

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.

Budget and Administration

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.

6402 - Federal Administrative Responsibilities (Rev. 1, 05-21-04)

Among the responsibilities of the parties are obligations imposed upon the Federal government. The following are delegated to the Regional Offices:

- Setting policy and policy interpretations;
- Providing consultation to necessary agencies involved in administering the Federal requirements;
- Paying the appropriate and allowable costs of the SA functions relating to the administration of regulations and guidelines for CLIA;
- Making determinations of allowable State costs submitted for Federal payment; and
- Controlling payment of funds to appropriate State agencies for costs incurred in administering CLIA.

6404 - Nature and Source of Payments to States (Rev. 1, 05-21-04)

6404.1 - Funds for Clinical Laboratory Improvement Act Related Activities (Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) mandates that the CLIA program be self-funded. Program participants (laboratories that do clinical testing of human specimens for diagnostic purposes) bear all financial burden for implementation, day-to-day operations, enforcement and other Federal/State oversight expenses of the program. The funds needed to run the program come from the variety of mechanisms put in place to administer the program. The sources include:

- Certificate of Registration fees, from the start-up period, that are to accompany the initial registration;
- Certificate fees for Federal administration of the program; and

- Compliance determination and enforcement fees to cover the costs incurred by the State and Federal government to ensure program requirements are met.

6404.2 - Laboratory Remitted Funds

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

When a lock-box contractor receives these laboratory-remitted funds, they are deposited into a CMS CLIA account where they are available for State advances and payments for CLIA work. The States bill CMS for payment for surveys, visits or re-contacts, complaint visits, follow-ups and other CLIA work, by preparing a Form CMS-670 , “Survey Team Composition and Workload Report,” (Exhibit 74) and a Form CMS-102, “Budget Requests, Clinical Laboratory Improvement Amendments Program,” (Exhibit 116). The Form CMS-670 for CLIA is intended to capture the total time expended on a laboratory survey, or other CLIA-related workload from beginning to end. All work performed, including all discussions, report preparation and similarly related work expenditures for all employees involved in the process are to be reported. Payments to States under §1864 of the Act are made from user fees collected from the laboratories at registration. These fees pay for administrative expenses (including advances or payment to States under §1864) as authorized for expenditure from the CLIA user fee account.

As surveys and related CLIA work are performed, actual expenditures are determined and forwarded to the RO for review and action. They are then forwarded to CMS’ CO or their representative for approval. An end of year reconciliation and balancing of accounts will occur between CMS and each State. Actual expenses data will then be used by CMS as a basis for determining and setting future fee schedules for the participating laboratories.

6406 - State Agency Administrative Responsibilities

(Rev. 1, 05-21-04)

The SA is responsible for:

- Establishing and maintaining organizational relationships with other State and local governmental groups, as necessary, for attaining program or related program goals;
- Knowing the needs of laboratories in the State which affect their ability to comply with program standards, and devising and executing plans to address those needs;
- Advising the RO of program needs and trends, and of responsive actions which have been taken;
- Providing the material, equipment, and the training and support of personnel to perform the above functions; and

- Furnishing necessary records and accounting to justify costs claimed for payment by CMS.

6408 - State Agency Responsibility for Records and Reports
(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

SAs are to establish and maintain basic records and prepare operating reports in the form of the Form CMS-670, (Exhibit 74), and the Form CMS-102, (Exhibit 117). These report the essential administrative and fiscal information, records and reports which will help to provide an:

- Evaluation of the effectiveness of program operations;
- Analysis of workloads and degree of accomplishment;
- Identification of administrative or technical problem areas;
- Development and justification of payments; and
- Documentation to support the expenditure of CLIA funds for compliance determination surveys and oversight activities.

SAs are responsible for maintaining records and reports, on a continuing or special request basis, which are pertinent to the managing of agency operations and reflect the agency's workload. Records and reports are to be designed to fit within the framework of the SA operations. The design of those records and report mechanisms need not be limited to paper applications; it is acceptable for all parties to strive to use good modern management practices and tools to support the CLIA effort. Computer formats of CMS forms and reports have been developed for State use. The CMS requirement for a minimum of specific records and reports is not intended to limit in any way SAs fiscal and administrative practices. Reasonable costs to facilitate the implementation of quality modern databases and information systems are to be available for CLIA funding. However, if a State's fiscal and administrative requirements are in excess of the CLIA-mandated requirements, then expenses for work done above and beyond that prescribed by CLIA is not normally to be borne by the laboratories nor the CLIA program. However, the State has the authority to charge those laboratories in their CLIA-exempt program according to any fee schedule they determine is appropriate. Federal surveys of a sample of the CLIA-exempt laboratories will be billed according to the Federal fee schedule in 42 CFR Part 493, Subpart F. SAs will not be paid for work done in excess of that prescribed by CLIA.

6410 - State Agency Responsibility for Staff Training and Development (Rev. 1, 05-21-04)

6410.1 - Staff Training

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

The SA is responsible for providing continuing education to employees. In conjunction with, and subject to, the approval of the Regional Training Administrator (RTA), SAs must have a procedure for identifying the training needs of the surveyors. That procedure must insure that SOM revisions, RO instructional letters, and the results of regular and Federal Monitoring Surveys (FMS) are included in the training agenda. Training may be provided in a variety of forms: in-service training; formal education; State, regional or national conferences; seminars or workshops. Costs for all courses and training must be within approved fiscal limitations.

6410.2 - In-Agency Training

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

The SA must have its own program of staff development which responds to the needs of new employees for orientation and basic training, and to the needs of experienced employees for continuing development and education.

6410.3 - Outside-of-Agency Training

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

In evaluating the appropriateness of any outside training activity for CLIA funding, SAs and the RO must consider the degree to which the trainees will benefit when carrying out the CLIA survey and certification program.

6412 - Role of the CMS RO With State Agency Program Administration (Rev. 1, 05-21-04)

The RO is the CMS representative at the regional level for all CLIA survey and certification functions. The RO is responsible for:

- Reviewing and recommending action on each budget submittal;
- Furnishing program guidance and policy interpretation;
- Coordinating communications with the SA representatives, accredited providers, and laboratories on CLIA survey and certification activities; and
- Consulting on a regular basis with the SA, contractors or representatives for mutual assessment of program activities, achieving stated objectives, and establishing future goals.

Before approving each State budget submittal, the RO evaluates all information available and determines answers to the following questions:

- Is the plan of program activities appropriate to national CLIA annual and biennial goals?
- Do the workload and activity plans and staffing estimates properly place emphasis on fulfilling program goals?
- Does the budget request represent a consistent application and understanding of approved principles of reasonable cost to the SA's specific circumstances?

6414 - CLIA Budget - RO Procedures

(Rev. 1, 05-21-04)

6414.1 - General

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

CLIA is a self-funded program. Fees from compliance determination and oversight covering all CLIA-related expense must be established and collected. There are no other funds available from any source to administer the program other than from those laboratories subject to CLIA requirements.

6414.2 - Regional Administrative Responsibilities

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

The ROs have the primary responsibility for the efficient and effective administration of the CLIA program in the States in their respective regions. It is the RO's responsibility to:

- Issue the budget call letter to each State;
- Furnish the SA with administrative, budget and program guidance, policy interpretation, and leadership;
- Review, negotiate, and recommend action on each SA budget and subsequent quarterly expenditure reports;
- Coordinate communications relating to CLIA between the SAs and other CMS components;
- Consult with SAs to develop mutual agreement on the conduct of program activities, the achievement of stated objectives, and the establishment of future goals;

- Make determinations of allowable State costs submitted for Federal payment; and
- Control payment of funds to SA for costs incurred in administering CLIA.

