/owner has had a laboratory certificate revoked within the last two years. Include the completed or updated Form CMS-209 in each survey package. Use this information during the on-site 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, 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 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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 IX for information concerning conducting surveys of multiple testing sites under one certificate.)

Inform the laboratory that the survey will include a tour of the facility, 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 the SOM, Chapter 6, §§6124 and 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 Facilities and Processes
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

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 guidelines, and if necessary, repeat or restate the response given by the staff 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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 amount 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 prescribed positions 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 CMS-209 form 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 who do not perform testing, or individuals who do reagent preparation, specimen preparation, microbiology plating, etc., but no actual testing.*
- *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.*

- ***Bachelor Degree in Nursing** - A bachelor's degree in nursing meets the requirement of having earned a bachelor's degree in a biological science for high complexity testing personnel. 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's degree in nursing meets the requirement of having earned an associate's degree in a biological science for moderate complexity testing personnel. The laboratory may show a PSV report verifying that an associate's 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 §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)(3) for moderate complexity testing and 42 CFR §493.1489(b)(4)(ii) 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)** - An RBD is a baccalaureate degree program designed for adult students. The basic principle 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, physical, biological, or clinical laboratory science, or medical technology…" The RBD without the designation of one of the above majors does not meet this requirement, as it is a general education degree. These individuals' transcripts can be evaluated in order to qualify as high complexity testing personnel at 42 CFR §493.1489(b)(2) or general supervisor at 42 CFR §493.1461(c)(2)(i).

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), or if an individual does not fulfill the responsibilities of the position.

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, or the corresponding responsibilities of that position are not met at the time of survey. The list of mandatory citations is at §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 Forms CMS-1557 and 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. An associate's or bachelor's degree in nursing meets the requirement of having earned a degree in a biological science for moderate complexity testing personnel. 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 bachelor's of science in nursing diploma as evidence of compliance.*
Does this satisfy the personnel requirement?
Answer: Yes. A bachelor's degree in nursing meets the requirement of having earned a bachelor's degree in a biological science for high complexity testing personnel. The laboratory must show a PSV report verifying the degree, a diploma showing the type of degree earned, or transcripts as evidence of meeting the personnel requirement.

Example 10: *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)(1) states that high complexity testing personnel will have earned a "…bachelor's degree in a chemical, physical, biological, or clinical laboratory science, or medical technology…" The documentation in the PSV report did not state the type of BS 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 BS degree does not meet the personnel requirement.

6116.5 - Credentialing of Foreign Trained Laboratory Personnel
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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 §493.1405(b)(3) or 42 CFR §493.1433(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 (1) meet the qualifications of 42 CFR §493.1449(b) or (k), or (2) possess a current license as a cytotechnologist issued by the State in which the laboratory is located, if such licensing is required, and meet one of several sets of requirements. One set of requirements states that on or before September 1, 1994 cytotechnologists examining cytology slide preparations must have full-time experience of at least two years or equivalent examining cytology slide preparations within the preceding five years in the United States under the supervision of a physician qualified under 42 CFR §493.1449(b) or (k)(1), and on or before September 1, 1995, have met the requirements in 42 CFR §493.1483(b)(1) or (2).*

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

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 Condition-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 §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 the RO on whether other Federal regulations are applicable. If the laboratory is subject to a State Licensure Program, consult with the State Agency 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 - Completing the Survey Report (Form CMS-1557)

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

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

The information required to complete Form CMS-1557 (Exhibit 12) is collected at the time of the survey, and includes survey data that must be entered into ASPEN. It includes information used in preparing the Statement of Deficiencies and Plan of Correction, Form CMS-2567. Electronic data input in ASPEN also includes the Federal Surveyor ID number of the surveyors on the CMS Form 670, as well as the determination of compliance with program requirements.

When completing the Form CMS-1557 during the survey, the surveyor should pay particular attention to Personnel and the Specialties/Subspecialties. For molecular diagnostics or genetic testing, select the specialty/subspecialty that fits the specific gene being analyzed. For those genetic tests described by CPT codes, refer to the laboratory codes (LC) mentioned in the CPT-4 and HCPCS Codes Subject to CLIA Edits list. The LC codes that are CLIA applicable to non- microbiology molecular genetic testing are:

- *010 - Histocompatibility,*
- *210 - General Immunology,*
- *310 - Chemistry,*
- *400 - Hematology, or*

- *900 - Cytogenetics.*

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

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

6120.1 - *Regulatory Compliance Decision*

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

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 Condition 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 Conditions, Mandatory CLIA Citations and/or supporting CLIA Standards that are not met by the laboratory. Upon citing Condition(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 Condition-level non-compliance. If the surveyor concludes no IJ is present, proceed with citing Condition(s) as identified under Step four.

When determining if the Condition-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?

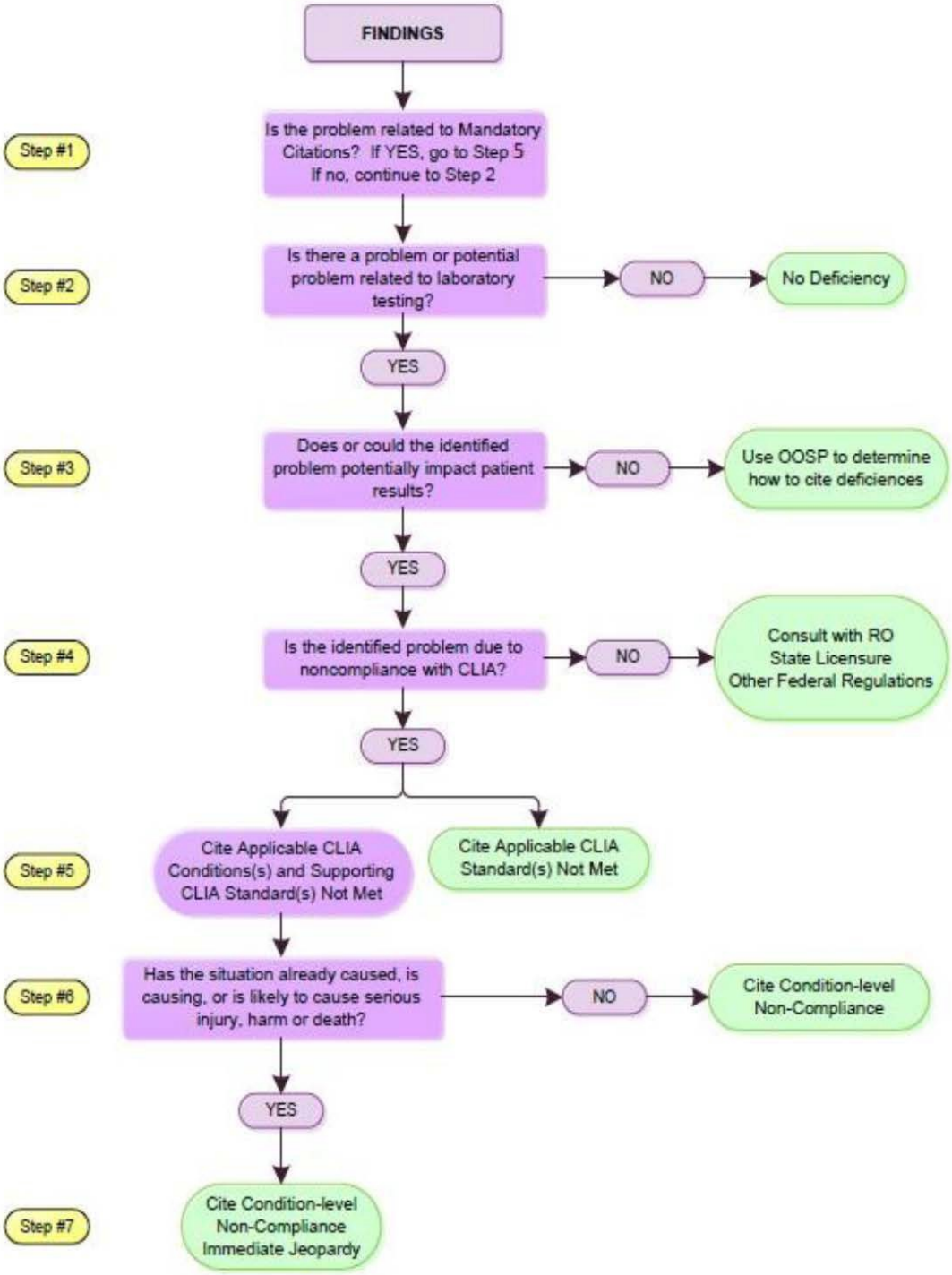
- *Is there information or data not available at the time of the survey, or within a reasonable time frame, that must be provided by the laboratory in order to determine if the deficient practice has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death?*

In summary, the steps for regulatory considerations include:

1. *Are CLIA regulatory deficiencies identified?*
2. *Does the deficiency(ies) constitute(s) Condition-level non-compliance?*
    - *Do the deficiencies prevent certification?*
3. *Does the Condition-level non-compliance pose an immediate jeopardy to patient health and safety?*
    - *Is there an option for other enforcement remedies?*

Refer to QSOG-19-9-ALL, 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Prior to the exit conference, the surveyor(s) review 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 Condition or standard may be cumulative and interrelated and result in general, pervasive inadequacies in determining test results.

6126 - Exit Conference

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

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 QSOG-19-9-ALL, 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 the RO/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 calendar days. The laboratory must also be informed they are to return the PoC or credible AoC in 10 calendar days;*

- *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 the RO 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. 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. (See §2724.)

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

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

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 at D6021and/or D6094 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 (http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Interpretive_Guidelines_for_Laboratories.html).

For some cited deficiencies, the Automated Survey Processing Environment (ASPEN) 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. Use the list provided on Form CMS-1557 that identifies the code number for each specialty and subspecialty (e.g., the code number for the specialty of hematology is 400). ***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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

There are four CLIA Condition-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 Condition-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 Condition-level citations. Citations should include the Condition 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 Condition-level citations and D-tags and the Standard-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 Condition-level citation where no Standard-level D-tag is cited in conjunction with the Condition-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 Condition-level citations and D-tags, and the potential standard-level citations and D-tags that correspond to the Condition-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 Table

MANDATORY CITATIONS

	IF YOU FIND NON-COMPLIANCE WITH. . .	***YOU MUST AT LEAST CITE THE STANDARD AT D-***	***YOU MUST AT LEAST CITE THE CONDITION AT D-***
	Non-enrollment in Proficiency Testing 42 CFR § 493.801		*D2000*
	Proficiency Testing Referral 42 CFR §	*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,*	*D2016*
Personnel Qualifications - Subpart M	*Laboratory Director PPMP*	*D5981*	*D5980*
	Testing Personnel PPMP	*D5991*	*D5990*
	Laboratory Director Moderate Complexity	*D6003*	*D6000*
	Technical Consultant Moderate Complexity	*D6035*	*D6033*
	Clinical Consultant Moderate Complexity	*D6057*	*D6056*
	Testing Personnel Moderate Complexity	*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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The post-survey certification processes are summarized as follows:

- *The surveyor completes survey documents. (see 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 calendar days of completing the survey. If there are citations, the SA allows the laboratory 10 calendar days to complete and return a PoC or credible AoC. If immediate jeopardy is identified, the SA follows the time frames in §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 §§ 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 Medicare/Medicaid/CLIA report 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 Medicare/Medicaid/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 name of the laboratory director and 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 §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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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:

a. 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);

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

c. 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

d. 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 RO, but it must have corrected dates that are within 12 months after the "date survey completed" listed on the 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 RO/SA within 10 days of receipt. If the response attempts to refute a citation, the SA contacts the laboratory to resolve the disagreement. If not resolved, the laboratory should put its protest in writing in a form suitable for disclosure, but must still provide its plan and time frame for correction.

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

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

6132.3 - *Allegation of Compliance (AoC)*

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

When Condition-level noncompliance is determined by the RO or State Agency 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:

a. *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);*
b. *An explanation as to how the laboratory has identified other patients who may have been affected by the deficient practice(s);*
c. *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*
d. *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:

a. *Made by a representative of a laboratory with a history of having maintained a commitment to compliance and taking corrective action when required;*
b. *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,*
c. *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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

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

Strategy for Repeat Deficiencies:

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

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

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

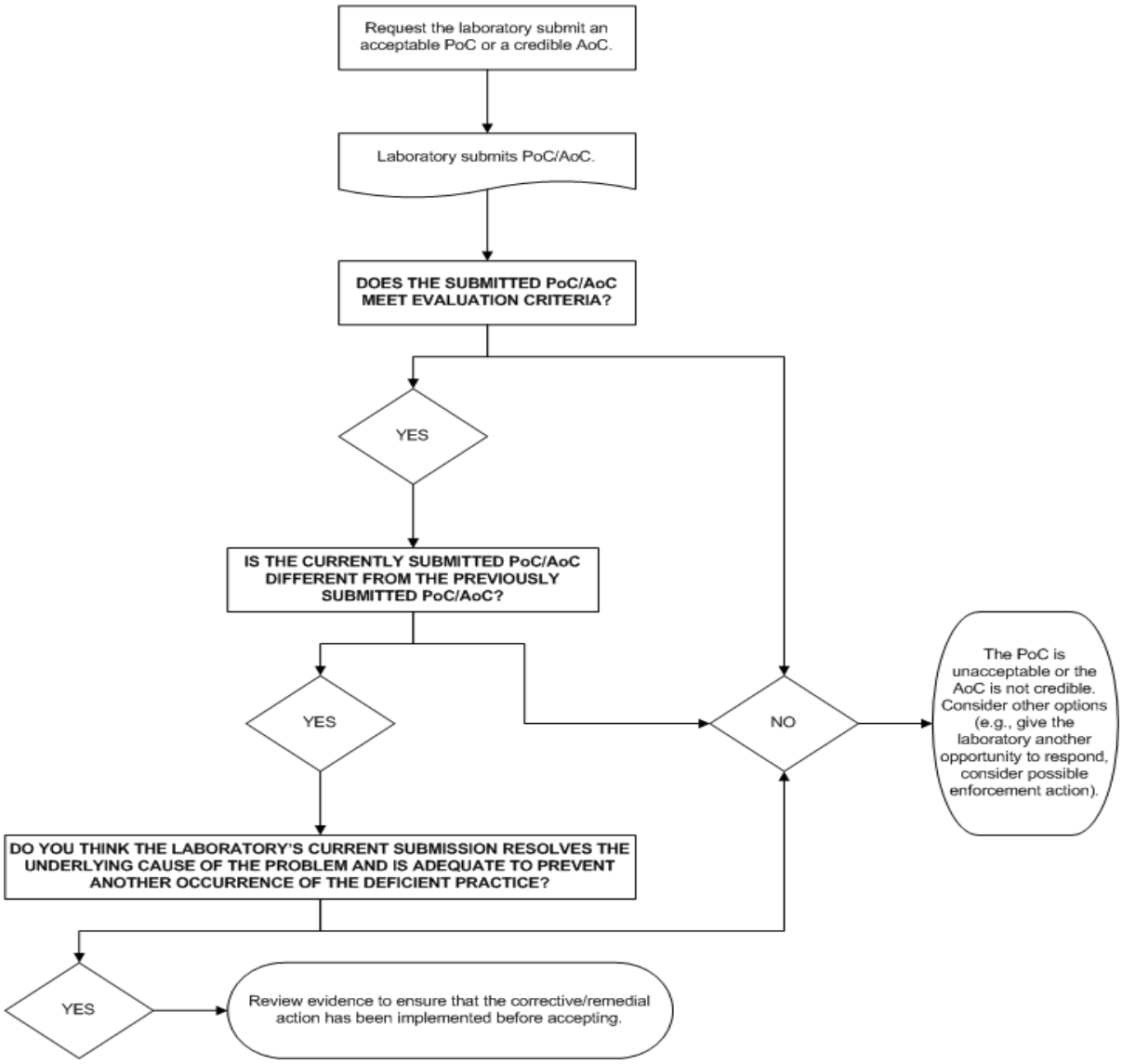
4. *If the laboratory's submission meets established criteria for an acceptable plan of correction or a credible allegation of compliance, compare the currently submitted*