Before approving each State budget submittal, the RO considers the following questions:

- How does the plan of program activities appropriately address the pertinent priorities and program emphases?
- Does the workload activity plan and the staffing estimate reflect the proper emphasis needed to fulfill the priorities listed in the budget call letter?
- Has the RO approved all appropriate reasonable costs that are peculiar to each SA's specific circumstances? If not, has the RO communicated this and a proper explanation to all concerned parties?
- Do all approved SA budgets reflect a consistent application and understanding of the programmatic, administrative, and fiscal principles and guidelines set forth in the SOM and the budget call letter?

6416 - Budget Call - RO Procedures

(Rev. 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 Agency 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.

6422 - Planning the Annual Workload - SA Procedures

(Rev. 1, 05-21-04)

The need for professional skills and additional personnel can only be ascertained after the workload is identified and a plan for accomplishing the work is outlined. Since the survey and certification program requires that laboratories be inspected within a biennial timeframe, the SA sets goals by categories of laboratory. The SA establishes schedules for surveys of the laboratories. The activity plan is to establish a program which permits survey and certification work to be done on an orderly basis throughout the year and with an even workload distribution over the 1- and 2-year cycle.

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

(Rev. 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.

6426 - Format for the Annual Activity Plan - SA Procedures

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

The SA uses any format for presentation of the SA annual activity plan. The SA includes the topics essential to the RO's management and budget review that are:

- a. A narrative explanation (as necessary) for significant figures included on the workload data sheet.
- b. A plan for using professional staff in survey and certification activities when more than one surveyor is required:
 - Division of responsibilities for survey;
 - Deployment of teams in relation to specific areas of workload; and
 - Geographic deployment.
- c. A plan for meetings with appropriate special interest groups, e.g., informational and educational programs for Ombudsmen, consumer groups, State and county laboratory and medical societies, to discuss issues and concerns regarding CLIA implementation.

- d. A list of CLIA activities delegated to personnel organizationally located outside the SA.
- e. The names and health professions or specialties of currently qualified surveyors.
- f. A description of the State's use of any laboratory testing or evaluation program in connection with CLIA activities.
- g. An outline of program training planned for the staff:
 - Staff training meetings;
 - Formal courses attended;
 - Seminars;
 - In-service training programs; and
 - Special problems of decentralized agencies.

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

(Rev. 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.

6432 - Promotional and Public Informational Activities - SA Procedures (Rev. 1, 05-21-04)

The §1864 agreement assigns significant responsibilities to the SA for conducting public information (PI) activities. Similar activities are carried out by CMS. The SA answers queries about CLIA when at all possible. CLIA queries are referred to the RO only if the information being requested is not available at the SA level or if it is clearly one that must be responded to by appropriate CMS authorities.

Certain other professional relations activities fall into the dual categories of public information and public relations. SA personnel are to develop and maintain ongoing relationships with members of the health professions and their organizations. The SA should encourage employees to participate as speakers, panelists, or consultants at meetings of professional organizations (laboratory or medical technologist associations, hospital associations, and medical societies) in the interest of furthering compliance with CLIA standards and objectives. These costs may be reasonable costs subject to CLIA funding.

6434 - The State Budget Request

(Rev. 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

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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	<u>2</u>
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 - State Budget Request Submittal - Clinical Laboratory Improvement Amendments
(Rev. 1, 05-21-04)

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.

6444.2 - Routing and Number of Copies
(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The SA forwards the proposed budget package (the original and one copy of each document) to the RO. The SA submits the budget in accordance with the due date provided by the RO but no later than July 30 preceding the Federal fiscal year to be funded. The deadline ensures that CMS can complete the budget approval process in time to prevent an interruption in cash flow when one fiscal year ends and the succeeding year begins.

Effective October 2002, State Agencies are required to use the automated Survey and Certification / CLIA reporting system to submit their final negotiated yearly budgets to the CMS regional offices. State Agency users will enter negotiated budget data into the various records and formats of the system. Once negotiations with the regional office are complete, the State certifying official will review the data, finalize the record, then certify the record, which will act as an electronic signature. The certifying official is the executive officer of the state agency charged with the duties of administering (or supervising the administration of) the CLIA program.

6446 - Developing Budget Approval - RO Procedures (Rev. 1, 05-21-04)

6446.1 - Budget Request Package

(Rev. 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.

6446.2 - Basis for Budget Approval

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

State budget proposals must be submitted to the region in accordance with the approved automated Survey and Certification / CLIA reporting system procedures. Regional offices may approve State budget submissions only after proper certification by the approved State certifying official. The RO approving official must obtain Central Office clearance prior to taking any approval action on a State budget request. RO approval schedules should be developed to ensure that budget approvals are completed on or prior to September 30 of the fiscal year to ensure that funding authority can be made available to the State prior to the start of the upcoming fiscal year. The basis for approving the line item budget is the number of facilities to be surveyed and the amount of staff and money needed to survey them. The 1988 amendments to CLIA mandate that all laboratories be surveyed every two years. Thus, the budget plan should address itself to the basic question of how the SA will accomplish this goal. It is important that the RO evaluate the accomplishments of the past performance period to determine the goals that need to

be set and accomplished for the next performance period. Budget constraints or unexpected revisions may affect hiring or any of the myriad of budget line items. Revised national and regional priorities may also impact upon workload plans and accomplishments, so the RO should be flexible and diplomatic in subsequent negotiations with the SA. The RO should not rely solely on written justification when approving a State's CLIA budget.

6446.3 - Line Item Negotiation and Approval

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

The budget approval is a detailed concurrence or revision to State estimated survey program costs. The RO negotiates the budgets by line item, according to the category of the proposed expenditure. The approval process is between the RO and the SA. The RO should be able to explain any adjustments and the method used to compute each amount.

The RO should caution the State that funds provided agencies, as a result of the budget approval, must be used only for necessary expenses and that financial shortfalls may occur that would dictate reduction of budget allocations to each State after approval. This will reduce the potential for adverse consequences should there be a need to reduce expenditures.

6446.4 - Payable Reasonable Costs

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

The SA is entitled to receive advances to and payment of all reasonable costs for performing the CLIA survey workload. CLIA funds cannot be used to pay the SA for any non-CLIA related expenses incurred. Though CLIA-dedicated support staff will better facilitate the computation of CLIA-related expenses for budgeting purposes, it is possible that shared staff, who are involved in supporting multiple programs, may be employed. Since CLIA will pay States only for CLIA-related expenses, proper proration of expenses is mandatory.

Reasonable costs include all necessary expenses in accordance with the standards and are described in the manual. Any class or kind of administrative expenditure that is properly chargeable to Federal CLIA funds under approved plans may be funded by CLIA revenues. SAs are expected to exercise due care in the expenditure of funds, understanding that the funds must be used only for CLIA-approved activities and procurement.

6446.5 - Projected Workload

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

The projected workload, program emphases, the SA's hiring and training plans, and the experience of the 12-month preceding period, if appropriate, are the primary factors for the RO to consider when approving the line item budget. The RO uses these factors as a guide, negotiate the budget in a fashion that assures that national and regional goals are

met. When the RO makes changes to the State's proposal, it provides the rationale for the proposed change. The RO rationale should include:

- The revised estimate;
- The rationale for the change; and
- The basis for computing the revised estimate.

6446.6 - CO Assistance

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

CO personnel are available to assist with negotiating budget approvals. The RO may consult with CO staff on any issues that are troublesome. The RO should raise concerns or issues as early as possible in the budget process. Prompt consultation can minimize the impact of many problems.

How the SA establishes and maintains controls is less important than the fact that a control system is in place for the CLIA workload. A by-product of the control system should be management information that is useful in managing the pending workload. Thus, some ability to capture data about workloads scheduled, pending and completed by laboratory schedule and employee type (to the extent possible) should exist in whatever system or mechanism the SA chooses to use. Whatever form the controls take, it is important that documentation of actions involving the laboratories be retained in a retrievable format that allows for review of the data, if necessary. Individual laboratory case records should be permanent case records that are accessible for review and analysis at a later date. It is also essential that the RO maintain the laboratory action control records so that they can be readily accessed should the need arise. The RO uses established controls for following up on pending CLIA actions, scheduling surveys or complaint visits, PoC follow-up visits, and other CLIA-related activities.