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

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

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

The above strategy is summarized in the following flow chart:



6134.2 - *Follow-Up on* PoC*s and Post-Survey Revisit*

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

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

When the deficiencies are below the Condition-level for which the laboratory has submitted a PoC, the SA may certify a laboratory based on an acceptable PoC. The SA is certifying that the laboratory is able to furnish test results without hazard to the health and safety of patients, that the PoC will likely result in compliance within the time frame indicated, and that the time frame is acceptable. The SA conducts a revisit survey when only Standard-level deficiencies were cited within 12 months of the original survey. This required post-survey revisit is normally conducted by electronic transmission, mail or telephone contact. On-site post-survey revisits are not normally conducted when the only deficiciencies cited are Standard-level deficiencies. On- site verification of standard-level deficiencies is warranted in rare circumstances where the documentation or correction provided by the laboratory alone does not verify correction of the deficiency and/or the documentation provided is indicative of potential risk to the quality of patient test results.
The SA may consult with the RO for a determination regarding cases that are unclear. The SA obtains appropriate documentary verification (or on-site verification if warranted) before reporting a citation as corrected and completes a Form CMS-2567B.

If, at the time of the revisit, some deficiencies have not been corrected, the SA completes another Form CMS-2567 summarizing the deficiencies not corrected by using the appropriate data prefix tag number. The SA must ask the laboratory to provide a revised PoC 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 the RO.
In any event, the SA must record the survey findings in ASPEN within 45 days from the date of the survey; post-survey revisit information can be entered into ASPEN at any time thereafter.

6134.3 - Post-Survey Revisit Report, Form CMS-2567B

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

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

1. Laboratory identification information;
2. *Date of the revisit ;*
3. *Prefix tag;*
4. *Corresponding regulatory reference cited on the original Form CMS-2567; and*
5. *Date the correction was completed.*

The use of the CMS Form 2567-B is to become an internal document between the SAs and the ROs. The SAs are no longer required to complete the CMS Form 2567-B for provider/supplier notification to inform facilities that they have come back into compliance; however, SAs are required to produce the CMS 2567-B to the ROs.

Revisit determines that all deficiencies have been corrected, and no new deficiencies are cited.

- *A CMS Form 2567-B is issued by the SA to the RO only, listing all deficiencies corrected and dates that the corrections were completed.*
    - *The box at the bottom of the form entitled "Check for any uncorrected deficiencies" is not checked.*
- *The cover letter accompanying the CMS Form 2567-B states that all deficiencies were found to be corrected at revisit.*
- *No CMS Form 2567 is issued.*

6136 - *Evaluation of Compliance*

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

The CLIA requirements establish a single set of Conditions 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 a Medicare/Medicaid Certification and Transmittal, Form CMS-1539 are entered into the CLIA data system, an official determination of CLIA compliance is made. There are three types of compliance for any

laboratory:

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

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

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

6136.3 - Noncompliance
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

In situations where it is determined that a laboratory has failed to comply with one or more CLIA conditions, the SA requests an AoC and acceptable evidence of correction. If the laboratory fails to submit a credible AoC and acceptable evidence of correction, the SA notifies the RO of the noncompliance and recommends to the RO sanction action by completing Form CMS-1539. (See §6262.)

6136.4 - Survey Report Documentation and Data Entry
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Following the survey, enter into the CLIA database 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-1557, Survey Report Form (CLIA) - pages 1 and 2;

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

Form CMS-670, Survey Team Composition and Workload Report.

Enter into the data system, when applicable:

Form CMS-562, Medicare/Medicaid/CLIA Complaint Form.

Form CMS-668B has been developed to assess the survey process from the viewpoint of the laboratory. Leave this form with all laboratories that receive an on-site survey. The laboratory will complete this form and return it to CO.

6137 - Data Management

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

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

- *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 §6006.7)*
- *Form CMS-2567, Form CMS-670, and Form CMS-1557 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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 §1864 agreement). The 1864 agreement and Subpart R do not preclude limiting data captured to “essential” elements. For example, the deficiency codes and correction dates from the Form CMS-2567 are essential, but the narrative description of deficiencies or corrections are not.

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

Additional expectations are found in the CMS Records Schedule, which provides record descriptions and mandatory disposition instructions for the retention, transfer, retirement or

destruction of Agency records as approved by the National Archives & Records Administration. See Section XI for specific CLIA-related information.

However, where State law requires retention of records for a longer period or in specific formats, *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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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 data* system.

6138.2 - Deficiencies Cited

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

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

6138.3 - Exception

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

Form CMS-209 is completed at the time of the survey. This form is currently not available in electronic form in ASPEN. 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.

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

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 on-site survey.

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

- *Types of testing performed;*
- *Types of clients and/or facilities served, e.g., pediatric, geriatric, residential/emergency care, or health assessment screens;*
- *Location(s) participating in PT; and*
- *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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

As provided at 42 CFR §493.1775 of Subpart Q Inspection, a laboratory that has been issued a CoW certificate 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 the RO 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The SA/RO 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 RO contact. The complete list of SA/RO contacts can be found on the CLIA website at: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html. *The RO is responsible for coordinating the responses to all complaints. (See SOM Chapter 5, §§5500-5590, "Complaint Procedures" for guidance regarding complaint investigations).*

Sample Validation Surveys of Accredited Laboratories

6150 - Background - CMS Approval of Accreditation Organizations *(AO)*
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

The approved organizations are:

- AABB;
- *American Association for Laboratory Accreditation (A2LA);*
- *Accreditation Association for Hospitals/Health Systems/Healthcare Facilities Accreditation Program (AAHHS/HFAP); (formerly AOA)*
- American Society for Histocompatibility and Immunogenetics (ASHI);
- COLA;

- College of American Pathologists (CAP); and

- *T*he Joint Commission *(TJC)*.

6151 - Accredited Laboratories - Deemed Status

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

An accredited laboratory is a laboratory that has voluntarily applied for and been accredited by a private, nonprofit accreditation organization 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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 the RO. The SA and RO conduct the validation surveys according to established procedures for certification surveys of non-accredited laboratories (see Appendix C) in order to assure a fair basis for comparing the effectiveness of the accreditation organizations' programs. Validation surveys cover all CLIA conditions in the specialties and subspecialties *listed on the CLIA certificate* for which the organization is approved. Sample validation surveys are performed no later than 90 *calendar* days after the accreditation organization's inspection. As part of the validation review process, CMS may conduct onsite visits at the accreditation organization's headquarters to verify administrative integrity.

6154 - Objective of Validation Surveys of Accredited Laboratories

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

The Validation program is designed to evaluate the premise that a laboratory that receives accreditation is in fact meeting CLIA requirements. By comparing the CLIA findings on each

validation survey to the *accreditation* organization's inspection results, calculating the disparity rate as prescribed by the regulations, and reporting the results to Congress annually, CO fulfills the statutory responsibility. The results of the validation surveys provide:

- On a laboratory-specific basis, insight into the effectiveness of the accreditation organization's program, and

- In the aggregate, an indication of the organization's capability to assure laboratory performance equal to or more stringent than that required by CLIA.

6156 - Selection of Sample for Validation Surveys of Accredited Laboratories

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

The number of validation surveys and criteria for selection are indicated in the sections below. A complaint investigation of an accredited laboratory can also be counted toward the validation target. (See §6156.3 below).

6156.2 - Criteria for *Validation* Selection

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

The CO forwards *annual* inspection schedules *for each accreditation organization* to each RO. The RO, with SA input about travel schedules and other administrative matters, selects laboratories to receive validation surveys using the following criteria:

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

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

- *Selections of laboratories from each accreditation organization should be* proportionate to the total number of accredited laboratories *in the State.*

- *Avoid selecting a facility that received a CLIA validation survey during the previous survey cycle year.*

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

6156.3 - *Complaint Investigations Accepted for Validation Survey Target*

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

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

- *Conducted by the SA no later than 90 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 investigations that meet the above criteria are included in the pool for validation review by CO. (See SOM Chapter 5 for additional information regarding complaint investigation(s) involving an accredited laboratory).

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

6158 - Preparing for Validation Surveys of Accredited Laboratories

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

A validation survey is initiated when the RO *approves the survey in the CLIA data system and notifies the SA.* When scheduling the survey, the SA verifies the accreditation organization's inspection date to ensure that the validation survey takes place no later than 90 *calendar* days after the inspection. If the survey cannot be performed, the SA should notify the RO immediately.

Validation surveys may be performed simultaneously with accreditation organization inspections. (See §§6226-6228 for pre-survey arrangements and simultaneous survey procedures.)

Validation surveys are typically announced *unless performed simultaneously with an AO survey, which may be unannounced* (See§6106). The SA must ascertain the hours when testing is conducted in the laboratory to assure that the survey is conducted at a time when the laboratory is normally functioning.

In States with more than one laboratory surveyor, the SA rotates the validation survey assignments among all surveyors, whenever possible.

Within budgetary constraints and whenever possible, the SA coordinates validation surveys with other *survey* types.

At its discretion, the RO 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

If a laboratory selected for validation *fails to permit a* survey, the RO 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.*

The RO will send a copy of the letter to the accreditation organization, SA and CO. An accredited laboratory will be considered deemed to meet the CLIA Conditions when:

- It withdraws any prior refusal to authorize its accreditation organization to release 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The SA performs validation surveys according to established survey procedures. (See *§6100.)* The surveyor refrains from reviewing any inspection results of the accreditation organization that may be available on site until the validation survey is completed, so that compliance status is independently determined. In that manner, a fair basis will be maintained for evaluating the effectiveness of the accreditation organization. In instances where the survey is conducted by more than one CLIA surveyor, all team members should participate in the entrance and exit conferences, if they individually cannot be on site for the entire survey.

6164.1 - SA Responsibilities

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

- Upon receipt of *approval* from the RO, scheduling validation survey(s) to take place no later than 90 *calendar* days after the accreditation organization's survey;

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

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

- Upon completion of the survey*, documents all required information in the CLIA data system that includes:*

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

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

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

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

    - Form CMS-2567 (Exhibit 7) - Statement of Deficiencies

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

Any additional information/forms pertinent to the survey should be forwarded to the RO by attaching them to the survey in the CLIA data system or by other means acceptable to the RO, e.g., CMS-209 - Laboratory Personnel Report; Form CMS-116 CLIA Application for Certification; correspondence with the laboratory.

Include the following forms *in the data system*, when applicable:

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

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

6164.2 - Discrepancy With CLIA Data Information

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

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

The SA *ensures the laboratory completes the Form CMS-116 to include test volumes and signature of the laboratory director or designee. The SA* completes the Form CMS-1557 *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 the RO of test volume information.*

6166.1.1 - The SA

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

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

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

- Within three working days of the survey *exit date, completes all required information in the CLIA data system and attaches any additional information pertinent to the survey for RO review.* (See §6164.)

6166.1.2 - The RO

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

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

- Receives the SA recommendations and determines the appropriate actions according to the policies outlined in §6284. The RO initiates immediate action to suspend or limit the laboratory's certificate of accreditation, and may also impose one or more alternative sanctions as necessary to encourage compliance.

- *Promptly n*otifies 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, CO, and the applicable accredit*ation* organization.

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

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

6166.2.1 - The SA

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

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

- Explains that the Form CMS-2567 (Exhibit 7) will be sent by the RO to the laboratory in approximately 10 *calendar* days. A plan of correction *or allegation of compliance* 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 data system, and attaches any additional information pertinent to the survey for RO review* within 10 *calendar* days from the survey *exit date*. (See §6164.)

6166.2.2 - The RO

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

NOTE: For accredited laboratories, the RO rather than the SA is responsible for processing the enforcement actions listed in §62*90*.

- 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 §62*90*.

- *Notifies the laboratory that it is not in Condition-level compliance and it is no longer deemed to meet the CLIA conditions by virtue of its accreditation* ~~W~~within approximately 10 *calendar* days of *receipt of the Form CMS-2567 and any additional information pertinent to* the validation survey *from the State Agency.*

- Requests the laboratory to submit a*n 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 Condition-level compliance has been achieved.

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

- If, in 45 *calendar* days of the laboratory's receipt of the letter, the RO has not received acceptable evidence of correction, or the RO has determined that the laboratory has failed to provide a credible AoC, the RO follows the established enforcement actions. (See §62*90*.)
- If, in 45 *calendar* days, the RO has received acceptable evidence of correction and the RO has determined the laboratory provided a credible AoC, the RO notifies the laboratory that it continues to meet CLIA Condition-level requirements by virtue of its accreditation.

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

6166.3.1 - The SA

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

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

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

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

- Prepares a Form CMS-2567 and notifies the RO when the validation survey documentation is available in the CLIA data system. (See §6164.)

6166.3.2 - The RO

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

- *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 accredit*ation* organization.

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

6170 - Complet*ing* Validation Survey Information *in the CLIA Data System*

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

When the validation survey of an accredited laboratory and the follow-up activities have been completed, the RO will *ensure* the following forms and other survey information *are complete and available in the CLIA data system for use by* the CO CLIA component in the annual validation review:

- Form CMS-2802A(Exhibit 242);

- Form CMS-1557(Exhibit 12);

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

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

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

6172 - Notification Requirements of Approved Accreditation Organizations

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

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

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

- Immediate jeopardy situations (within 10 days);

- Newly accredited laboratories using the accreditation organization's program for CLIA compliance, including specialty and subspecialty information (within 30 days);

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

- Any adverse actions taken by the organization, i.e., denial, temporary loss, suspension, or withdrawal of accreditation, limitation of specialty/subspecialty, etc. (within 30 days); and

- Revisions in specialty/subspecialty testing (additions or deletions) in existing accredited laboratories (within 30 days).

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

When accreditation has been removed from a facility, it then comes under CMS' jurisdiction for CLIA purposes. The other mechanism by which a laboratory is no longer deemed to meet the CLIA requirements is when the RO removes the certificate of accreditation due to Condition-level noncompliance that has not been corrected. [*See* §493.569(a)].

6204.2 - Selection of Validation Surveys

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

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

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

- Select laboratories that are geographically dispersed.

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

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

Validation surveys are typically announced unless performed simultaneously with *an AO that is recognized and operates within an exempt State (ES),* which *has* policies of unannounced surveys. (See *§6227.3.1* for complete guidance on when to refrain from announcing CLIA validation surveys.) The RO laboratory surveyors should conduct validation surveys, to the extent possible, on a rotating basis so that no one surveyor conducts all the validation surveys.

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

If a laboratory representative refuses to permit a validation survey, the RO requests the State to explain the protocol to the laboratory. If the laboratory still refuses, the RO requests the State to

take enforcement action under their licensure program.

6208 - Conducting Validation Surveys of CLIA-Exempt Laboratories

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

The RO has direct responsibility for the entire validation survey process for CLIA- exempt laboratories, unless CO utilizes a CMS designated contractor, e.g., survey of cytology. The RO surveyor conducts the survey according to established procedures for certification surveys (See *§6100*). At the exit conference the RO surveyor informs the laboratory of any Condition-level findings and the CLIA compliance determination. The validation survey may be conducted simultaneously with the State licensure inspection, however, the RO surveyor makes an independent CLIA compliance determination and completes all necessary documentation and survey forms. The RO sends to the State Program a notification of determination (letter) with Form CMS-2567 (Exhibit 7), and a copy of both to the laboratory. See, §§6210.2.1 and 6210.3.1 for specifics related to the type of deficiencies.

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

6210.1.1 - The RO

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

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

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

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

6210.1.2 - The *Exempt* State *(ES)* Program

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

- Takes the appropriate enforcement actions based on the enforcement policies of its approved licensure program. Within 10 *calendar* days of the survey, notifies the RO of the action taken.

6210.1.3 - The RO

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

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

6210.2.1 - The RO

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

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

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

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

6210.2.2 - The *Exempt* State Program

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

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

6210.2.3 - The RO

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

Follows up with the State Program within 45 *calendar* days if not notified of the action taken.

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

6210.3.1 - The RO

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

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

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

6210.3.2 - The *Exempt* State Program

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

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

6212 - Processing Validation Survey Records

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

The RO inputs the survey information into the *CLIA data* system within 45 *calendar* days of completing the survey. The applicable documents should be completed and processed (see *§6100*).

6216 - Onsite Visit to *Exempt*-State Laboratory Program

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

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

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

- Survey workload;
- Enforcement activities;

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

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

6218 - Notification Responsibilities of Approved State Licensure Program

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

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

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

1. Immediate jeopardy situations (within 10 *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 State 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 the RO assembles information for the annual laboratory registry and for use in the evaluation report of the State's operations.

6226.1 - Simultaneous Validation Survey - Definition

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

A validation survey of an accredited or CLIA-exempt laboratory in which the CLIA surveyor accompanies the accreditation organization or approved State program inspector during the inspector's fact-gathering, and uses the outcome-oriented survey principles (see *§6100*) to determine whether the laboratory meets the CLIA Condition-level requirements.

6226.2 - Purpose

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

The main purpose of the simultaneous validation survey is the same as any CLIA validation survey: to verify that the laboratory meets all applicable CLIA conditions. While determining the laboratory's Condition-level compliance status, the CLIA surveyor gains insight into accreditation or State program processes.

6226.3 - Relationship to *Comparative* Validation Surveys

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

The simultaneous *survey* offers an additional approach for conducting validation surveys. Like the *validation survey performed after the AO or State 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 accreditation organization or approved State program inspection, the surveyor performs *the survey* while accompanying the *AO or State* inspector.

6226.5 - Team Size

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

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

6227.2 - Surveyor Responsibilities

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

The CLIA surveyor *promotes professional and collegial* communication *during* pre- survey and onsite activities. Direct contact by the surveyor with the accreditation organization or

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

6227.3 - Pre-Survey Arrangements for Accredited Laboratories

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

When a laboratory is selected for a simultaneous validation survey, the special tasks listed below are performed in addition to the usual survey scheduling tasks, in order to fully coordinate among all the parties.

6227.3.1 - Coordinating With Accreditation Organization (AO) Contact Person

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

The surveyor *contacts* the accreditation organization's designated contact person (current names and *contact information* can be obtained from the RO.) 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 THEIR INSPECTION WILL BE ANNOUNCED OR UNNANOUNCED. If unannounced, *DO NOT CONTACT THE LABORATORY.*

6227.3.2 - Arrangements With Laboratory

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

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

EXCEPTION: Do not have any pre-survey contact (written, electronic or oral) with a laboratory accredited *by an AO with a policy of unannounced inspections.* (*S*ee §6227.3.1).

6227.3.3 - Coordinating With *Accreditation Organization Inspector*

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

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

- *The CLIA surveyor 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 for a smooth-flowing survey.*

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

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

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

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

6227.4 - Pre-Survey Arrangements for CLIA-Exempt Laboratories

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

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

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

The accreditation/State program inspector sets the flow of the fact-gathering. The surveyor accompanies the inspector, and at the same time determines if sufficient information is obtained to evaluate compliance with CLIA Conditions, using the outcome-oriented survey principles. (See *§6100*.) The surveyor's approach may be tailored to the facility and circumstances, based on professional judgment and survey experience. If the fact-gathering and discussions with the inspector do not result in sufficient information to make a CLIA compliance determination, the CLIA surveyor and the inspector mutually agree on the next course of action. The CLIA survey need not end at the same time as the accreditation/State program inspection, however, there may be blocks of time, such as the inspector's period for administrative tasks, when the surveyor can gather sufficient additional information to make the compliance determination.

6230 - CLIA State Agency Performance Review (SAPR)

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

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

The CLIA SAPR is *a comprehensive review of the SA's survey and certification activities and may include, but is not limited to: workload completion, survey process (including the results of the CLIA Federal Monitoring Survey (FMS), proficiency desk review, writing and evaluating statements of deficiencies, handling complaints, financial management, and enforcement. CO will make the determination which criteria are evaluated each fiscal year. The CLIA SAPR is structured to evaluate and report SA performance in an objective and consistent manner. The CLIA SAPR is distinguished from the CLIA Federal Monitoring Survey (FMS) (see §6232) by its scope. The SAPR focuses on the SA activities, in aggregate, related to its survey and certification responsibilities while the FMS focuses on individual surveyors.*

SA Responsibilities

The SA has the following responsibilities in regard to the SAPR process:

- *Implement internal systems to organize, complete and track survey and certification responsibilities.*
- *Monitoring and reviewing the SAPR requirements to ensure their programs meetthe*

SAPR criteria.

- *Hire qualified staff to implement the CLIA program.*
- *Provide a Corrective Action Plan (CAP) or Quality Improvement Plan (QIP) when required to improve SA performance.*

RO Responsibilities

SAPRs are conducted either onsite or remotely via document review, or a combination of both, in collaboration with the SA. The RO will ask the SA to submit documentation on how the SA has fulfilled each criterion. The RO has the following responsibilities in regards to the SAPR process:

- *Overall program oversight of the SA.*
- *Educational and supportive role to the SA.*
  - *Recognize strengths*
  - *Identify areas needing improvement*
  - *Identify SA personnel training needs*
- *Prepare for a SAPR review that provides an efficient and timely assessment of SA CLIA program responsibilities.*
- *Utilizing CASPER reports to augment the documentation provided by the SA.*

CO Responsibilities

CO has the following responsibilities in regard to the SAPR process:

- *Select criteria to be evaluated for each fiscal year (FY).*
- *Issue the Administrative Info Memo.*
- *Review any changes, new processes for next FY with ROs.*
- *Review SAPR drafts submitted by ROs prior to issuing to SAs.*
- *Track receipt and storage of all drafts, finals, CAPs, QIPs.*
- *Provide clarification to ROs as needed.*
- *Utilize the data to update and clarify policy and to determine national training needs.*

6232 - CLIA Federal Monitoring Survey (FMS) Selection

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

The primary purpose of the FMS system is to monitor each SA surveyor's use and performance of the CLIA Outcome-oriented Survey Process (O*O*SP) to: determine training needs, provide timely feedback for surveyor education and improve survey process performance. The RO's FMS strategy should be consistent with this approach. Actual monitoring survey targets and allocation requirements will be established at the beginning of each fiscal year through a CO component negotiation process. *In general, the expectations for the FMS targets are one percent sample of laboratories surveyed during the year.* As a basic rule, however, the RO does not include in the FMS sample selection any facility against which adverse action has been

initiated by the State survey agency.

6234.1 - Definition

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

An FMS is any survey in which an RO *Representative* accompanies or follows the SA survey to monitor the surveyor's use and performance of the CLIA *O*OSP. Laboratories under direct Federal jurisdiction are exempt, from the CLIA FMS process (see §602*8*).

6234.2 - Purpose

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

The RO performs the survey for the following reasons:

- Monitoring and improving SA performance in interpreting and applying CLIA requirement(s), applying survey policies and procedures;
- Identifying training/or technical assistance needs of surveyors such as issues pertaining to test results and patient outcome;
- Identifying problems that surveyors and/or laboratories encounter in implementing Federal regulations and survey procedures; and
- Providing documented feedback to the RO, SA and Central Office (CO) *on selected surveys that are performed as an Observational (O), Comparative (C), or Participatory (P) FMS in individual States*.

NOTE: New surveyors' work products (e.g., survey packages) are reviewed and/or verified, and signed off with supervisory review prior to the new surveyor being released to independently perform surveys. Upon completion of the *CLIA Orientation Program and CLIA Surveyor Training*, the RO can use the CLIA FMS as a supplement to training until the surveyor has completed the formal Surveyor Training Module(s).

6234.3 - Scope of FMS

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

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

6234.4 - CLIA-FMS Types *Used to Assess Individual Surveyor Performance*

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

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

- The **Observational** CLIA-FMS is a survey in which the RO surveyor accompanies the SA surveyor and interacts as necessary during the survey process. The interaction is also intended to provide guidance at the appropriate times during the survey process. *The RO surveyor and SA surveyor communicate about findings, observations, decisions and regulatory interpretations during the survey in a collaborative and cooperative environment.* The RO surveyor serves as a resource to enable the SA surveyor to strengthen skills, knowledge base, and adherence to the CLIA regulations, policies, and the *O*OSP. It is important that the RO surveyor communicates and interacts in a neutral non-judgmental manner, providing objective and constructive feedback about the SA surveyor's strengths and weaknesses. The SA surveyor prepares the Form CMS-2567 after discussing the deficiencies with the RO surveyor. *The RO hours are not included in the SA's CMS-670 form in the SA certification kit.*

- The **Participatory** CLIA-FMS is a survey in which the RO surveyor observes the SA surveyor and participates in the survey. The Participatory survey facilitates a collaborative relationship between the RO and SA. As in the Observational FMS, the RO surveyor serves as a resource to enable the SA surveyor to strengthen skills, knowledge base, and adherence to the CLIA *O*OSP, regulations, and policies. *The Participatory FMS also affords an opportunity for the RO surveyor to demonstrate a different survey approach when deemed necessary.* The goal is to jointly identify deficiencies by the RO and the SA surveyor. Both the SA and RO surveyor collaborate on a final compliance determination when there are different conclusions. *The RO's hours are included in the SA's CMS-670 form in the SA's certification kit as well as any deficiency citations written by the RO surveyor.*

- The **Comparative** CLIA-FMS is a survey in which the RO surveyor surveys the laboratory after the SA surveyor, preferably within 30 days but no later than 60 days from when the SA performs its survey. The deficiency citations of the RO surveyor are compared to those of the SA surveyor. When assessing comparability, the RO surveyor must keep in mind the possibility that deficiencies may not have been present in the laboratory at the time of separate surveys. If an issue arises, then the RO surveyor must contact the SA surveyor for clarification. *The RO's hours are not included in the SA's CMS-670 form in the SA's certification kit.*

6234.5 - Additional RO Responsibilities on FMS Surveys

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

The Regional Office's (RO) role is to obtain sufficient information to make an appropriate determination regarding the surveyors' adherence to CLIA policies and procedures. An additional aid for the RO to determine skill and training needs for the SA surveyor(s) are the 4 skill sets which can be used as a guide for improvement, not only for the RO, but also for the SA and surveyors. The RO may identify other applicable skills during their FMS reviews and should apply good judgment in their recommendations to the SA in these supplemental areas

for improvement on education and/or training. The skill sets include organization, communication, information gathering, and investigation and are summarized below. Each of the 4 types of basic skill sets are interrelated and are part of performing the various CLIA survey functions/activities effectively. All 4 skills need not be separately observed; rather a single situation may demonstrate one or more skills simultaneously.

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 on-site 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.

6236 - CLIA-FMS Procedures

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

Modifications *updating procedures used to perform Comparative, Observational, and/or Participatory FMS are included as needed annually through national policy memoranda.*

6236.1 - Scheduling of Surveys

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

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

6236.2 - Survey Findings

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

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

If the RO determines that CLIA Conditions are out of compliance, see §§6250-6294 for enforcement process. The RO is responsible for subsequent enforcement actions under these circumstances. However, the RO may request that the SA *conducts* any necessary follow-up visits except for Federal jurisdictional surveys. The RO forwards to the SA the survey findings and copies of all correspondence with the entity.

The RO requests that the SA obtain a PoC from the facility, and monitors the SA's follow-up activities. The RO may wish to work with the *facility* and the SA directly if the seriousness of the findings warrant *such action*.

6236.3 - Feedback to the SA Surveyor and the SA Supervisor

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

*The RO surveyor **must** provide verbal feedback to the SA surveyor at the conclusion of every Observational/Participatory/Comparative CLIA-FMS. Written feedback is provided by the RO surveyor after an observational, participatory, and comparative FMS.*

1. Verbal Feedback. The RO 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 and Principles of Documentation (PoD). Following a Comparative survey, the RO should contact the SA surveyor regarding specifics noted in the FMSA Worksheet.

2. Written Feedback. No later than 60 calendar days after the survey, the RO surveyor sends written feedback to the CLIA SA supervisor and a courtesy copy to the surveyor. The written feedback includes the RO's assessment based on the FMSA Technical Skills Criteria and any recommendations to the SA and reflects the verbal feedback given to the surveyor following the survey.