6448 - RO State Agency Budget Review - Form CMS-102

(Rev. 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.

6450 - Employee Salaries and Wages - RO Procedures (Rev. 1, 05-21-04)

6450.1 - Distribution of Staff Time for Program Purposes (Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

CLIA funds may be used to pay CLIA-only program expenditures. However, some personnel may be involved in multiple program activities. The RO should determine that a method for capturing the appropriate manpower split by program is developed when such time-sharing occurs. The proper pro-rata splits must be employed and documented to facilitate proper budget preparation, approval, and execution. Distribution of shared staff time to the appropriate separate program areas of State activity is required.

In the event staff are shared, the RO requests that periodic studies be conducted that will determine the proper prorated formula. A prorated portion of the cost of such studies, work sampling, data recording, and reporting is also a necessary and reasonable CLIA-related expense.

6450.2 - Determination of Necessary Staff (Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

The following method may be used by the SA to determine a proper split of costs for CLIA versus other State program administration costs:

- Determine the number of inspections and related manpower needed to fulfill the requirements of the CLIA laboratory inspection program; and
- Determine manpower requirements which are related to the requirements of other programs.

The ratio of countable CLIA activities to the sum total of the countable activities of all programs can be applied to the cost of the total multi-program activity.

Using this prorate method is acceptable when miscellaneous costs cannot be specifically identified as a CLIA or other program-specific expense. However, specific applications of this general principle will have to be developed jointly by the SA and the RO. This method permits adjustments for circumstances a particular agency may encounter. However, it is possible that such difficult to identify charges may already be accounted for in the indirect cost allocation rate and should not be included here. If the RO is in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, contact CO. They will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case. There are instances in which commonly-shared personnel, such as a typing pool, may be covered by agreement with the Department in the indirect cost allocation. If it were included in the Indirect Cost Allocation, inclusion in another line item would create double billing for this item.

Since no two indirect cost allocation agreements are exactly the same, the RO should not presume that what goes for one SA goes for the others in its region.

All such SA proposals to use sampling or prorate formulas must be approved by the RO before charges can be made under them. The RO may conduct studies, or direct that the SA conduct them to verify results.

6452 - Retirement Contributions and Fringe Benefits - RO Procedures (Rev. 1, 05-21-04)

Retirement and fringe benefits that are in accordance with State and Federal laws are acceptable as CLIA reimbursable expenses. It is possible that these charges may already be accounted for in the indirect cost allocation rate and should not be included here. If in doubt, the RO should contact CO. CO will contact the Office of Assistant Secretary for Management and Budget, HHS to determine if these costs should be included here.

6454 - Travel - RO Procedures (Rev. 1, 05-21-04)

The cost of travel, including, where appropriate, per diem or subsistence, in lieu of per diem, may be charged to CLIA. The travel must be done in accordance with the State's laws, regulations, and administrative procedures applicable to travel by State employees.

6454.1 - CLIA Laboratory Survey and Administrative Travel (Rev. 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.

6454.2 - Travel Involving Multiple Program Activities
(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Travel expenses for an employee performing multiple program activities (Medicare/Medicaid and CLIA) for the State should be prorated in accordance with the distribution of direct personal service time spent on each program involved in and recorded for each trip. Alternatively, such trip records may be accumulated for an accounting period and prorated accordingly. For example, if at the end of the period such records showed that two-thirds of the employee's productive time while in travel status was devoted to the State survey and certification program, and one-third of the time was devoted to CLIA activities, then the agency would charge one-third of the total travel cost to CLIA (including transportation, per diem, etc.) and the other two-thirds to the other appropriate program funds.

6454.3 - Training and Conference Travel
(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

This category of travel includes that travel which is not directly related to the line operations of surveying laboratories, consultation, and administration, as described above. Examples of travel performed are:

- Incident to orientation and basic training of new employees; and
- For meeting the needs of experienced employees for retraining.
- Also included is travel relating to:
 - Conferences;
 - Meetings;
 - Training;
 - Workshops; and
 - Seminars if the agenda material is directly related to the laboratory survey functions of the agency.

Travel for such purposes may be funded by CLIA.

It is possible that some common travel charges may already be included for payment by the indirect cost allocation and should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect allocation rate, the RO should contact CO. They will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case.

6456 - Communications and Supplies - RO Procedures (Rev. 1, 05-21-04)

6456.1 - Basis for Charges

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

Communications and supplies should be direct CLIA charges if separable from other program costs and identifiable as to unit cost. These expenses may be charged on a prorata basis if used for multiple program purposes. For example, if long distance calls are routed through a switchboard or can otherwise be identified as to program, the CLIA calls can be made a direct charge. Otherwise, all long distance charges should be prorated, using an identifiable and justifiable method or formula. It is neither equitable nor legal to charge the CLIA program for installation and rental of telephones used exclusively by other programmatic State staff. If CLIA and non-CLIA personnel share lines and telephones, payment must be on a prorata basis. The SA method of proration or the formula used must be included in their budget supporting documentation. Any blank or zero in this item must be explained. If it is included in the indirect cost allocation rate, it should be so stated.

6456.2 - Communications

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

Such items as services including teleconferences (except such items as are payable on travel expense accounts), postage, postage meter charges, printed stamped envelopes, registry and special delivery or express mail fees, insurance charges on fourth class mail, or postage due charges for CLIA employees and CLIA-program related activities are chargeable to CLIA.

For services such as satellite training or conferences, the SA has been advised to contact the RO to determine if the expense is a reasonable expense. The RO weighs the facts on an individual basis when such an inquiry is received. If found to be reasonable and necessary, it may be incorporated in the CLIA-approved budget. Expenses that, in some instances, may be justifiable as reasonable are those for:

- Cell phones,
- Modems, and
- FAX machines and other communication related expenses.

If the RO concurs that the circumstances do indeed substantiate such an expense, the RO may include it in the approved budget computations. It is incumbent upon the SA to be in close consultation to assure that any planned unusual expenses are approved.

6456.3 - Supplies

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

The items that follow are payable by CLIA if they are used to support CLIA personnel and CLIA-related activities:

- Such general office supplies as paper, pencils, folders, unstamped envelopes, clips, etc.;
- Non-consumable items such as staplers, pencil sharpeners, file baskets, books, electronic calculators and planners, computers not purchased as part of a major computer system, etc., which do not exceed Departmental and/or OMB dollar guidelines for cost-per-unit procurements;
- Printing or duplicating expenses and the cost of procuring forms such as printed or duplicated general office forms; and
- Costs of transportation or shipment of any of the above items.

The cost-per-unit above shall apply unless a different amount is specified by State law, in which case the amount so specified shall control. If purchases are co-mingled with other than CLIA program purchases of the same nature, documentation and justification of the expenses, on a prorata basis is necessary.

It is possible that some common communication and supply charges are included for payment in the indirect cost allocation agreement negotiated by the State or SA with HHS. If so, they should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, the RO should contact CO. They will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case.

6458 - Office Space - RO Procedures

(Rev. 1, 05-21-04)

6458.1 - Cost of Office Space

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

The cost of office space for CLIA laboratory survey functions is a proper charge against CLIA funds. The rules governing all such rentals and leases are the same for CLIA as they are for all other CMS rentals and leases. These guidelines replicate those rules and guidelines. Such charges may take the form of:

- Rent, service, and maintenance cost in privately owned buildings;

- Monthly rental charges based on the cost of initial construction or purchase of publicly owned buildings; or
- Meeting the costs of service and maintenance in lieu of rent in publicly owned buildings.

In addition, charges may be made for repairs and alterations to either privately or publicly owned buildings. Payment usually should be made only for periods of occupancy. If unusual situations arise and no precedent exists, the RO consults with CO before the RO approves the State request.