- *For Observational and Participatory surveys, the 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, Principles of Documentation, and the CLIA OOSP.*

- *For Comparative surveys, the 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.*

6238 - Completion of FMS Workload and Time Expenditures

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

To provide accurate information on both the number and types of monitoring surveys the RO completes the Form CMS-670 which is entered into the system for each survey performed, regardless of the type or extent of the survey, or the size of the survey team. For CLIA surveys, the Form CMS-670 will generally capture SA time, RO time, CO (administrative) time, and appeals time expenditures. This more comprehensive accounting of time is necessary to meet the self-funding requirement of CLIA. *The RO 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 RO into the ASPEN record for FMS Surveys. For the Participatory survey, the RO's hours are included in the CMS-670 in the SA certification kit as well as any deficiency citations written by the RO surveyor.*

6240 - Other Special Purpose Federal Surveys – Definitions

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

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

should be surveyed under CLIA if the laboratory performs laboratory tests on human specimens referred to it by a laboratory in the U.S. or its territories. *CO has regulatory oversight of CLIA certified international laboratories. Surveys of international laboratories are handled by an RO assigned to perform the survey by CO. SAs do not have jurisdiction over international laboratories and should refer all inquiries to CO with a copy to their RO. CO 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 RO may conduct complaint surveys. Refer to Chapter 5, "Complaint Procedures," for additional information about complaint investigations in a laboratory.

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

6250 - Purpose of and Basis for Enforcement Action

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

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

6250.2 - 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

- ***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 end 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's 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 per annum except cytology.

6254 - *Enforcement Options for All Laboratories*

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

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.
ALL MODEL LETTERS FOR ADVERSE ACTIONS MAY BE FOUND AT:
https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/

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

6256 - *Sanctions(s) - General*

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

6256.1 - *Choice of Sanction - Factors to Consider*

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

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

- *Whether the deficiencies pose immediate jeopardy;*
- *The nature, incidence, severity, and duration of the deficiencies or noncompliance;*
- *Whether the same Condition-level deficiencies have been identified repeatedly;*
- *The accuracy and extent of the laboratory's records (e.g., remedial action) in regards to the noncompliance and their availability to the SA, 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 - *Number of Alternative Sanctions*

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

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.

6256.3 - *Principal Sanctions*

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

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 testing in the areas limited, and will be unable to bill Medicare or Medicaid for the laboratory work in the applicable 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 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.

6256.4 - Alternative Sanctions

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

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

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

6256.5 - Additional Sanctions

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

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.*

6256.6 - Civil Suit

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

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.

6256.7 - 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

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

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 the RO in accordance with the Delegations of Authority.

6260 - Certificate Changes When Enforcement Action is Pending

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

6260.1 - Laboratory Gives Notification of Going Out of Business

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

*A laboratory **not facing enforcement action** may voluntarily withdraw from all testing, and, therefore, relinquish its CLIA certificate and go out of business by notifying the RO or SA of its intent, in writing. The SA completes the necessary actions. If the SA learns that a laboratory **facing enforcement action** intends to close, the SA notifies the RO 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 the RO.*

6260.2 - Laboratory Gives No Notification of Going Out of Business

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

*If a laboratory **not facing enforcement action** voluntarily withdraws from all testing, and refuses new requests for testing, it voluntarily relinquishes its CLIA certificate. If the SA learns that a laboratory may be going out of business, it verifies the situation and completes the necessary actions. If the SA learns and verifies that a laboratory **facing enforcement action** has closed, the SA notifies the RO in writing (e.g., email).*

6260.3 - Voluntary Withdrawal When Enforcement Action Is Pending

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

The RO should proceed with the enforcement action despite the laboratory's withdrawal, particularly if the RO decides that the laboratory's performance warrants inclusion on the annual Laboratory Registry and public notification, actions that are triggered by imposition of the adverse action.
If the RO decides to proceed with the enforcement action, it prepares a notice to the laboratory explaining that, although it has withdrawn from the CLIA program, its CLIA certificate will remain active until the enforcement action takes effect so that CMS may exercise its right to take its enforcement action to conclusion. The RO will restate in the notice the laboratory's appeal rights mentioned in the notice of sanction.

If the RO decides to discontinue the revocation, it notifies the SA to process the withdrawal.

6260.4 - Requests to Change Certificate Type When Enforcement Action is Pending

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

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

If the RO proceeds with the enforcement action, the RO notifies the laboratory that its 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, the RO or SA proceeds with the change of certificate type.

6260.5 - Request to Change Accreditation Organization When Enforcement Action is Pending

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

The RO proceeds with the enforcement action proposed against a laboratory's existing certificate if the laboratory's deficiencies warrant it.If the RO proceeds with the enforcement action, the RO notifies the laboratory that its current certificate will remain active until the enforcement action becomes effective, at which time the request may be acted upon. In addition, the RO 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, the RO or SA proceeds with the change of AO.

6262 - *Reissuance of Certificates to Laboratories Found Out of Compliance*

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

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

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

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

The RO 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The RO provides written notice of the imposed sanction(s) at least five days before the effective date in immediate jeopardy situations, and at least 15 days before the effective date in situations that do not pose immediate jeopardy.

6266 - *CLIA Conditions Not Met - Additional Sanctions Related to Medicare Payments - Principal and Alternative Sanctions for Laboratories that Participate in Medicare*

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

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 Public Health Service Act 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

CMS always cancels a laboratory's approval to receive Medicare payment for its services if CMS suspends or revokes the laboratory's CLIA certificate.
Cancellation of Medicare approval to receive Medicare payment for its services is applied to those specialties and subspecialties that are affected by a limited CLIA certificate.

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

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

- *The laboratory fails to submit an 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

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

CMS may impose this sanction in the following situations:

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

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

After proper written notification, the RO will 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 Condition-level deficiencies or CMS cancels the laboratory's approval to receive Medicare payment, but never beyond 12 months from the last date of the survey that identified the deficiencies; one or the other must occur. In this situation, the SA and RO should be in communication throughout the process so that any enforcement action can be timely.

If the laboratory corrects all Condition-level deficiencies, the RO 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), the RO cancels the laboratory's approval to receive Medicare payment for its services.

If the sanction of suspension of Medicare payment is recommended, the RO includes in the notice a statement asking the laboratory whether or not it intends to continue charging Medicare beneficiaries, their private insurance, fiscal intermediary, or carrier for those specialties and subspecialties for which testing is being limited. The RO informs the laboratory that if it agrees not to charge its Medicare beneficiaries, their private insurance, fiscal intermediary, or carrier, it will have its payment for affected Medicare covered laboratory services suspended on the effective date of the sanction.

6266.2.2 - Suspension of All Medicare Payments

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

CMS may suspend Medicare payment for all Medicare-approved laboratory services (i.e., testing in all specialties and subspecialties). CMS suspends payment for all Medicare covered laboratory servies when either of the following conditions are met:

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

- *The laboratory has had the same Condition-level deficiency(ies) during three consecutive surveys, and the laboratory agrees not to charge Medicare beneficiaries, their private insurance carrier, the FI, carrier, or MAC for those services for which payment is suspended. The laboratory also agrees to waive any rights to appeal Medicare claims that are denied during the period of suspension. The laboratory may make this agreement in return for not having its Medicare approval canceled immediately.*

After proper written notification, the RO will instruct the appropriate Medicare carrier, intermediary, or MAC to suspend Medicare payment for services furnished on and after the effective date of the sanction for those specialties or subspecialties for which the laboratory is out of compliance. CMS suspends Medicare payment for all tests performed on or after the effective date of the sanction. This sanction remains in effect until the laboratory corrects all Condition-level deficiencies, but never beyond 12 months from the last date of the survey which identified the deficiencies.

If the laboratory corrects all Condition-level deficiencies, the RO instructs the MAC to resume Medicare payment and eligibility to receive Medicaid payment, effective for all services furnished on or after the date the deficiencies are corrected. If all deficiencies are not corrected by the end of the 12-month period specified above, the RO cancels the laboratory's approval to receive Medicare payment for its services.

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

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

6268.2 - Limitation of Any Type of CLIA Certificate
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

When the RO 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.

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

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)), the RO may impose a principal sanction. (Refer to §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* Action*s 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The RO 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 has:

- *Been found (e.g., through findings during the survey process, or through documents submitted to CMS, the RO 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 the RO or CMS' agent for any information or work on materials that the RO or CMS' agent conclude is necessary to determine the laboratory's continued eligibility for its CLIA certificate or continued compliance with performance standards set by CMS (no hearing necessary before the action);*

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

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

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

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

If the RO determines that any of the above CLIA violations have occurred, the RO imposes a principal sanction.

Also, the RO 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

If CMS determines that a laboratory has intentionally referred its proficiency testing to another laboratory for analysis, CMS will categorize the PT referral into one of three categories (see 6276.2.1-6276.3). What is meant by "intentional" is the intent to act, regardless of motive; that is, a knowing and willful act.

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 the RO or the SA, it is forwarded to the PT Referral Team at CO.

6276.2.1 - *Category 1*

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

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, the RO:

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

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 cutoff date, but reports its own PT sample results, will be considered a

Category 2 PT referral.

In these instances, the RO:

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

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, the RO:

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

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

If the RO determines that any of the above CLIA violations have occurred after consultation with CO, the RO imposes the appropriate sanction(s). Also, the RO determines whether referral to OIG is necessary.

6276. 3 - *Adverse Action Based on Exclusion from Medicare*

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

If the Inspector General (OIG) 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 the RO 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 §6294.2)

6276.4 - *Procedures for Suspension, Limitation, or Suspension: Exceptions*

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

6276.4.1 - Suspension or Limitation: Exceptions

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

CMS generally may not suspend or limit a CLIA certificate until after an ALJ hearing decision that upholds the suspension or limitation. However, CMS may suspend or limit a CLIA certificate prior the ALJ hearing 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

CMS does not revoke any type of CLIA certificate until after an ALJ hearing (if one is requested) 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

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

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

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

- *The laboratory intentionally referred PT samples to another laboratory for analysis. (See §6260.2.1, 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

For a laboratory's initial unsuccessful participation in PT, the RO 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 the RO. The RO 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 the RO.

This only applies to initial unsuccessful participation. Any non-initial (i.e., subsequent) unsuccessful participation for PT must be immediately forwarded to the RO 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 poor compliance history*

6278.2 - *Subsequent (Non-Initial) Unsuccessful Participation in PT*

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

If a laboratory fails to successfully participate in PT for a specialty, subspecialty or analyte, the RO will suspend or limit the CLIA certificate 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 specialty, subspecialty, or analyte prior to the written notification proposing sanctions, the laboratory may demonstrate satisfactory performance on two consecutive events (either regularly schedule or off-cycle or a combination) and be reinstated prior to the 6 month

suspension or limitation.

6280 - Alternative Sanction*s*

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

The RO may impose a directed PoC for a laboratory that has Condition-level deficiencies. Under this sanction, the laboratory is directed to take specific corrective action within specific time frames in order to compel the laboratory to achieve compliance. The laboratory must correct every deficiency addressed in the directed PoC. If the RO does not impose a directed PoC as an alternative sanction, it 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

When imposing this sanction, the RO 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, the RO cancels the laboratory's approval to Medicare payment for its services and notifies the laboratory of its intent to impose a principal sanction against its CLIA certificate. The directed PoC remains in effect until the effective date of the principal sanction against the laboratory's CLIA certificate.*

6280.1.3 - Procedures for Directed Portion of PoC (dPPoC)
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

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

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

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

    - *The name and address of the laboratory;*

    - *The nature of the noncompliance; and*

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

The notice will also indicate that the client may contact the SA if additional information is needed. It is the SA's responsibility to obtain information or needed clarification in order to respond to clients' concerns about making an informed decision regarding patient notification and retesting or the use of another laboratory's services.

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

The RO determines if a CMP will be based on a "per day of noncompliance" or "per violation". When a laboratory has Condition-level deficiencies, the RO 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 the RO in the Civil Money Penalty Tracking System (CMPTS) tab of the AEM system.

NOTE: *See §6276.2 for requirements related to CMPs in cases of PT referral.*

6280.2.2 - Amount of Penalty

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

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

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

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

As of 2017, the amounts were as follows:

1. ***Immediate Jeopardy (Higher Range) -** The penalty will range from $6,134 to $20,111 per day of noncompliance or per violation.*
2. ***No Immediate Jeopardy (Lower Range) -** The penalty will range from $101 to $6,033 per day of noncompliance or per violation.*
3. ***Changes in Penalty Amount***

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

- *Conversely, if deficiencies cited during the survey did not pose immediate jeopardy and the RO proposed a penalty in the lower range, the RO 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The RO 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, RO may reduce the proposed penalty amount by 35 percent.*

6280.2.5 - Accrual of Penalty

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

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

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.*

6280.2.7 - Computation and Notice of Total Penalty Amount

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

After the laboratory's compliance is verified or its CLIA certificate has been suspended, limited, or revoked, the RO computes the total penalty amount due. This 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, the RO may reduce the proposed penalty amount by 35 percent.*

The RO sends a written notice to the laboratory informing it of the daily or per-violation penalty amount, the number of days or violations for which the penalty is imposed, the total amount due, and the due date for payment of the penalty. Payment is due 15 days from the date of the notice. At the RO's option, it may choose to approve a plan allowing the laboratory to pay the penalty, plus interest, over a period of up to one year from the original due date. The RO computes interest in accordance with 42 CFR Part 405.378(d). [See updated sample letters at https://www.cms.gov/CLIA].

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

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

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 Condition-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 the RO and each State. The hourly survey rate as negotiated during the budget process includes salary, fringe benefits, travel, and other direct and indirect costs negotiated by the RO and the State. Form CMS-670 is used to collect this data.

6280.3.2 - Duration of Sanction

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

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

6280.4 - *Duration of Alternative Sanctions*

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

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

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

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

- *Cancels the laboratory's approval to receive Medicare payment for its services, and discontinues any Medicare alternative sanctions as of the*

date the cancellation is effective;

- *Notifies the laboratory of its intent to impose a principal sanction against the laboratory's CLIA certificate and of its right to a hearing; and*

- *Imposes (or continue to impose) any alternative sanctions that do not pertain to Medicare payments. Sanctions imposed against the CLIA certificate may continue for more than 12 months from the date of survey while a hearing on the proposed limitation, suspension, or revocation of the laboratory's CLIA certificate is pending.*

6280.5 - *Lifting of Alternative Sanctions*

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

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

6282 - *Exception for Laboratories With Certificates of Waiver*

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

Alternative sanctions are not imposed on laboratories with certificates of waiver that receive Medicare payments for their services, because there are no Condition-level requirements for these tests. However, the fact that a deficiency is not at the Condition- level does not preclude taking adverse action based on the provisions contained in 42 CFR Part 493.1840. For example, if a laboratory is not following a manufacturer's instructions it is not considered to be meeting the requirements in subpart B and the certificate can be suspended or revoked. If the SA finds that a a laboratory is performing nonwaived tests under its certificate of waiver, the SA must notify the RO. The RO may take action against the laboratory's s certificate (i.e., suspension or revocation). When a laboratory's certificate of waiver is revoked or suspended, its approval to receive Medicare payment for its services is concurrently canceled.