6458.2 - Standard of Comparable Rental

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

Charges against CLIA funds for office space must follow other CMS guidelines and may not exceed the rental rate of comparable privately owned space in the same or similar locality. Because the rental rate of comparable privately owned space is not a fixed amount for any particular locality, the rental rates may vary within a locality as well as between localities. However, a realistic determination of the rental rate of comparable privately owned space must be made.

The basis and documentation for the establishment of the rental rate of comparable privately owned space should be kept on file in the SA. The RO may want to obtain a copy of the documentation in any precedent setting situation.

6458.3 - Privately Owned Space

(Rev. 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.

6458.4 - Space in Publicly Owned Buildings

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

The following standards apply to charges for office space in a publicly owned building:

- Actual Cost which is the amount charged for office space in a publicly owned building must not exceed actual costs over a long-run period. The SA is required to produce records of actual costs if the RO wishes to examine them; and
- 75% Rule which is the amount charged for office space in a publicly owned building may not exceed 75% of the lowest comparable rental for privately owned space unless there are special considerations justifying a greater charge. Use of this standard should be used only as an interim measure in the absence of actual

cost data. This allows the SA to claim costs that are not in excess of 75% of the lowest cost of privately owned space. The SA is allowed to do this without prior review or approval by the RO.

When a monthly rental charge based on the cost of initial construction or purchase of publicly owned buildings exceeds 75% of lowest comparable rental for privately owned space or when the cost of service and maintenance in lieu of rent in publicly owned buildings exceeds 75%, the SA is required to obtain prior approval from your office. The RO may wish to consult with CO prior to granting approval for such expenditures.

It is possible that some common space charges are included for payment in the indirect cost allocation agreement negotiated by the State or SA with HHS. If so, they should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, the RO should contact CO. CO will contact the Office of Assistant Secretary for Management and Budget, HHS, to determine if such is the case.

6458.5 - Charges Based on Meeting Cost of Service and Maintenance (Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

When the total charges for service and maintenance in a publicly owned building exceed 75% of the lowest comparable rental for privately owned space, the SA must submit, prior to its claim, the following data for review and approval by CMS:

- Total useable floor space and the amount of space allocated to the CLIA laboratory inspection program personnel;
- Total costs of service and maintenance and the portion to be charged to CLIA funds;
- The elements of cost; and
- The rental cost of comparable privately owned space with at least three statements of appraisals.

6460 - Equipment - RO Procedures

(Rev. 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.

6462 -Training - RO Procedures **(Rev. 1, 05-21-04)**

The budget request should provide for the cost of training CLIA personnel. The SA should use the number of employees to be trained, rather than full time equivalents (FTEs) when computing this figure. Included should be the cost of the courses to be taken, the cost of travel and per diem associated with training sessions. A narrative justification should indicate the types of courses to be taken by employee type and by number of employees to be trained.

It is possible that some training costs may have been included in the indirect cost allocation agreement negotiated by the State or SA with HHS. If so, they should not be included here. If in doubt as to whether all or part of a line item is already included in the indirect cost allocation rate, the RO contacts CO. CO will contact the Office of Assistant Secretary for Management and Budget, HHS, where copies of the agreements are maintained, to determine if such is the case.

6464 - Consultants - RO Procedures **(Rev. 1, 05-21-04)**

The SA should include the proposed cost of hiring consultants who are not State employees but who are used on a part-time, fee-for-service, or temporary basis to perform CLIA-related work.

6466 - Subcontracts - RO Procedures
(Rev. 1, 05-21-04)

The SA should include projected cost of subcontracts to be employed in the conduct of CLIA-related work. Subcontract costs attributable to CLIA survey activities are allowable and payable. The SA budget justification should provide the RO with the specific details, the reasons for, and approximate cost of each separate subcontract.

6468 - Miscellaneous - RO Procedures
(Rev. 1, 05-21-04)

Reported in these spaces should be any unusual budgeted items that have not been reported in any of the preceding classifications. To facilitate decision making, the SA should have attached to the budget package a narrative justification that explains all proposed expenditures. The RO should consult CO as necessary to resolve any questions.

6470 - Indirect Costs - RO Procedures
(Rev. 1, 05-21-04)

The indirect costs provided would be the rate negotiated and approved by the HHS Division of Cost Allocation for use during the fiscal year, together with the line item base it is applied against (approved rate x base). The Department negotiates these rates with States, SAs, or programs. The rate negotiated may be for a whole State or for each program or grant in a State. It is probable that no two rate formulas include the same provisions. It is important that CLIA not pay the SA for anything that the SA is going to be paid for by any other program or provision. Where doubt exists, the RO questions any budget item and assure that an investigation is initiated. If the SA is unfamiliar with what is included in the indirect cost allocation and cannot get clarification for the RO from their financial experts, the RO contacts CO. Provide as much detail as the RO can as early in the budget process as possible so that the Office of the Assistant Secretary for Management and Budget can be queried for an answer.

6472 - Hourly Rate Requested - RO Procedures
(Rev. 1, 05-21-04)

The dollar amount of the hourly rate of payment requested by the State is usually computed by dividing the total budget cost by the agreed upon number of available hours for actual survey-related activities.

6474 - Planned Workload Report - Form CMS-105 - RO Procedures
(Rev. 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 - Schedule for Equipment Purchases - Form CMS-1466 - RO Procedures **(Rev. 1, 05-21-04)**

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](#)).

6476.2 - Completion of the Form

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

Name of Agency - The official name of the agency and the State will be inserted automatically when the State selects the type of form and the period for which equipment funds are requested.

Column (a), Description of Equipment - Entered here are the items of equipment being requested or reported as purchased. Items previously approved but which are being rebudgeted should be included and noted by the SA. The State submission for approval will include supporting comments on the bottom or reverse of the form. It should also explain why a purchase was not completed in the prior budget period, if such is the case. If this justification is missing, the RO obtains the justification from the SA.

Column (b), No. of items on hand - The number of similar items on hand (in the SA's inventory) at the time the form was prepared should be listed. SA equipment planning for one program should not be co-mingled with those of another. If sharing is taking place, the equipment costs should be prorated.

If this purchase represents a new and different item, “None” should be shown in this column.

Columns (c) and (d), Number of Units (Additional) or (Replacement) - The number of units approved by the SA should be listed. Are these to be replacement units or additional units? Is employee sharing of equipment done currently? Is equipment sharing a realistic and manageable option? Do not arbitrarily dismiss such options as viable alternatives to one-for-one equipment purchases.

Column (e), Unit Cost - The unit cost for each item listed in column (a) should be entered here.

Column (f), Gross Cost - The SA computes and enters the gross cost for each item in column (a) by multiplying the number of units in columns (c) and/or (d) by the unit cost, column (e). $\text{Column c} + \text{column d} \times \text{column e} = \text{gross cost, column (f)}$.

Column (g), Net Cost - Shown here should be a summarized total amount for each item listed in column (a). This may be the same figure as that shown in column (f). If there are reductions that should be applied to the gross cost, thus increasing or lowering the net cost, the reduction should be explained and the proper Net Cost should be entered in column (g).

Total Net Cost of Equipment - This is the sum of all amounts shown in column (g) above. The SA should have entered this amount on the CMS-102, item 9. If the RO approves this amount, it enters the figure on the CMS-104 (Exhibit 7), item 6, column (c).

Date, Signature, Title - The form must be dated and signed by the SA. The title of the individual signing the schedule should be shown.

6478 - Preparation of List of Positions - Form CMS-1465A - RO Procedures (Rev. 1, 05-21-04)

6478.1 - Usage

(Rev. 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.

6482 - Need for Additional Funds - RO Procedures

(Rev. 1, 05-21-04)

SAs should periodically check their current rate of expenditure. If it appears that expenditures may exceed the budget approved or the current allotment, the SAs should consult with the RO as soon as possible.