6284 - Noncompliance With One or More Conditions - Immediate Jeopardy *Exists*

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

When a laboratory's deficiencies pose immediate jeopardy, the RO requires the laboratory to take immediate action to remove the jeopardy and it may also impose one or more principal and/or alternative sanctions as necessary to encourage compliance. If the RO has reason to believe that continuation of any activity by the laboratory (either by the entire laboratory operation or in any specialty or subspecialty of testing) would constitute a significant hazard to the public health, it may bring suit and seek a temporary injunction or restrainiFng 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, the RO notifies the laboratory that CMS will suspend or limit its CLIA certificate. In instances of immediate jeopardy, a suspension or limitation of the laboratory's CLIA certificate is not delayed because the laboratory has appealed and the hearing or hearing decision is pending. The laboratory's suspended CLIA certificate may be revoked following a hearing, when one is requested, if the ruling is in CMS' favor.

6284.1 - *Processing Immediate Jeopardy Enforcement Actions*

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

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

1. ***Survey Date -*** *The survey date is the date on which the survey process is completed by the SA or RO.*

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

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

   The SA sends written notice (e.g., overnight mail, facsimile followed by mail, email) notifying the laboratory of the IJ and requesting an AoC as well as the Form CMS-2567 to the laboratory. In some cases, the RO may combine the request for an AoC along with the Form CMS-2567 and proposed sanctions in lieu of the SA sending the letter and Form CMS-2567. The letter which accompanies the Form CMS-2567 includes the following:

   - *The Conditions which are out of compliance and the determination that these deficiencies constitute immediate jeopardy;*

   - *The sanction or sanctions recommended; if the letter is sent by the SA, the SA letter will clearly state that if condition-level compliance is not achieved, the case will be referred to CMS for sanction action. CMS will make the final determination and will advise the laboratory in writing of the sanction(s) to be imposed and/or enforcement action(s) that will be taken*

and will also notify the laboratory of their appeal rights at that time. The sanction(s) must consist of at least suspension or limitation of the laboratory's CLIA certificate and may include one or more alternative sanctions. If the laboratory participates in Medicare, all (or, in the case of the limitation of a CLIA Certificate, part or all of Medicare) payments must be canceled or suspended.

- *The rationale for the possible proposed sanction(s);*
- *The projected effective date and duration of the proposed sanction(s) (RO only);*
- *The authority for the proposed sanction(s);*
- *The time allowed (ten calendar days from the date of the notice) for the laboratory to respond to the notice;*
- *The CMS authority at 42 CFR §493.643(b) to assess additional fees for costs incurred to verify compliance;*
- *The opportunity for the laboratory to notify the RO and/or the SA immediately if the jeopardy has been removed or the deficiencies have been corrected and there is evidence to support the allegation of compliance and;*
- *The intent for the RO to post a public notice on the CMS website should the sanction(s) be imposed (RO only with proposed sanction(s));*

The SA forwards an electronic copy of the Form CMS-2567 and all supporting documentation to the RO or attaches all the documentation to the survey kit in the CLIA data system.

RO Responsibilities

- *Credible AoC is received, and alleges conditional-level compliance and removal of IJ:*
  - *RO authorized SA to perform an onsite revisit to verify compliance; and*
  - *If condition-level compliance and removal of IJ is verified, the RO sends a letter to the laboratory notifying them of the condition-level compliance and removal of IJ; or*
  - *If condition-level compliance and removal of IJ is not verified, the RO sends a letter to the laboratory notifying them that condition- level compliance has not been achieved and IJ has not been removed.*
  - *In either case, the RO will also notify the laboratory if any of the proposed sanction(s) will be imposed.*

6286 - *Noncompliance With One or More Conditions - No Immediate Jeopardy Exists*

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

When condition-level deficiencies are identified, but immediate jeopardy does not exist, and an enforcement action is warranted, the RO completes enforcement procedures within 90 calendar days. The RO 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 Calendar Day*** *- No later than ten days following the survey date, the SA will notify (e.g., overnight mail, facsimile, email) the laboratory in writing of the cited deficiencies, including Condition-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. The SA will state that they will make a determination of compliance within 45 days of the survey, if a credible allegation of compliance is received and verified.*

3. ***Twentieth Calendar Day*** *- The laboratory must submit a credible AoC to the SA.*

4. ***Forty-Fifth Calendar Day to the Fifty-Fifth Day*** *- If the laboratory has submitted a credible allegation of compliance, the SA will determine whether compliance must 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 the RO 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. RO must approve subsequent SA onsite revisits which usually occur between the 45th and 55th day.*

If the laboratory fails to submit a credible allegation of compliance, a revisit is not required. The SA will notify the RO that enforcement actions need to be initiated. In these cases, and those in which a revisit found continued noncompliance, the SA or RO will prepare and send written notification to the laboratory which includes the following information:

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

- *The sanctions recommended for imposition against the laboratory (SA) or proposed sanction(s) (RO);*

- *The rationale for the proposed sanction(s);*

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

- *The authority for the proposed sanction(s);*

- *For alternative sanctions, the time allowed (at least ten calendar days from the date of the notice) for the laboratory to respond to the notice and the instructions for the laboratory to notify the SA or RO if the deficiencies have been corrected and there is evidence to support the allegation;*

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

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

- *The intent to post a public notice on the CMS website (RO only).*

5. ***Sixtieth to Seventieth Calendar Day -*** *The SA will review any response received from the laboratory or from the revisit and determine whether compliance has been achieved. If compliance can be verified on the basis of evidence presented by the laboratory or from the revisit, the SA will certify compliance and will notify the RO to unflag (L32, L33) in the certification kit.*

   If compliance cannot be verified on the basis of evidence submitted by the laboratory or from the revisit, the SA will notify the RO that the laboratory has not achieved compliance. If a credible AoC is not received, and compliance cannot be verified, the RO will prepare a proposed sanction notice. If the submitted AoC cannot be verified as implemented based on the revisit, the SA will prepare the Form CMS-2567 which includes those deficient practices which have not been corrected as well as any new deficient practices found on the revisit. The SA will also notify the RO of their determination and forward the Form CMS-2567 and supporting documentation as well as sanction recommendations to the RO.

6. ***The RO*** *sends an official enforcement action notice (i.e., proposed sanction(s)) to the laboratory which includes the following information*

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

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

conducted by the SA;

- *The sanctions it proposes to impose against the laboratory. If a civil money penalty is recommended, the per day or per violation amount proposed will be specified;*
- *The rationale for imposing the sanction(s);*
- *The projected effective date and duration of the sanction(s), and the effective date of the sanction(s) if Condition-level compliance is not achieved;*
- *The authority for imposing the sanction(s);*
- *The opportunity for the laboratory to notify the RO immediately if the Condition-level deficiencies have been corrected and there is evidence to support the allegation;*
- *The CMS authority at 42 CFR 493.643(b) to assess additional fees for costs incurred to verify compliance;*
- *The laboratory's right to appeal; and*
- *The intent to post a public notice on the CMS website.*

***NOTE**: The post on the CMS website must at least explain the reasons for the adverse action as well as the effective date and effect of the action. When the CLIA certificate is limited, if the laboratory participates in Medicare, the notice must specify the specialties and subspecialties of tests that the laboratory is no longer authorized to perform, and, therefore, are no longer approved for payment under Medicare.*

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

If the RO concurs on the basis of evidence presented or the outcome of a revisit that there are no remaining Condition-level deficiencies, it certifies compliance (i.e., unflag (L32, L33) in the certification kit). The RO advises the laboratory that compliance has been achieved. If the laboratory fails to make a credible allegation of compliance, no revisit is necessary and enforcement procedures continue.

7. ***Ninetieth Calendar Day** - If compliance has not been achieved, the CLIA proposed*

sanctions will be imposed, however, the Medicare sanctions must take effect on the 90th day or effective date. If a principal sanction is imposed, the RO arranges to publish a public notice immediately.

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

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

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

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

If the laboratory corrects all Condition-level deficiencies and participates in Medicare, the RO resumes Medicare payment effective for all services furnished on or after the date the deficiencies are corrected. If all deficiencies are not corrected by the end of the 12- month period specified above, the RO cancels the laboratory's approval to receive Medicare payment for its services. The RO may impose a principal sanction against the laboratory's CLIA certificate. The RO notifies the laboratory in writing of the sanction(s) that CMS is proposing to impose and its right to due process.

6288 - *Condition-level Deficiencies Corrected but Other Deficiencies Remain -12-Month Maximum for Correction*

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

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 the RO 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 At Condition Level*

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

If a laboratory has deficiencies that are not at the Condition 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, the RO 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, the RO may consider the laboratory's failure to comply with reasonable requests for information for purposes of 42 CFR §493.1840(a)(4) and may initiate a principal sanction 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, the RO cancels the laboratory's approval to receive Medicare payment for its services and imposes a principal sanction against the laboratory's CLIA certificate.*

6290 - Laboratory Found *Not in* Compliance *Following Validation Survey or Complaint Survey*

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

***NOTE**: Refer to SOM Chapter 5, Complaint Procedures regarding additional information about complaint investigations/surveys.*

If deficiencies identified are Condition-level and pose immediate jeopardy to the health and safety of individuals served by the laboratory or that of the general public, the RO follows the adverse action procedures described in §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, the RO follows the adverse action procedures described in §6286. The RO notifies the laboratory that it has been found out of compliance with a Condition(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 Condition-level compliance or until such time as it loses its Certificate of Accreditation. Accredited laboratories found out of compliance at the Condition-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, CO should also be notified of enforcement actions proposed and/or imposed against accredited laboratories.

***NOTE**: The RO should provide notices and documentation related to enforcement actions to the appropriate AOs.*

6290.1 - *Allegation of Compliance*
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

If the RO, in conjunction with the SA, determines that the AoC is credible, the RO sends written notification to the laboratory and to the accreditation organization.

If the RO, in conjunction with the SA, determines that the AoC is not credible, the RO 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

When an accredited laboratory is determined to be in compliance with all CLIA conditions, the RO notifies the laboratory and the accrediting organization accordingly.

6292 - *Procedures for Noncompliant Federal and State Operated Laboratories*
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

If the RO surveys a Federal or State operated laboratory and finds Condition-level noncompliance, the RO will function as both the SA and the RO and follow the enforcement procedures outlined in the section.

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

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

6294.1.2 - Acceleration of Timetable
(Rev. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The RO may switch from the no immediate jeopardy procedures to the accelerated procedures of §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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

Only verified correction of noncompliance can stop an enforcement action. (S&C-01-22)

A change in the laboratory director does not affect completion of an enforcement action. However the RO or SA does not solicit an AoC or PoC from the new laboratory director.

Changes in ownership does 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

If compliance can be verified on the basis of an AoC or PoC and supporting evidence submitted by the laboratory or by a revisit, the RO 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, the RO 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, the RO may lift the sanction(s) as of the last day of the revisit.

6294.4 - Credible Allegation of Compliance Submitted During Adverse Action

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

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

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

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

6294.5 - Entering Enforcement Cases in ASPEN Enforcement Management (AEM)

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

It is the RO's responsibility to enter all information related to enforcement cases in AEM.

6296 - *Table 1 - Required Sanction(s) When Specific Action(s) are Taken by CMS*

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

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 C.F.R §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 C.F.R §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 C.F.R §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 C.F.R §493.1832(a)*

6298 - *Summary of RO Responsibilities during the CLIA Adverse Action Process*

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

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

- *Notifies the laboratory of the exact enforcement action to be imposed against it, the authority for the action, and the effective dates;*
- *Generates revised CLIA certificates, if necessary;*

- *Suspends or limits the CLIA certificate if a laboratory's noncompliance poses immediate jeopardy;*

- *Assists in the collection of evidence and other information related to criminal actions by the laboratories;*

- *Notifies carriers and fiscal intermediaries or MACs of Medicare payment sanctions imposed against laboratories; and*

- *Provides appropriate notice to Medicaid State Agencies.*

6300 - Application of Appeals *Process*

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

The procedures under the CLIA program for reconsiderations, hearings and appeals, and civil actions outlined in this section apply to all laboratories that meet the definition for a laboratory under CLIA and, where indicated, prospective laboratories. These procedures are set forth in 42 CFR Part 493.1844 and are explained in the following sections.

6302.2 - Right to Reconsideration

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

A reconsideration may be given only to a prospective laboratory (i.e., a laboratory that is applying for a CLIA certificate (or for both a CLIA certificate and approval to receive Medicare/Medicaid payment for its services) or to a laboratory that applies to test in new specialties or subspecialties. The RO reconsiders only initial determinations as outlined below and in 42 CFR Part 493.1844(b). Appeals of initial determinations of laboratories that already hold a CLIA certificate and/or have previously been approved to participate in Medicare/Medicaid are submitted directly to an ALJ. There is no reconsideration given at RO level for these types of cases.

The following are the initial determinations applicable to prospective laboratories, and, therefore, are valid reasons for which prospective laboratories may provide the SA (or the RO directly) with a written request for a reconsideration:

- The denial of a laboratory's request for a CLIA certificate;

- The denial of a laboratory's request for additional specialties or subspecialties; and

- The denial of a laboratory's request for approval to receive Medicare payment for its services.

In 42 CFR Part 493.1844(c), there is a list of administrative actions that are not initial determinations and are, therefore, not appealable and not subject to a reconsideration.

Previously approved laboratories are not given reconsideration determinations.

6302.4 - Actions upon Receipt of Request for Reconsideration

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

The RO 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 the RO from the SA. Any additional information the SA subsequently receives from the prospective laboratory that may affect the reconsideration or hearing will be forwarded to the RO. All reports of onsite visits and telephone contact with the prospective laboratory will also be sent to the RO from the SA.

6304 - RO Notice of ReconsideredDetermination

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

If the initial reconsideration is denied, the RO prepares a notice to the laboratory outlining:

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

The denial notice must be signed by the RO in accordance with the Delegations of Authority. All information related to the reconsideration should be recorded in AEM on the specialty tab.

6304.1 - DeterminationReversal (Approval)

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

If a reconsideration is requested and a laboratory's application is subsequently approved, the RO notifies the laboratory within 20 days of approving the prospective laboratory's application to participate in the CLIA program. After confirming that the Form CMS-116 (Exhibit 125) is correct, the RO *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 *of* 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. 199, Issued: 01-17-20, Effective: 01-17-20, Implementation: 01-17-20)

The RO *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. If the ARA did not sign the initial denial notice, he or she should sign the reconsidered denial notice.

6304.3 - Administrative Evidentiary Hearing

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

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).

6306.1 - Actions Which Are Appealable

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

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

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 the RO decides to impose principal and/or alternative sanctions on laboratory's CLIA certificate, it may do so within the time frames that the RO communicates to the laboratory in the notice of sanction(s). If the laboratory does not request a hearing, the RO will finalized 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 C.F.R. §§ 493.1840(d) and 493.1842(b)(2)).

In addition, alternative sanctions may continue for more than 12 months from the last day of inspection 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, the RO lifts the alternative sanction as of the day the principal sanction is effective.

6306.3 - *Procedure for* Request*ing a* Hearing

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

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 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 C.F.R. §§ 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, the RO explains in writing to the laboratory why the request for an appeal is premature and provides instructions to the laboratory or prospective laboratory explaining the procedures for correctly filing the appeal.

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

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 §§493.1840(a)(4) or (a)(5) are not met.

6308 - Processing of Hearing Requests

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

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)*. The RO sends all hearing requests that are sent to it*, or received by the SA and forwarded to the RO, to the DAB (see §6306.3).*

If the laboratory requests a hearing prior to receiving a notice of sanction or a notice of reconsidered determination, the RO explains in writing to the laboratory why the request for an appeal is premature and provides instructions to the laboratory or prospective laboratory explaining the procedures for correctly filing.

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

Any laboratory or prospective laboratory dissatisfied with the ALJ's decision may, within 60 days from the receipt of the notice of the ALJ's decision, file a written request for review in accordance with Subpart E of 42 CFR Part 498. The authority to change a decision rests solely with the DAB. If the SA receives the request, it transmits the request immediately to the RO. The RO will keep the SA apprised of action on such cases.

NOTE: After the CLIA administrative appeal process is exhausted, a laboratory dissatisfied with the final decision to impose a CMP or principal sanctions may file a petition for judicial review with the U.S. Court of Appeals of the circuit in which the laboratory has its principal place of business. (See 42 CFR §493.1846(f)(3).)

6314 - Readmission to CLIA Program

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

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

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

- A list of laboratories that have been convicted under Federal or State laws relating to fraud and abuse, false billing or kickbacks;
- A list of laboratories that have had their CLIA certificates suspended, limited, or revoked, and the reason for the adverse actions;
- A list of persons who have been convicted of violating CLIA requirements, as specified in §353(1) of the PHSA, together with the circumstances of each case and the penalties imposed;
- A list of laboratories on which alternative sanctions have been imposed, showing:
    1. The effective date of the sanctions;
    2. The reasons for imposing them;
    3. Corrective action taken by the laboratory; and
    4. If the laboratory has achieved compliance, the verified date of compliance;
- A list of laboratories whose accreditation has been withdrawn or revoked and the reasons for the withdrawal or revocation;
- All appeals and hearing decisions;
- A list of laboratories against which CMS has brought suit under 42 CFR 493.1846 and the reasons for the actions; and
- A list of laboratories that have been excluded from participation in Medicare and Medicaid and the reasons for the exclusion.

6318 - Freedom of Information Act (FOIA)

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

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 the RO 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 State Agency 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 RO/CO 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 RO/CO must go through FOIA process)*
- *Form CMS-116 - name of LD must be redacted prior to release (**NOTE**: **Form CMS-209 may not be released**)*
- *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, RO, and/or CO 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.*

6400 - The CLIA Federal/State Relationship

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

The Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578) continue to foster a close and integrated relationship between the Federal government and SAs charged with the implementation, maintenance and enforcement of Federal requirements. Regulations and guidelines developed are the interpretative documentation that both State and Federal agencies will follow as we jointly seek to assure that the clinical laboratory improvements mandated by Congress are initiated properly and fulfilled in the most effective manner possible.

The SA is the key local interface and representative of CMS with the clinical laboratories that are not State or Federally owned. Although CLIA has expanded the Federal government's oversight role to virtually all laboratories in the country that do testing for diagnostic purposes, it is through the SAs or their agents that virtually all non-Federal CLIA oversight of laboratories occurs. SAs or their agents are responsible for hiring, training and managing personnel needed to fully implement and assure the ongoing effective conduct of regulations promulgated for CLIA in accordance with contractual provisions in the 1864 Agreement. The law further mandates that CLIA be a self-funded program. Fees for compliance determination and oversight covering all CLIA-related expenses must be established and collected. There are no other funds available from any source other than from those laboratories subject to CLIA requirements. Therefore, for CLIA laboratories, workload planning and budgeting are key features in the CLIA Federal/State administrative partnership. This is a negotiated process that closely involves the SA, each State's budget process, the laboratory surveys and related workloads and the cost to accomplish the required workload. The SA is the responsible State organization in this process. The RO is the Federal government's representative for helping the States develop acceptable work plans and appropriate budgets to accomplish the required workload targets. For CLIA-exempt and accredited laboratories, payment of the initial fees and fees covering the Federal oversight activities constitutes the main exchange between the State and CMS in the budget process. The CLIA-exempt State or accrediting body may make additional charges to individual laboratories.

The budget process begins with the State preparation of the Planned Workload Report (with its narrative activity work plan) and a Budget Request that is forwarded to CMS. Next comes budget approval and the advancement of CLIA funds. Survey Team Composition and Workload Reports are prepared and submitted for each completed survey and related support activity, and quarterly reports of work completed are filed for Federal payment for SA completed work on the CLIA workload.

6416 - Budget Call - RO Procedures

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

Each fiscal year, CO issues a budget call letter. This letter serves as official notification to begin the budget process with each State for the coming fiscal year. The call letter provides national program emphasis including the workloads to be accomplished during the next fiscal year and should be adhered to closely.

Upon receipt of the budget call letter, the RO prepares State call letters to inform the States of the national and regional goals and priorities for CLIA. Upon receipt of each State's proposed budget, the RO records the date received. This is the actual beginning of the negotiated budget process between the SAs and the RO.

Each budget submission requires close attention and proper scrutiny. It is imperative that the RO manage the SA's CLIA activity, including budgets, aggressively for efficiency and productivity. Contracts and purchases planned by the SAs and approved by the RO, especially large purchases of computer hardware and software, must be guided by the latest Office of Management and Budget (OMB) circulars and CMS standards, policies, and guidelines. It is

imperative that costs be contained and appropriately managed. Therefore, when the RO encounters any unusual plans or purchases, it assures that they are supported by adequate written justification and that the RO is convinced of the actual need to support efficiency and productivity.

It is important that the RO question and challenge unsupported spending levels, or **supported** requests that the RO does not feel are needed or the program cannot afford. Aggressive monitoring throughout the year can help to lower the cost of managing the CLIA program. Questions or problems the RO has regarding State budgets may be directed to the CO budget staff.

It is important that CLIA budget requests, funding requirements and expenditure reports be submitted separate from those for the Medicare and Medicaid programs. CLIA specific forms have been developed and must be used for CLIA program expenditures.

6418 - Regional Allocations

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

CO provides State-specific budget allocations to the Regions. The allocations reflect both the needs and special priorities of each program workload, as well as national and regionally-specific priorities. The RO must be aware of and apply these constraints and priorities when negotiating the CLIA budget with the States and during the review and approval of subsequent quarterly expenditure reports. It is important that the required workload be accomplished within the approved budget. The RO should communicate significant problems or changes to the CO as soon as they are identified.

6420 - The SA Annual Activity Plan

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

In accordance with established yearly schedules, the SA completes the Form CMS-102 (Exhibit 116), and forwards it to the RO. Include a description of planned program activities for the ensuing fiscal year and a Form CMS-105, "Planned Workload Report, Clinical Laboratory Improvement Amendments Program," (Exhibit 119). Working with SA and CMS CO, the RO assesses the amount of activity planned and the proposed cost to conduct the work by each State and helps to keep the costs in line for the nation as a whole. From this information and in discussions with the State and CO, the RO will be able to determine the adequacy and appropriateness of the programs planned by each State as they relate to the legislatively mandated goals and budget estimates. The information on the activity plan should agree with the State budget request.

6424 - Elements in the Annual Activity Plan - Planned Workload Report - SA Procedures

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

The Planned Workload Report lays out the SA Plan to conduct the surveys and other related

activities for the fiscal year by laboratory schedule as it relates to workload volume and based on the yearly CLIA Budget Call Letter. The SA then translates this workload into narrative staffing and activity plans and project related costs.

The workload to be reflected in the State CLIA workload plan is to include initial surveys, re-visits, follow-up visits, and complaint visits for the various schedules of laboratories. The narrative plan is to conform to and confirm the numerical counts planned. Form CMS-105 is to be used in developing CLIA SA workload plans.

For CLIA survey budgeting purposes, there are two types of certificates provided to laboratories. These are Certificates of Compliance, and Certificates of Accreditation. Those holding a Certificate of Compliance are inspected once every two years. Those holding a Certificate of Accreditation are inspected at an administrative goal of five percent biennially. The specific validation surveys are assigned by the RO. If complaints are received about any laboratory, a survey can be scheduled to investigate the complaint.

6428 - Survey Team Composition and Workload Report-CMS-670 (Exhibit 74) - SA Procedures

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

The Form CMS-670 (Exhibit 74) is intended to provide CMS with the work-power utilization information needed to determine the total number of hours spent on each type of CLIA laboratory survey-related activity. From this and combined with other CLIA cost information, CMS can compute the costs of performing the CLIA-related work and can compute the amount of money to be paid to a given SA to pay for the work performed. Laboratory surveyors, other State employees or contractors and others, including RO employees, involved in the CLIA-related processes must keep an accurate record of the number of hours spent working on a given laboratory's survey or similar CLIA activities. All payment to the State for survey work-power costs will be matched against the CMS-670 data. Once the Form CMS-670 data has been received, CMS computes the cost of survey-related activities and initiates any necessary action to create a bill for costs not already paid for by the laboratory.

REMINDER: Hours spent performing State required activities that are in excess of those activities mandated by CLIA are not billed to CLIA. The SA does not complete a Form CMS-670 for those hours.

The SA prepares the Form CMS-670 for every type of CLIA survey-related activity including:

- Initial surveys;
- Recertification surveys;

- Recontacts;
- Complaint surveys;
- Re-visits;
- Validation surveys;
- Sanction activities; and
- Hearings/appeals.

For the most part, the SA completes a Form CMS-670 after concluding all survey-related activities, including follow-up contacts and resolution of corrective action. The SA includes time spent on each activity and based upon employee records, beginning with the pre-survey preparation time and ending with the closeout of the survey activities, on the Form CMS-670. (See Exhibit 74.)

Time spent by the RO staff conducting the oversight sample reviews of accredited and CLIA-exempt laboratories will be billed based upon the charges set forth in 42 CFR Part 493, Subpart F.

6430 - Basis for Determining CLIA-Related Costs - SA Procedures

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

Public Law 100-578 mandates that the CLIA program be completely funded by the laboratories being regulated. The total cost of the work expended by all CLIA personnel, both Federal and State, is to be paid by the regulated laboratories. More specifically, each laboratory is to pay all costs incurred in regulating that laboratory, including the costs of survey, complaint investigation, hearings and appeals (if the SA and CMS are sustained) or other related CLIA outlays such as administrative and enforcement overhead.

There are circumstances in which the specific laboratory may not be specifically billed for the cost of the CLIA work-power expenditure, e.g., if a laboratory appeals an action and the ALJ sustains the laboratory or a settlement in favor of the laboratory is reached prior to the official hearing, the appeal-related work-power outlay (Federal and State) are entered on a CMS-670 (Exhibit 74), but the laboratory is not billed directly for these expenses. The SA prepares a Form CMS-670 for the nonappeal-related work-power outlays and a separate Form CMS-670 is prepared for those work hours spent in preparation for the appeal, hearing and related expenses. In either case, the SA and CMS are paid for all CLIA work-power expenditures. The laboratory is billed for the survey related costs that preceded the decision leading to the appeal, but not for the appeal costs.

If the SA and CMS are sustained in the ALJ hearing or the laboratory agrees to the findings or settles prior to the hearing in a SA/CMS favorable decision, the SA documents on the

Form CMS-670 all costs related to the action, e.g., hearing preparation, documentation, staff preparation time including the time spent preparing the Form CMS-670. The laboratory is billed for those costs and the State is paid from the funds received. Unsubstantiated complaint costs are not be billed to the laboratory by CMS, but rather are paid from the administrative funds of CLIA. In such cases, the Form CMS-670 that the SA submits initiates payment. No bill goes to the laboratory.

As the SA schedules each laboratory survey, it maintains a record of the time spent in preparing for and conducting and closing out the survey, including the monitoring and recontacts involved in resolution and the preparation for an administrative hearing of a laboratory appeal. As each CLIA survey or support activity is performed, the SA records the time spent on the activity. Thus, any time spent preparing for a laboratory survey and time spent in follow-up contacts to ensure compliance are shown for all CLIA SA or RO personnel involved. Telephone discussions, report preparation, on-site visits and even the time spent preparing the Form CMS-670, are chargeable work-power expenditures. The SA reports the total time consumed for each laboratory action in hours at the close of the action in a Form CMS-670, identifying the type of action that precipitated the work-power expenditure. CMS records and stores the data when received. CMS then multiplies the total hours reported by the dollar hourly rate computed for each State CLIA budget for that fiscal year. The computed dollar figure becomes the amount of the bill that is submitted to the laboratory involved in the specific CLIA action and which the SA claims payment.

Use the Form CMS-670 for reporting CLIA work-power expenses by both State and Federal oversight personnel. It is the mechanism for generating a laboratory bill and a State claim for payment for work-power expended.

6434 - The State Budget Request

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

In the CLIA budget process, CMS' CO and RO staffs obtain input from the States and laboratories to develop the baseline data needed to formulate each State budget. This data is used to develop the CLIA workload estimates, expenditure, time parameters, and hourly rates. This is a negotiated process that starts with CMS' preparation of the Budget Call Letter. Input for the Budget Call Letter includes an estimated unit cost of each workload, time parameters, and a derived hourly dollar rate for the staff conducting agreed-to work.

The RO forwards the Budget Call Letter to the States which develop workload estimate and corresponding budgets by completing the Form CMS-102 (Exhibit 116); Form CMS-105 (Exhibit 119); Form CMS-1465A, "State Agency Budget List Of Positions," (Exhibit 47); and CMS Form-1466 "State Agency Schedule For Equipment Purchases," (Exhibit 54). The completed Form CMS-102, Form CMS-105, Form CMS-1465A, and Form CMS-1466 and the narrative supporting documentation are forwarded to the RO which analyzes the data presented and works with the SA to assure that the workload estimates are accurate and reasonable for each of these workloads: Initial Surveys; Resurveys, Follow-up Visit/Surveys, Complaint Surveys/Visits estimates. Once agreement on the workload estimates is achieved

the number of Full Time Equivalent (FTE) employees is computed. Though the SA does not perform the oversight surveys for State-exempt laboratories, it is possible that SA may incur some related costs. If such costs do arise, it is important that they be identified to the RO so the RO can determine their appropriateness and advise the SA accordingly.
As the SA conducts CLIA work, the surveys are completed. The SA prepares the Form CMS-670 (Exhibit 74), to begin the laboratory billing and State payment processes. Each quarter the SA completes the Form CMS-102 detailing expenditures for the elapsed quarter and for the budget year to date. Analysis of this data will provide a complete status of revenues expended that can be compared to the total State approved budget. The SA should identify shortfalls and, if necessary prepare a Form CMS-102 and submit it for processing and approval.