6482.1 - Adjustment in Quarterly Allotments

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

During the first three-quarters of the fiscal year (October - June), if the agency concludes that expenditures will exceed the current allotment, an information statement should be submitted to the RO. This statement should explain in which line items the SA believes additional funds will be needed and give the agency's reason for this conclusion. SAs may request an adjustment in the quarterly allotment schedule to make additional funds available at this time. A supplemental budget should be submitted when it appears funds will be exhausted before close of the fourth quarter of the fiscal year.

6482.2 - Supplemental Budgets

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

At the beginning of July each year, SAs should review their fiscal requirements for the balance of the fiscal year. If at this time it appears that additional funds will be required, the SA should submit a supplemental budget. The supplemental budget should be completed for the full fiscal year and include a statement concerning the anticipated expenditures in each category and the net additional amount needed. The supplemental request should be prepared on the same form(s) and in the same number of copies as a regular budget request. Supporting information comparable to the kind found on regular requests should accompany the supplemental budget.

Even though no supplemental budget is submitted at the time of the July review, SAs should continue to check their expenditure rate for the balance of the fiscal year. An end of year reconciliation and balancing of accounts will occur between CMS and each State. Actual expenses data will then be used by CMS as a basis for setting future fee schedules for the participating laboratories.

6484 - Need for Additional CLIA Funds - SA Procedures (Rev. 1, 05-21-04)

Periodically, the SA should check its current rate of expenditure. If it appears that expenditures may exceed the budget approved or the current allotment, it should consult with the RO. The SA should take full advantage of line-item flexibility (see §6434) before concluding that additional funds are needed.

6484.1 - Adjustment in Quarterly Allotments (Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

During the first three-quarters of the fiscal year (October - June), if the SA concludes that expenditures will exceed the current allotment, it submits an informational statement to the RO. This statement should explain in which line-items the SA believes additional funds are needed and give its reason(s) for this conclusion. The SA requests an adjustment in the quarterly allotment schedule to make additional funds available at this time and submits a supplemental budget when it appears funds will be exhausted before the close of the fourth quarter of the fiscal year.

6484.2 - Supplemental Budgets (Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

At the beginning of July of each year, the SA reviews its fiscal requirements for the balance of the fiscal year. If at this time it appears that additional funds are required, the SA submits a supplemental budget that should be completed for the full fiscal year, and include a statement explaining the anticipated shortfall for each category and the net additional amount needed. The SA prepares the supplemental request on the same form(s) and in the same number of copies as a regular budget request and includes supporting information comparable to the kind found on regular requests.

Even though no supplemental budget may need to be submitted at the time of the July review, the SA continues to check its expenditure rate for the balance of the fiscal year.

6486 - State Agency Accounts and Reporting (Rev. 1, 05-21-04)

The SA ensures that all estimates and reports of expenditures and other reports are prepared in accordance with appropriate budgetary and accounting methods and administrative practices adopted by the Secretary.

It is CMS' desire and intent to accept State practice in the manner in which funds received from the Federal government are handled and accounted for, and in a State's choice of a depository, subject to the general accountability required under Section C, Fiscal, of the agreement. However, funds advanced to a State must be identifiable on a

State's records. Establishing a separate account usually does this. The Fiscal and Reports Sections, along with instructions established by CMS for receiving advances of funds and submitting reports, have been drafted with a view to following State patterns to the fullest extent possible.

6488 - Support for Expenditures - SA Procedures (Rev. 1, 05-21-04)

The SA must provide, through SA accounting and statistical records, support for all expenditures incurred in connection with survey and certification activities. No particular kind of accounting record, method or procedure is required. The State's accounting records and supporting documents must permit verification by Federal fiscal audit and CMS administrative review of all charges, together with the status of the advances made to the State.

If the SA is receiving grants-in-aid administered by HHS in connection with its regular program, it uses the accounting and procurement methods and procedures described in SA approved plan for such grant-in-aid programs. The SA is responsible for securing the necessary data from local or district offices, and assuring the validity of all data used for budgetary and other purposes.

6490 - Certificate of Authority - SA Procedures (Rev. 1, 05-21-04)

A certificate is placed on file with CMS stating the official title of the State person authorized to submit an estimate of funds, to certify fiscal documents and to represent the SA in fiscal matters.

The SA forwards two copies of the certificate to the RO. If the authority passes to a new office, or the scope of the authorization is changed, the SA submits a new certificate.

6492 - Cash Basis - SA Procedures (Rev. 1, 05-21-04)

The method of financial reporting recommended is the "cash basis." Thus, the data is based upon "cash accounting" which requires that charges against CMS CLIA funds be entered on SA records when formal vouchers, electronic transactions or other documents that may initiate payment are prepared.

6494 - Limit on Expenditures - SA Procedures (Rev. 1, 05-21-04)

The total amount approved in the SA annual budget shall be the limit on expenditures for the fiscal year.

6496 - Periodic Analysis of Accounts - SA Procedures (Rev. 1, 05-21-04)

Since total expenditures for a fiscal year may not exceed the amount approved for that period, the SA reviews the status of accounts at least once each month. This allows the SA to observe expenditure trends as they occur and helps the SA to avoid both over-expenditure of funds and over-accumulation of large amounts of unliquidated obligations. It also provides early identification of any need for supplemental funds.

6498 - Cash Balances and Expenditure Authority - SA Procedures (Rev. 1, 05-21-04)

Unexpended funds on hand at the end of each quarter are available for expenditure in the succeeding quarter without formal reallocation. However, this is NOT applicable if the succeeding quarter is in a new fiscal year - no new obligations may be incurred after the last day (September 30) of the fiscal year. This provision applies to all funds on hand whether they were received in a CMS advance or from other sources. Formal reallocation is not a prerequisite for expenditure of any funds on hand.

6500 - Unliquidated Obligations - SA Procedures (Rev. 1, 05-21-04)

Fiscal controls should provide current information on unliquidated obligations. For purposes of CMS financial reporting, unliquidated obligations are defined as bills received, but not yet prepared for transmission to the State fiscal officer for payment, or obligations incurred for which there is acceptable evidence of a commitment or promise to pay for goods, facilities, or services in any category of expenditure, whether or not the goods or services have been received or a bill rendered. Examples of unliquidated obligations are:

- Equipment which had been ordered, but not paid for (whether or not received); and
- Items charged on a semi-annual or annual basis. For example, for an item charged for an annual basis, the unliquidated obligation reported for the first quarter in the year would represent one quarter of the estimated annual charge. The unliquidated obligation reported in the second quarter would represent one-half of the estimated annual charge. Should the obligation not be paid off at the expected time, the SA continues to report the accumulated amount due.

6502 - Nothing to Report on a Given Line - SA Procedures (Rev. 1, 05-21-04)

If there is nothing to report on a given line, the SA should so indicate by the use of a dash (-) or a zero (0).

6504 - SA Forwarding Materials to the RO (Rev. 1, 05-21-04)

The RO may request that the SA forward documentation to the RO supporting the SA laboratory survey-related activities. If required to do so, the SA retains a copy of the materials for SA records and sends the original to the RO. Copies of all material must be legible and must contain the appropriate signatures.

6506 - State Agency Files Used for Case Control and Reporting (Rev. 1, 05-21-04)

The RO may also need more specific information about some aspect of SA CLIA operations, or may need other special tabulations and reports concerning an area of program activity. RO may need:

- The number of applications pending for various lengths of time;
- Laboratory survey schedules; and
- The progress made through consultation with a facility.

The SA may use this additional data for SA own purposes as well. All such data is to be readily available from SA records.

Many States are employing their own unique filing system and finding improved methods of control and ways of incorporating additional data such as licensure information, details on the improvements in the quality of service through consultative efforts. The SA may use any technique as long as it affords a positive control over pending cases and provides for adequate tallying and documentation of certification activities. The data extracted from the system for RO reports is rudimentary and easily tallied. Therefore, the case control system probably does not warrant employing data processing equipment. In some cases, the SA already use data storage and retrieval equipment, so it would actually be less expensive and simpler to employ existing equipment than to use a manual case control system.