Funds provided agencies as a result of the budget request are used only for necessary expenses and only for CLIA-related expenses. The SA may shift funds from one expenditure category to another, except equipment or laboratory surveyor training funds that may only be reprogrammed with prior approval.

6436 - State Budget Request, Clinical Laboratory Improvement Amendments Program, Form CMS-102 (Exhibit 116)

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

The budget request is a detailed estimate of CLIA survey program costs. The SA classifies such costs according to the category of the proposed expenditure. Explanations for the specific categories of expense are essential in both budget preparation and subsequent analysis. Therefore, the SA should make sure the budget request contains complete rationale regarding each line item. The detail in which these statements are developed makes possible a close estimate of financial needs and enables the RO to make more rational adjustments in the total operating budget. Line item justification consists of narrative statements providing specific rationale for budgetary needs.

The basis for estimating line item expenditures will be the number of laboratories the SA intends to survey in one year and the number of work hours needed. The SA includes in the estimates the number of surveys to be initiated due to complaints; for enforcement purposes, such as to verify the correction of action items identified during a prior survey; and follow-up contacts or discussions required to close out a survey-related workload item.

- **RO Assistance** - RO personnel are available to assist in preparing budget requests. The SA should consult with appropriate RO staff on any problem with the budget preparation process. Begin consultations as early as possible and submit the budget in accordance with the due date provided by the RO. Timely submissions help assure timely CMS completion of the budget approval process.

  The Form CMS-102 (Exhibit 116) is a multipurpose form designed to budget for and capture line item expenditures by State agencies for laboratory survey activity. The State agencies will complete and certify the Form CMS-102 prior to the start of each

Fiscal Year as part of *its* yearly budget submission. This data, when reviewed and approved by CMS regional and central offices, will serve as the approved state budget for the fiscal year.

- **Agency** - Insert the name of your State.
- **Region/State Code** - Insert the CMS Regional Office to which the State is assigned.
- **FY Quarter Ending** - Leave blank for initial budget submission; complete only when reporting actual expenditures.
- **Budget Period** - Insert the fiscal year for which the budget request is being made.
- **Request** - Indicate if the submission is a regular, i.e., whole year budget submission, or a supplemental budget request for additional funds for the remainder of the fiscal year.

Section A - Salaries

1 (a,b,c), 2, 3

The budget justification is to describe the type of staff being employed in the conduct of the CLIA workload, broken into the two categories, Professional (surveyor, non- surveyor, and supervisor) and Clerical. The SA estimates the number of staff years in full-time equivalents. This will provide the actual work years of personnel involved in the CLIA workload. Place the number of FTEs in column (a), and STAFF YEARS, and the yearly salary cost column in (b), AMOUNT. The SA adds the estimated staff years and the estimated yearly salaries and inserts those amounts in the respective column next to Total Salaries.

Section B - Other Direct Costs

4, 5 - Rate / Retirement Contributions and Fringe Benefits

Enters the computed rate and dollar value of retirement contributions and fringe benefits mandated by State/Federal law, Union/Management or Employee/Management agreements or other legally binding contracts/agreements. Explains the computation in the budget request narrative.

6 - Travel

Enters the estimated travel costs for CLIA personnel, including where appropriate, the per diem or the subsistence in lieu of per diem, applicable to the CLIA survey program. Derives estimated costs based on provisions of State law, regulation and administrative procedures applicable to travel of State employees. Indicate in the narrative budget justification an estimate of the expected number, type and extent of trips. For out-of- State travel, indicate the

number of trips, purpose and basis for charges to the CLIA program. Include the basis for charges for all out-of-State travel other than to meetings arranged by CMS.

7 - Communications

Enters the estimated costs to be incurred for telephone services, including costs for teleconferences, mail (including express mail), special handling, postage and postage stamps, postage meters, insurance on mailed items, postage due-charges, FAX costs and other communication-related expenses.

8 - Office Supplies

Enters the estimated cost of office supplies to be used by CLIA personnel only. Include the costs of paper, pencils, pens, envelopes, clips, pencil sharpeners and other usual desk materials, file baskets, books and other required desk reference materials, photocopier supplies, FAX supplies, computer equipment-related supplies, and other reasonable CLIA-related supplies.

9 - Office Space

(See §§6524-6534.) Enters the costs of office space, considering possible variations, and describe as follows:

a.Agency in Identifiable Space

Enters the costs of space that can be attributed to CLIA personnel use only. Analysis of the budget request and estimates must contain the following elements for each location:

b. Total rental cost/pro rata cost of CLIA space;

c. Square feet of space/CLIA-related square footage;

d. Cost per square foot; and

e. Services included in the rental.

The SA identifies, also, office space that is State-owned and includes it either separately or as part of the State's indirect cost rate.

f. **Office Space - Agency in Shared Space** - Analysis of base period expenditures and the budget estimate must contain these elements:

i. Total cost of space to the agency;

ii. Basis of proration;

iii. Locations where CLIA staff are housed; and

iv. Estimate of square feet allocated to all State programs and those used by CLIA personnel.

State-owned space should be identified as such.

g. **Office Maintenance** - Includes in the budget estimate narrative, a breakout of the major items of expense, e.g., light, heat, janitorial service, machine repair. If office maintenance, in whole or in part, is included in the rental contract, the SA notes this fact. The SA need not separate the amount.

9 - Equipment

Enters the reasonable costs of equipment to support CLIA-specific positions such as desks, chairs, computers and computer-related equipment, file cabinets, tables, and other machines (FAX machines, photocopiers, etc.) necessary for CLIA operational, administrative or management needs. Equipment authorized in the present fiscal year, which will not be purchased by the end of the fiscal year, must be requested in the budget for the succeeding fiscal year if the SA still needs it. In addition to line item justification, the SA documents the budget estimate through the use of the Form CMS-1466 (Exhibit 54).

10 - Training

The budget estimate should provide for the cost of training CLIA personnel. The SA uses the number of employees to be trained rather than FTE's when computing this figure and includes the cost of the courses to be taken, the cost of travel and per diem associated with training sessions. The narrative justification should indicate the types of courses to be taken by employee type and by number of employees to be trained.

11 - Consultants

Provides the estimated cost of consultants or those who are not State employees but who are used on a part-time, temporary, or fee-for-service basis to perform CLIA-related work.

12 - Subcontracts

Provides the estimated cost of subcontracts to be employed in the conduct of CLIA- related work. Subcontract costs attributable to CLIA survey activities are allowable and payable. The budget justification should provide in detail, the reasons for, and approximate cost of each separate subcontract.

13 - Miscellaneous

Provides the estimated cost of other items that have not been reported in any of the preceding classifications, breaking them into compatible groups of expenses (sections a, b, c, and d), if possible. The SA uses narrative justification to explain all proposed expenditures.

14 - Total Other Direct Costs

Enters the total of lines 4-14.

16 - Total Direct Costs

Enters the total of lines 1-15.

Section C - Indirect Costs (Approved Rate X Base)

17 and 18

Provides the rate negotiated and approved by the HHS Division of Cost Allocation for use during the fiscal year, together with the line item base it is applied against. Expenditures included in this category must not be duplicated under direct costs.

Section D - Total Budget Requested

19

Enters the sum total of lines 16 and 17.

20

Leave blank for initial budget submission. Data entry is only required when reporting actual expenditures during the fiscal year (amounts to be reported and non-cumulative, i.e., report only the current balance as of the quarter ending).

Section E - Hourly Rate Requested

Divides the Total Budget Requested by the Total Number of Staff Years and divide again by the Hours Available per Staff Year to derive Hourly Rate, as in the example.

Example:

Budget Amount..	..$100,000
Divided by Staff Years	2
Equals.	...$ 50,000 per Staff Year

$50,000 divided by 1,600 hours in the Staff Year Formula equals a $31.25 hourly rate.

6438 - Form CMS-105, Planned Workload Report - CLIA (Exhibit 119)- SA Procedures

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

The Form CMS-105 (Exhibit 119) provides the State's estimate of the number of laboratory surveys it expects to perform in a budget period. The workload plan will list by laboratory type

the number of surveys to be conducted in the Fiscal Year. (This form also accompanies the States quarterly and cumulative expenditure reports.)

The SA uses the Form CMS-105 only to estimate the laboratory survey workload under CLIA. The SA provides an estimate of the planned workload for each laboratory schedule. The laboratory schedule can be found in the CLIA user fee regulation.

A completed Form CMS-105 should accompany a Form CMS-102 (Exhibit 116) and an analytical budget justification narrative anytime a CLIA budget request or supplemental budget request is submitted to the RO. It is essential that the estimates of planned workloads be as accurate as possible. Accurate workload estimates can be developed from prior workload history, where one exists, and results in a more accurate and timely budget approval.
The SA:

Heading - Inserts State name and Federal fiscal year in the appropriate boxes.
Column (a), Number of Sites - In reviewing the workload plans for the year, determines the number of separate laboratory sites that will be visited for surveys, follow-up visits and complaints.

Column (b), Initial Visits - Enters the planned number of initial compliance determination surveys (laboratory surveys) to be conducted for each type of laboratory. (See 42 CFR 493.638ff for the schedule of laboratories and fees to be charged.) Include a five percent sample of those that hold a Certificate of Accreditation since a sample of those laboratories are to be inspected for compliance in accordance with the SA oversight role and responsibility.

Column (c), Resurvey Visits - Enters the total number of non-initial compliance surveys planned. This figure is to reflect the number of other than first time laboratory surveys to be conducted in a fiscal year.

Column (d), Follow-up Visits - Enters the number of follow-up surveys planned for the fiscal year. These are visits to verify compliance or to verify a completed plan of corrective action or for some other enforcement purpose. Prior history may indicate that a portion of all laboratories require actual follow-up visits as opposed to re-contact via telephone or mail to finalize the laboratory compliance survey report. Follow-up visits are not routinely required by CLIA.

Column (e), Complaint Visits - Enters the number of complaint surveys planned for the fiscal year.

Column (f), Total Visits - Provides the totals to column (f) and computes the totals at the bottom of the form. Signs and dates the form and submits it with the Form CMS-102.

6440 - Form CMS-1466, State Agency Schedule for Equipment Purchases (Exhibit 54) - SA Procedures

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

Usage - This form has a 2-fold purpose: The SA uses it when requesting budget approval of equipment purchases, and completes and submits it to the RO when an actual purchase has been completed. The form is applicable for CLIA, LTC and non-LTC equipment requests and purchases. A separate form must be prepared for equipment purchase for each program. When equipment is actually purchased, the SA prepares and forwards a Form CMS-1466 (Exhibit 54) with the appropriate program's budget expenditure report.

The SA:

Heading - Inserts the official name of the agency and the State name in the designated spaces. Indicates the period for which equipment funds are requested. Indicates if this is accompanying a regular budget submission or a supplemental budget submission.

Column (a), Description of Equipment - Enters the items of equipment being requested or reported as purchased. Uses an asterisk or other notation to note items previously approved by the RO but which are being re-budgeted or requested again. On the bottom or reverse of the form explains why the purchase was not completed in the prior budget period.

Column (b), Number of Items on Hand - Lists the number of similar items on hand in the State CLIA survey unit at the time the form is prepared. If a new and different item is being shown, shows "None" in this column.

Columns (c) and (d), Number of Units (Additional-c) or (Replacement-d) - Lists the number of units being requested in the appropriate column, (c) or (d).

Column (e), Unit Cost - Enters the unit cost of each item in column (a).

Column (f), Gross Cost - Computes and enters the gross cost for each item in column (a) by multiplying the number of units in columns (c) or (d) by the unit cost, column (e).

Column (g), Trade in Value if Replacement Item - Computes and enters the trade-in- value of item identified in column (d) as a replacement for existing equipment.

Column (h), Net Cost - Enters the amount shown in column (f) for each item listed in column (a), less any amount shown in column (g).

Total Net Cost of Equipment - Enters the sum of all amounts shown in column (g) above. For CLIA, enters this amount on the Form CMS-102 (Exhibit 116), item 6.

Date, Signature, Title - Dates and signs the Form CMS-1466. Shows the title of the individual signing the schedule.

6442 - Form CMS-1465A, State Agency Budget List of Positions - (Exhibit 47)

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

Usage - The SA uses the Form CMS-1465A (Exhibit 47) for all program position

approvals. Separate forms and approvals are required for each of the programs: Title XVIII NON-LTC, Title XVIII LTC, Title XIX and CLIA. The SA uses the most recently approved form or computer form format to assure proper information collection.

The SA:

Heading Information:
Name of Agency - Inserts official name of the agency.

State - Enters name of State.
Fiscal Year - Enters the Federal period for which funds are being requested.

Position Title/Name - Lists each position type employed and the names of each employee actually occupying each position type. This will help the SA distinguish between the number of positions it has filled as opposed to the number allocated. Differences could mean substantially different approved budget levels. This information may prove useful when determining the number of employees that require training in a given discipline. Remember that individual employees are trained, not the number of full-time equivalents employees.

City Where Located - Provides this for all position types and employees. Monitors differences and changes in staffing levels by location.

No. of Pos. (Number of Positions) - After completing the Position Title/Name columnar entries for all positions, enters the number of actual allocations for each position, e.g., the actual number of employees occupying that position title.

Staff Years - Computes the actual number of staff-years by Position Title. Representations of full and part-time employees are no longer necessary. Rather, it is important to compute the number of work or staff years using the work hours employed by each Position Title. Includes anticipated overtime usage by all categories of positions in this computation.

Funds Required - For each Position Title, computes the budget dollars required by multiplying the total work years for each Position Title times (X) the total dollar figure computed for and relevant to that Position Title. Includes overtime in the calculations for all the positions listed.

If possible, the SA discerns from the Position Titles which are professional and which are clerical positions. If the SA cannot, do whatever is necessary to clarify and classify all positions accordingly. Once the SA has classified the positions into the two types, total the staff years and dollar amount for each of the two categories.

6444.1 - List of Materials and Order of Assembly

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

The SA assembles the budget documents in descending order, as follows:

- Form CMS-102, “Budget Request, Clinical Laboratory Improvement

Amendments Program," (Exhibit 16);

- Form CMS-105, "Planned Workload Report, Clinical Laboratory Improvement Amendments Program," (Exhibit 119);
- Form CMS-1465A, "State Agency Budget List of Positions," (Exhibit 47);
- Form CMS-1466, "State Agency Schedule for Equipment Purchases," (Exhibit 54);
- State justification arranged in line item order; and
- Any exhibit referred to in the line item justification.