6508 - SA Establishment of Case Controls (Rev. 1, 05-21-04)

It is of utmost importance that the SA initiate and maintain proper workload controls. A good workload control system helps to encourage good management practices. Though this section uses the word “system” to describe a mechanism that can help track workload pending and accomplishments, it does not arbitrarily categorize such as a computer-based control system. A simple manual case control system may be something as unsophisticated as a card system that can be used to track the progress of each CLIA workload. Most States already have control systems in place which track other programmatic (survey) workloads. Many are quite sophisticated and computerized.

Similar mechanisms may be adapted to CLIA or new more responsive systems may need to be designed to accommodate the CLIA workload. The type of physical system used is less important than the actual capture of the basic information needed to establish and maintain management control over the workload. The SA should make sure any control system considered, whether manual or automated, is able to facilitate the establishment, update and storage of the basic control data. It must also provide the controls that allow for management of pending workloads, laboratories to be surveyed, resurveyed, and hearings pending. Data retention capability should be for a minimum of three years.

6510 - Payment by Electronic Transfer of Funds - SA Procedures

(Rev. 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.

6514 - Employee Salaries and Wages - the Distribution of Staff Time for Program Purposes - SA Procedures (Rev. 1, 05-21-04)

CLIA funds are to be used only to pay CLIA program expenditures. However, it is recognized that some personnel may be involved in multiple program activities. Though the magnitude and scope of the CLIA program is such that time-sharing may not occur or even be readily possible, it may by necessity, occur. Thus, an important administrative goal must be to assure that a method for capturing the appropriate work-power split by program is developed, when such time-sharing occurs. The SA should employ the approved methods for determining the proper pro-rata splits and document them to facilitate budget preparation, approval, and execution. It is necessary for the SA to distribute shared staff time to the appropriate separate program areas of State activity.

In the event staff is shared and a cost proration is necessary to determine the related costs for each program, a prorated portion of the cost of such studies, work sampling, data recording, and reporting is a necessary CLIA-related expense. Studies determined necessary or requested by the RO are a necessary and reasonable CLIA expense.

6516 - Determination of Necessary Staff - SA Procedures (Rev. 1, 05-21-04)

The SA may use the following method to determine a proper split of costs for CLIA versus other State program administration costs. The SA should determine the number of surveys that are planned for each program and determine the amount of staff needed for CLIA surveys and survey-related activity. Workload plans should fulfill the specific requirements of the CLIA laboratory survey program. The SA determines commonly shared staff and estimates the staff requirements for each program. The ratio of countable CLIA activities to the sum total of the countable activities of all programs can be applied to the cost of the total multi-program activity. Using the ratio derived is acceptable when miscellaneous costs cannot be specifically identified as a CLIA or other program-specific expense. However, the SA should develop specific applications of this general principle jointly with the RO, to allow for circumstances a particular agency may

encounter, and ensure the comparability of such activities between programs. Such tools for deriving SA staffing estimates must be approved by the RO before charges for payment can be made. Studies may be conducted to verify the comparability of the activities or to validate the proposed formula for adjustments made in charging expenses to CLIA.

6518 - Retirement Contributions and Fringe Benefits - SA Procedures (Rev. 1, 05-21-04)

Retirement benefits and fringe benefits that are reasonable costs and in accordance with State and Federal laws are acceptable and payable under CLIA.

6520 - Travel - SA Procedures (Rev. 1, 05-21-04)

The cost of travel, including, where appropriate, per diem, or subsistence in lieu of per diem, is charged to CLIA in accordance with provisions of State law, regulations, and administrative procedure applicable to travel of State employees.

6520.1 - CLIA Laboratory Survey and Administrative Travel (Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Laboratory survey travel includes travel to a facility:

- To conduct laboratory surveys;
- For re-visits or recontacts with a facility about compliance action items, or plans of actions;
- To perform laboratory complaint or oversight surveys; and
- For meetings with CMS personnel on CLIA-related activities.

Administrative travel is defined as travel within the State:

- For management purposes related to the CLIA laboratory survey program;
- To attend agency administrative staff meetings related to CLIA;
- To attend State CLIA program meetings or activities conducted or sponsored by CMS; and
- For planning or liaison visits to other agencies having to do with certification.

Travel to participate in sanction meetings or negotiations, or to appear before an ALJ in a Hearing (to provide testimony or support for a sanction activity against an alleged non-compliant laboratory) may also be charged to CLIA.

6520.2 - Travel Involving Multiple Program Activities
(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Travel expenses for an employee performing multiple program activities (Medicare/Medicaid and CLIA) for the State is to be prorated on the basis of direct personal service based upon time spent on each program involved in and recorded for each trip. Alternatively, such trip records may be accumulated for an accounting period and prorated accordingly. For example, if at the end of the period records showed that 2/3 of the employee's productive time while in travel status was devoted to the Medicare/Medicaid survey and certification program, and 1/3 of the time devoted to CLIA activities, then the agency would charge 1/3 of the total travel cost to CLIA (including transportation, per diem) and the other 2/3 to the Medicare/Medicaid survey and certification program funds.

6520.3 - Training and Conference Travel
(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

This category includes travel not directly related to the line operations of inspecting laboratories, consultation, and administration, as described above. Examples are travel performed (1) Incident to orientation and basic training of new employees in areas appropriate to SA activities in the laboratory survey and certification program; and (2) For meeting the needs of experienced employees for retraining. Also included is travel relating to conferences, meetings, training institutes, workshops, and seminars if the agenda material is directly related to the laboratory survey functions of the agency. Travel for such purposes may be funded by CLIA.

6522 - Communications and Supplies - SA Procedures
(Rev. 1, 05-21-04)

6522.1 - Communications
(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

Telephone services chargeable to CLIA include:

- Teleconferences;
- Postage;
- Postage meter charges;
- Printed stamped envelopes;

- Registry and special delivery or express mail fees;
- Insurance charges on fourth class mail; or
- Postage due charges incurred by CLIA employees and for CLIA program-related activities.

For services such as satellite training or conferences, contact the RO to determine if the expense is a “reasonable” expense that is payable in accordance with the CLIA-approved budget. Expenses for cell phones, modems, FAX machines and other communication-related expenses may, in some instances, be justifiable, and, thus, chargeable to CLIA in accordance with the previously approved budget. The SA should consult with the RO to assure payment.

6522.2 - Supplies

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

The following items are chargeable to CLIA if they are used to support CLIA personnel and CLIA-related activities:

- General office supplies such as paper, pencils, folders, unstamped envelopes, clips;
- Non-consumable supplies such as staplers, pencil sharpeners, file baskets, books, which do not exceed a \$50 per unit cost;
- Printing and duplicating expense and the cost of procuring forms such as printed or duplicated general office forms; and
- Costs of transportation or shipment of any of the above items.

The \$50 unit cost for non-consumable items shall apply unless state law specifies a different amount, in which case the amount so specified shall control. If purchases are commingled with other than CLIA program purchases of the same nature, the SA documents and justifies the expenses on a prorated basis.

6522.3 - Basis for Charges

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

Communications and supplies should be direct CLIA charges if separable from other program costs and identifiable as to unit cost. The SA charges these expenses on a prorated basis if used for multiple program purposes. For example, if long distance calls are routed through a switchboard or can otherwise be identified as to program, the CLIA calls can be made a direct charge. Otherwise, all long distance charges are to be prorated, using an identifiable and justifiable method or formula. It would not be equitable to charge the CLIA program for installation and rental of telephones used exclusively by

other State staff. If CLIA and non-CLIA personnel share lines and telephones, payment is computed on a pro-rata basis. If an employee is engaged in multiple program activities, including CLIA-related activities, CLIA is to be billed only on a prorated share basis. The SA includes the documentation of the method of proration or the formula used.

6524 - Office Space - SA Procedures **(Rev. 1, 05-21-04)**

The cost of office space essential for CLIA laboratory survey functions is a proper charge against CLIA funds. The rules governing all such rentals and leases are the same for CLIA as they are for all other CMS rentals and leases. These guidelines replicate those rules and guidelines. Such charges may take the form of:

- Rent, service, and maintenance cost in privately-owned buildings;
- Monthly rental charges based on the cost of initial construction or purchase of publicly-owned buildings; and
- Meeting the costs of service and maintenance in lieu of rent in publicly-owned buildings.

In addition, charges may be made for repairs and alterations to either privately or publicly-owned buildings. Payment will be made only for periods of occupancy unless approval is received from CMS for payment for periods of nonoccupancy.

Charges against CLIA funds for office space must follow other CMS guidelines and thus, may not exceed the rental rate of comparable privately-owned space in the same or similar locality. Although the rental rate of comparable privately owned space is not a fixed amount for any particular locality, and the rental rates may vary within a locality as well as between localities, it is expected that a realistic determination of the rental rate of comparable privately-owned space be made. The basis and documentation for establishing the rental rate of comparable privately-owned space is to be kept on file.

6526 - Privately-Owned Space - SA Procedures **(Rev. 1, 05-21-04)**

Charges against CLIA funds for privately-owned space, including expenses of services and maintenance, repairs, and alterations, must not exceed the rental rate of equivalent space and facilities in the same or similar locality.

In negotiating a lease for privately-owned space, the SA includes cancellation or conditional clauses in rental agreements. The following guides are applicable with respect to the rental of space in privately-owned buildings when renewing an existing lease or when obtaining new or additional space under a lease:

6526.1 - Cancellation Clause

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

When executing or renewing leases, the SA should make every effort to include a reasonable right of cancellation (30 days, if possible) in favor of the State, if such right can be included in light of rental rates, probable permanency of occupancy, and other pertinent factors. The SA should attempt to secure a cancellation clause in all rental agreements covering space for more than 1 year.

6526.2 - Lease Not Exceeding One Year

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

When the SA is unsuccessful in securing a cancellation clause, it should make an attempt to secure leases not to exceed one year's duration, if possible, with an annual renewal option for an extended period, such as three years or longer.

6526.3 - Consulting the RO

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

Where neither of the above is possible, the SA consults the RO at least 30 days in advance of the date the lease is to be signed.

6528 - Space in Publicly-Owned Buildings - SA Procedures

(Rev. 1, 05-21-04)

The following standards apply to charges for office space in a publicly-owned building:

6528.1 - Actual Cost

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

The amount charged for office space in a publicly-owned building must not exceed actual costs over a long-run period. The SA is required to produce records of actual costs for examination as necessary. The SA will:

- Not include the cost of land as part of the cost of initial construction or the purchase of publicly-owned buildings in deriving the rental charges. This exclusion is based on the fact that land has no actual physical depreciation. The State would always have the land as an asset long after the building had become obsolete or been demolished, and value could be realized.
- Establish the estimated useful life of the building if depreciation is included as an element of cost. In case the building is vacated before the end of its useful life, adjust past claims for amortization to a reasonable depreciation basis.

6528.2 - Cost After Building Amortization

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

After the initial cost of a building has been amortized, the SA charges only the costs of service and maintenance.

6528.3 - 75 Percent Rule

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

The amount charged for office space in a publicly-owned building may not exceed 75 percent of the lowest comparable rental for privately-owned space unless there are special considerations justifying a greater charge. The use of this standard as an expedient interim measure in the absence of actual cost data, enables the SA to claim costs that are not in excess of 75 percent of the lowest cost of privately-owned space without prior review or approval by the RO.

6528.4 - Ratio of Charge-to-Rental Rates in Privately-Owned Space

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

Experience gained in analyzing the elements of rental rates in privately-owned space shows that approximately 75 percent of the rate represents the expense of service, maintenance, and depreciation. The portion in excess of 75 percent of the rental rate of comparable privately-owned space generally represents taxes and profit on investment that would ordinarily accrue. Therefore, whenever a charge is made for space in a publicly-owned building that is not in excess of 75 percent of the lowest cost of comparable privately-owned space in the same or similar locality, the SA assumes that such charge is reasonably related to the expense of service, maintenance, and depreciation. The SA verifies the reasonable relationship of such charges to actual costs over a long-run period. When a monthly rental charge based on the cost of initial construction or purchase of publicly-owned buildings exceeds 75 percent of lowest comparable rental for privately-owned space or when the cost of service and maintenance in lieu of rent in publicly-owned buildings exceeds 75 percent, the SA obtains prior approval from CMS.

6528.5 - Charge Based on Cost of Initial Construction or Purchase

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

When rental charges are based on costs of initial construction or purchase of a publicly-owned building and such charges exceed 75 percent of the lowest comparable rent for privately-owned space, the SA submits justification for review and approval by CMS prior to acquisition or occupancy of the space.

6528.6 - Charges Based on Meeting the Cost of Service and Maintenance

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

When the total charges for service and maintenance in a publicly-owned building exceed 75 percent of the lowest comparable rental for privately-owned space, prior to the SA's claim, the SA submits the following data for review and approval by CMS:

- Total useable floor space and the amount of space allocated to the CLIA laboratory survey program personnel;
- Total costs of service and maintenance and the portion to be charged to CLIA funds;
- The elements of cost; and
- The rental cost of comparable privately owned space, with at least three statements of appraisals.

6530 - Repairs and Alterations - SA Procedures

(Rev. 1, 05-21-04)

Charges may be made for repairs and alterations in privately or publicly-owned space necessary to the maintenance of proper facilities for efficient administration of the State survey unit.

6530.1 - Maintenance Repairs

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

The SA includes maintenance repairs such as painting, repairs to plaster, patching roofs and minor repairs to doors, elevators and electrical equipment in the rate for service and maintenance.

6530.2 - Major Repairs and Replacements

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

Major repairs and replacements, such as structural changes in buildings, new roofs, and new heating systems may be amortized over a period of years provided the total cost for space on an annual basis does not exceed lowest comparable rental, or in the case of publicly-owned buildings, 75 percent of the lowest comparable rental for privately-owned space. If the cost is amortized, the repairs and alterations must be of a permanent nature. Repairs and alterations that remain the property of the agency are usually classified as moveable equipment.

6530.3 - Alterations

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

Normally, quarters completely adequate for the SA should be obtainable from the lessor, and the cost of necessary alterations would be borne by the landlord. However, where the landlord is unwilling to bear the cost of necessary alterations, CMS funds can be authorized to meet the cost of alterations provided the proposed alterations are needed for better utilization of the space, and the improvements are not obligations of the lessor under the terms of the lease. In some situations, lessors will not agree to make necessary alterations but will offer space at a relatively low rental rate. In such cases, the SA should try to negotiate an arrangement under which the lessor would make necessary alterations and the SA would amortize the cost by an increase in rent for a stipulated length of time. Before agreeing to an arrangement providing for repair or alteration, the SA should secure approval from the RO.

6532 - Identifiable (Direct) Costs - SA Procedures

(Rev. 1, 05-21-04)

When locating program personnel in extra identifiable space, the SA charges CLIA for the cost of such space.

Where SA CLIA program personnel share space with the SA regular personnel, the SA apportions the cost of such space between the programs. The apportionment is based upon the SA proration plan and must be approved by CMS. The method approved will apply only to rental fees paid for locations where SA program personnel share occupancy. The SA should re-evaluate the basis for prorating rental costs when changes in physical facilities or other conditions may result in inequitable cost sharing.

The SA submits the SA's rental cost apportionment plan each year as part of the budget documentation. Approval of the budget constitutes approval of the plan of apportionment.