6446.1 - Budget Request Package

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

In response to the budget call letter, the RO receives a CLIA budget submittal from each SA using the automated Survey and Certification / CLIA Reporting System. The data is transmitted electronically, from State to RO, RO to CO. The automated copy of the data should be certified by the approved State certifying official using the approved "electronic signature" feature of the system. Each budget package should contain:

- Form CMS-102, "State Agency Budget Request, Clinical Laboratory Improvement Amendments Program," (Exhibit 116);
- Form CMS-105, "Planned Workload Report, Clinical Laboratory Improvement Amendments Program," (Exhibit 119);
- Form CMS-1466, "State Agency Schedule For Equipment Purchases," (Exhibit 47);
- Form CMS-1465A, "State Agency Budget List of Positions," (Exhibit 54); and
- The narrative budget plan that explains hiring, training plans, equipment purchases, budget exceptions, and variances or omissions in general. Documentation should be sufficient to support the budget plan. Narratives should be retained within the regional office and made available to CO only upon request.

6448 - RO State Agency Budget Review - Form CMS-102

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

A review of the line items in the Form CMS-102 (Exhibit 116) should reveal that they conform to the guidelines that follow. It is important that the RO obtain an explanation of all line items that contain no money amounts. Blanks or zeros in items such as office space, communications, and supplies or equipment should be explained in writing. If the cost for one or more line items

is included in the indirect cost allocation rate reported on the form, it should be so stated and explained.

6454.1 - CLIA Laboratory Survey and Administrative Travel

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

Laboratory survey travel includes travel to and from a facility:

- To conduct laboratory inspections;
- For revisits or to verify PoC*/AoCs*;
- To perform laboratory complaint or oversight inspections; and
- For meetings with CMS personnel on CLIA-related activities.
- Administrative travel is defined as travel for management purposes related to the CLIA laboratory inspection program:
- To attend agency administrative staff meetings related to CLIA;
- To attend State CLIA program meetings or activities conducted or sponsored by CMS; and
- For planning or liaison visits to other agencies concerning certification.

Travel to participate in sanction meetings or negotiations or to appear before an ALJ in a hearing (to provide testimony or support for a sanction activity against an alleged non- compliant laboratory) may also be charged to CLIA.

6458.3 - Privately Owned Space

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

Charges against CLIA funds for privately owned space, including expenses of services and maintenance, repairs, and alterations, must not exceed the rental rate of equivalent space and facilities in the same or similar locality.

6460 - Equipment - RO Procedures

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

Form CMS-1466 (Exhibit 54) should be attached to the budget package the RO is reviewing. Purchases planned should conform to the latest CMS hardware and software acquisition guidelines. Documentation to support the proposed purchases should be complete. Reasonable purchases of equipment to support CLIA specific positions are permitted. Such

purchases may include computer systems and computer-related equipment, office furniture and file cabinets, and other machines (Fax machines, photocopiers, etc.) necessary for CLIA operational, administrative, or management needs.

When the RO reviews the Form CMS-1466, it checks to see that the SA has included appropriate details and reasonable requirements. If purchasing new computer systems, peripherals, such as printers, being planned should appear on this form. If printers are not shown, the RO should question what the SA would use to print products. Software being purchased in conjunction with the hardware purchase would not be included on this form, but rather would show up as a miscellaneous item on the Form CMS-102 (Exhibit 116). It is wise for the RO to review the software being considered. It should comply with CMS guidelines and software standards. Consultation with both the SA and CO may be necessary and is advisable if plans for unusual purchases are noted.
Equipment authorized in the present fiscal year that will not be purchased by the end of the fiscal year must be requested in the budget for the succeeding fiscal year if still needed by the SA. If hiring constraints are going to restrict staffing plans, it is advisable that the RO and the SA reevaluate the timing of planned equipment purchases. Planning equipment purchases sufficient to provide for those to be hired should be considered.

6474 - Planned Workload Report - Form CMS-105 - RO Procedures

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

Form CMS-105 (Exhibit 119) provides the State's estimate of the number of laboratory surveys it expects to perform in the budget period. The workload plan will list by laboratory type (schedule) the number of surveys to be conducted in the fiscal year. The workload report should reveal in detail how the SA plans to do the work. The State is required to survey every laboratory that does not have a certificate of waiver, a certificate for PPM procedures, or is under Federal jurisdiction every two years. It is essential that the estimates of planned workloads be as accurate as possible and be at the levels mandated by national and regional goals. The RO will be able to determine the propriety of the workload plans by review of prior workload history, where they exist, and evaluation against regional and national goals. The workload plan submitted should be supported by the other parts of the budget plan. If it does not provide sufficient detail from which the RO can determine that the work paid for will be accomplished, the RO must obtain the needed information or clarification. Negotiate discrepancies to acceptable levels.

6476.1 - Usage

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

The Form CMS-1466 (Exhibit 54) serves two purposes: it is used when requesting initial budget approval of equipment purchases and is completed and submitted to the RO when an actual purchase has been completed. When equipment is actually purchased, the State should prepare and forward a revised Form CMS-1466 with the quarterly expenditure report, Form CMS-102 (Exhibit 116).

6478.1 - Usage

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

Form CMS-1465A (Exhibit 47) is to be used for all program position approvals. Separate forms and approvals are required for each of the following programs:

- Title XVIII NON-LTC;
- Title XVIII LTC;
- Title XIX; and
- CLIA.

It is important that the SA use the most recently approved form to assure proper information collection.

6478.2 - Form Completion

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

Name of Agency - The official name of the agency and the State will be inserted automatically when the State selects the type of form and the period.

Fiscal Year - The SA enters the period for which funds are being requested.

Position Title/Name - The State should list each position type employed and the names of each employee actually occupying each position type. This will help the RO distinguish between the number of positions the SA has filled as opposed to the number they have allocated. Differences could mean substantially different approved budget levels. This information may prove especially useful when determining the number of employees that require training in a given discipline. Remember to count the number of employees who require training, not the number of FTEs.

City Where Located - This must be provided for all position types and employees. This will help the RO monitor differences and changes in staffing levels by location and may prove to be a source of information about the existence of multiple locations that may have larger program implications.

Number of Positions - After completing the position title/name columnar entries for all positions, the SA should enter the number of actual number of employees occupying that position title.

Staff Years - The State should have computed the actual number of FTEs by position title. Representations of full and part-time employees are no longer necessary. Rather, it is important to compute the number of work or staff years using the work hours employed by each position title. Overtime usage anticipated by all categories of positions should be included in this

computation.

Funds Required - For each position title, the SA computes the budget dollars required by multiplying the total FTEs for each position title times the total dollar figure computed for and relevant to that position title and includes overtime in the calculations for all the positions listed.

The RO should be able to discern from the position titles, which are professional and which are clerical positions. If the RO cannot, it should do whatever is necessary to clarify and classify all positions accordingly. Once the RO has classified the positions into the two types, the RO may wish to total the staff years and dollar amounts for each of the two categories. If needed, the RO may transfer the totals to the appropriate lines of the Form CMS-102 (Exhibit 116).

6480 - Line Item Approval for Personal Services - RO Procedures

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

In negotiating budgets, it is advisable to set a limit on the number of full-time equivalents chargeable to the CLIA program budget. With limits in place, a SA cannot exceed the approved full-time staff levels without prior consultation and authorization. This will enable the RO to monitor staffing, *(all disciplines),* especially the actual number of on- board surveyors, and allow the RO to better analyze State requests and requirements for additional support staff.

6510 - Payment by Electronic Transfer of Funds - SA Procedures

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

All State agencies with an approved budget will be paid by electronic transfer of funds through the use of DHHS, Division of Federal Assistance Financing's Payment Management System known as SMARTLINK II. The SMARTLINK II User's Manual details the equipment the SA need to implement the system, provides guidelines for maintaining security to the system and explains how the SA request payment using the system. It also provides the information the SA need about installing the DHHS-supplied KERMIT communications package and other system specific procedures.

6512 - State Expense Reporting

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

CLIA requires that certification fees be sufficient to cover the costs of implementing and administering this oversight program. There are no exceptions. Funds to run the program come from billing laboratories for all costs related to administering all aspects of the CLIA program, including payment of all Federal and State CLIA-related program expenditures. The SA is entitled to receive advances to and payment of all "reasonable costs" for performing CLIA-related work, including the cost of the personnel required to perform the CLIA-related work. CLIA funds cannot be used to pay the SA for any non- CLIA-related expenses incurred. To administer the CLIA program, it is probable that each SA will employ CLIA dedicated staff. CLIA laboratory compliance surveys will be performed by CLIA approved and dedicated

surveyors. Though CLIA dedicated support staff will better facilitate the computation of CLIA related expenses for budgeting purposes, it is possible that shared staff involved in supporting multiple programs may be employed. CLIA will pay States only for CLIA-related expenses, so proper proration of expenses is mandatory.

"Reasonable costs" include all necessary expenses that are in accord with these standards and within the limits of the approved SA CLIA budget. CLIA revenues will fund any class or kind of administrative expenditure that is properly chargeable to Federal CLIA funds under plans approved by the DHHS. Allowable costs are further defined in *Code of Federal Regulations Title 2, Part 200 "Uniform Requirements, Cost Principals and Audit Requirements for Federal Awards"*. The SA should exercise due care in the expenditure of funds, understanding that the funds must be used only for CLIA-approved activities and procurement. The completed Form CMS-102 (Exhibit 116), is to accompany the Form CMS-105 (Exhibit 119), and the budget plan and documentation, as a budget request package that is forwarded to the RO in response to the yearly Budget Call Letter. The Form CMS-102 line items are addressed in general and specifically in the following procedures.

States are required to submit their quarterly expenditure reports, via the automated reporting system, to their respective regional offices no later than 45 days following the end of each fiscal quarter. Final adjustments, when necessary, to quarterly expenditure reports are due to the region no later than 60 days following the end of each fiscal year. Regional offices will approve both quarterly as well as year-end final adjustments to quarterly expenditure reports within 15 days following submission of reports by the State.

6544 - Training of State Agency Personnel - SA Procedures

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

The reasonable costs of training personnel engaged in CLIA survey and related activities are chargeable to the CLIA program when the training is related to its responsibility for survey, certification and related enforcement activities. Training may include attendance at job-related meetings, conferences, seminars, workshops, and satellite training conferences or training courses. Training is to be related to SA CLIA-related responsibilities. Examples of professional meetings for which attendance may be justified and funded, subject to prior RO approval are periodic and annual meetings of regional or national laboratory and medical technologist professional societies and organizations such as, but not limited to, the American Society of Clinical Pathologists (ASCP), the *American Society of 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).

6544.2 - Requesting Approval

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

Funds for conferences and short-term training activity is normally requested, in advance, in the annual budget submittal. The SA submits any training that has not received prior CMS approval in the approved budget, in advance, to the RO for approval. Approval is to be on a

case-by-case basis.

At the SA's request, CMS will include a dollar authorization for short-term training activity over and above the cost of attendance at CMS-sponsored meetings within the funds approved for each fiscal year. This authorization covers travel, per diem, admission fees, and any other costs related to attendance at the meetings.

If the SA believes it necessary to exceed the allotment, see §6546. The SA can make expenditures for short-term training activities without consulting the RO for specific authorization provided the following conditions are met:

- No single meeting is attended for more than 5 working days;
- The proposed attendees are State CLIA employees who regularly perform CLIA-related functions;
- The training is related to your CLIA-related responsibilities;
- The SAs do not charge a higher percentage of the cost of the CLIA-related portion than is appropriate. The appropriate portion attributable to Medicare/Medicaid or other programs is to be charged to those programs;
- A Form CMS-102 (Exhibit 116) is submitted as a supplemental budget request, in advance, if the event was not previously approved in the budget process. If the employee entered on duty during that quarter or later, the SA charges the percentage applicable to the employee in the budget approval; and
- Ensures that there is adequate documentation of every expenditure, following State practice, for subsequent audit.

Where one or more of the preceding conditions are not met with respect to any particular meeting, the SA furnishes detailed justification well in advance of the planned training/event date.

The authorization of funds for short-term training is in addition to the cost of attending any meetings called by CMS. The SA should consult with the RO for budget information about proposed CMS meetings as part of the process of preparing the budget submittal.

6544.4 - Fiscal and Reporting Considerations - the Amount Requested for Travel Costs of Such Activity

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

The SA shows the total amount approved on the Form CMS-104 (Exhibit 118) for the CLIA program (the "State Agency Budget Expenditure Report", Form CMS-435(Exhibit 45) for the Medicare and Medicaid programs).

The SA does not break down the amounts expended for specific meetings, conferences or events. However, the SA maintains detailed records of all expenditures for audit purposes.

6548.1 - Definition

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

The definitions of the terms “goods,” “facilities,” and “services” and the criteria for application of the standards are those in effect for SA grant-in-aid relationship with the Department of Health and Human Services. Additional definitions are covered within the Federal Acquisition Regulations (subpart 31.6, “Contract with State, Local, and Federally Recognized Indian Tribal Governments”) and *Code of Federal Regulations Title 2, Part 200 “Uniform Requirements, Cost Principals and Audit Requirements for Federal Awards”.*

Medicare State Operations Manual
Chapter 9 - Exhibits

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

7	Statement of Deficiencies and Plan of Correction, CMS-2567	https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing-Items/CMS-2567.html
12	Survey Report Form (CLIA), CMS-1557	https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1557.pdf
16	Budget Request, Clinical Laboratory Improvement Amendments Program, Form CMS-102	https://scclia.cms.gov/SCCLIA/Default.aspx
45	State Agency Budget Expenditure Report, CMS-435	https://scclia.cms.gov/SCCLIA/Default.aspx
47	State Agency Budget List of Positions, CMS-1465A	https://scclia.cms.gov/SCCLIA/Default.aspx
54	State Agency Schedule for Equipment Purchases, CMS-1466	https://scclia.cms.gov/SCCLIA/Default.aspx
74	Survey Team Composition and Workload Report, CMS-670	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107_exhibit_074.pdf
106	Laboratory Personnel Report (CLIA), CMS-209	https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS008840.html
116	Budget Requests, Clinical Laboratory Improvement Amendments Program - CMS-102	https://scclia.cms.gov/SCCLIA/Default.aspx
118	1466 – CLIA Program State Agency Schedule for Equipment Purchases	https://scclia.cms.gov/SCCLIA/Default.aspx

119	Planned Workload Report, Clinical Laboratory Improvement Amendments Program, CMS-105	https://scclia.cms.gov/SCCLIA/Default.aspx
125	CLIA Laboratory Application, CMS-116	https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS012169.html?DLPage=1&DLEntries=10&DLFilter=116&DLSort=0&DLSortDir=ascending
232	Model Letter: Announcing to the State Laboratory Program, After a Sample Validation or Substantial Allegation of Noncompliance Survey, That a CLIA-Exempt Laboratory Does Not Comply With Applicable Program Requirements (No Immediate Jeopardy)	https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_232.pdf
242	Request for Validation of Accreditation Survey for Laboratories, CMS-2802A	https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS2802A.pdf
121	Payment Management System, SMARTLINK II, User's Manual	*Specific Items to Consider When Completing the Form CMS-1557 Deleted*