6534 - Office Maintenance - SA Procedures

(Rev. 1, 05-21-04)

6534.1 - Definition

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

Office maintenance includes services such as light, heat, time clock and water service, towel and janitor service, and machine repair service prorated on the same basis as rent, provided such services are not already included in rental costs.

6534.2 - Basis for Charges

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

If associated office maintenance costs, in whole or in part, are included in the SA's rental contract, the SA does not separate them; however, it notes their inclusion. The SA charges maintenance costs that are not included in rentals on the same basis as rental costs.

6536 - Equipment - SA Procedures

(Rev. 1, 05-21-04)

6536.1 - Definition and Quality of Office Equipment

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

Items which are of a non-expendable nature, i.e., they have a life expectancy of one year or more and a probable resale, salvage, or trade-in value, are classified as office equipment if they have a unit cost in excess of 50 dollars. However, if State law specifies a different amount, the amount so specified shall apply. The quality of items should not exceed the quality of similar office equipment in general use in other SA offices.

6536.2 - Title to and Accountability

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

Title to and accountability for office equipment purchased for State survey program purposes, or for shared use with other State or Federal programs, shall rest with the State. However, the purchase price(s) of individual pieces of office equipment may be shared with other State or Federal programs. Where the costs of equipment are prorated between Medicare and other programs such as CLIA, the SA should use the same proration in crediting residual value to the Medicare, or CLIA program for all disposed equipment. Where Medicare-only, CLIA-only, or Medicaid-only funds are used to fully fund equipment, the SA credits 100 percent of the residual value to the appropriate funding program, either Medicare, Medicaid or CLIA, but not all.

6536.3 - Purchase of Equipment

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

6536.3.1- State Practice

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

The SA follows established State law or regulations for procurement of equipment for the State survey program.

6536.3.2 - Purchases Related to Budget Process

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

Funds for equipment purchases are to be requested by State agencies and approved by CMS as part of the budget process. The SA should try to predict SA equipment needs during pre-budget planning, and request all needed equipment in the budget submittal. To estimate equipment needs, the SA determines the condition of equipment on hand and the appropriateness of the equipment for the tasks to be performed. The SA should also consider proposed staffing increases in SA budget projections.

The total expended for equipment during the budget period cannot exceed the total funds allocated for equipment for that period without prior approval of the RO.

6536.3.3 - Items Deleted by CMS

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

After reviewing an agency's estimate for equipment, CMS may delete an item or restrict the purchase of an item. If upon review of the CMS deletions, the SA want to resubmit the request it should do so. The SA submits the request with added supporting information. However, until the restriction is removed, the item cannot be purchased with Federal funds.

6536.3.4 - Purchase of Items Not Included in Budget Submittal

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

Although the SA is expected to anticipate the bulk of its equipment needs, the SA may occasionally find a need for equipment that was not included in its budget submittal. The SA must secure approval of the RO before purchasing such items of equipment. However, if sufficient uncommitted funds are available, the SA may purchase items not included in the budget approval without prior RO approval when the unit cost of the item is 50 dollars or less, and the item is of a kind approved in any previous budget period, e.g., tables, chairs, and coat racks. The SA lists such items and identifies them in the equipment schedule submitted at the end of the quarter in which purchased.

6536.3.5 - Reporting Equipment

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

The SA maintains an inventory of equipment, following usual State inventory practices, and makes an annual physical count of equipment items for comparison against the inventory records. In the event of equipment loss or substantial damages due to theft or fire, the SA submits a statement concerning such losses to the RO as soon as possible.

6536.4 - Rental of Equipment

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

Situations may occur where it will be advisable to rent certain office equipment instead of purchasing it. The rental of office equipment is allowable if it is not contrary to State law or regulations. Expenditures for equipment rental are considered “necessary” if:

- The rental is for a short period of time;
- The equipment is not available for purchase (leased telephone lines, electrostatic photocopy machines, etc.); or
- It can be shown that renting rather than purchasing an item of equipment is advantageous in terms of cost.

Secure prior approval from the RO if the SA wishes to rent equipment for more than 90 days.

6538 - Retirement and Social Security - SA Procedures

(Rev. 1, 05-21-04)

6538.1 - Retirement Contributions

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

Retirement contributions include SA cost (not employees’ share) of contributions to retirement funds such as State retirement or social security.

6538.2 - Prorating Costs

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

Where SA prorate personal services costs of State survey personnel, it prorates the retirement costs for these personnel.

6540 - Other Expenses - SA Procedures

(Rev. 1, 05-21-04)

“Other” expenses include expenditures that can be properly charged to the State survey program, but have not been provided for in any of the preceding classifications. Examples of such items are discussed below by category.

6542 - Consultants - SA Procedures **(Rev. 1, 05-21-04)**

Consultant services are generally defined as being furnished by persons who are not State employees, but who will be used on a part-time, temporary, or fee-for-service basis to provide needed skills to the State survey program.

6544 - Training of State Agency Personnel - SA Procedures **(Rev. 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).

6544.1 - Funding **(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)**

CMS will fund the entire cost of approved training of all employees. Funding for SA training is subject to the following considerations:

- Out-of-State attendance must be in accord with established State rules and regulations.

NOTE: When Federal requirements mandate that the training is necessary, SA travel policy for out-of-State travel is not an excuse for non-participation in the Federal training.
- Federal funds may not be used to attend any meetings or events if the attendee is paid by the sponsoring organization to attend or to speak or render other services in connection with the meeting.
- Attendance will not significantly impair work activities.

6544.2 - Requesting Approval

(Rev. 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.

6544.3 - Justification for Attendance

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

Where it is necessary to furnish detailed justification for attendance at short-term meetings, either in the original budget or later on in the fiscal year to the RO, (because, for example, the criteria in subsection B above are not met or the allotment is exhausted), the SA provides the following information:

- Name, position and title of each person proposed for attendance;
- A list of previous out-of-State training meetings attended by each proposed attendee during the current fiscal year (other than CMS-sponsored meetings) which were charged to Federal funds;
- An itemized listing of proposed expenditures for attendance, including travel, per diem, and admission fees; and
- Name, location, and dates of the meeting and a copy of the course announcement or bulletin, if available. Also, the SA submits a copy of the agenda or a list of the subject matter on the agenda and the name and address of the sponsoring organization. Where the description of the subject matter does not clearly establish that it relates to CLIA responsibilities, the SA provides an explanation of how the subject matter relates to CLIA responsibilities.

6544.4 - Fiscal and Reporting Considerations - the Amount Requested for Travel Costs of Such Activity

(Rev. 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.

6544.5 - Educational and Training Leave

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

Educational leave is leave granted for specialized professional or technical study in an accredited educational institution. Training leave is leave granted to an employee for attendance at short-term courses that will run longer than five working days, outside the agency. Approval of educational or training leave can only be granted if it is for purposes related to carrying out CLIA responsibilities. Additionally, State rules, regulations and practice must permit the taking of leave for such purposes. The SA obtains approval of training or educational leave, in advance, from the RO. Such

proposals are evaluated individually and specific circumstances and special problems are given proper consideration. The SA includes the following in its requests:

- Employee's name, type of appointment held, position and grade (salary), length of service with the SA, previous experience and education;
- Description of any other specialized training or courses taken by the employee within the previous 24 months;
- Name and location of training institution;
- Title and description of training in sufficient detail to demonstrate its scope, content, and how it relates to CLIA responsibilities. A copy of the training course announcement may help to fulfill this requirement;
- A statement indicating how this training will benefit the employee's work and improve the agency's activity;
- The training period showing the number of days and hours the employee will be absent from duty;
- A statement from the supervisor dealing with the ability of the unit to forego the services of the trainee during the training period; and
- The cost of tuition, fees, and books in detail. A copy of the training course announcement may help to fulfill this requirement.

6544.6 - Agreements by Employees to Continue on the Job
(Rev. 35; Issued: 04-18-08; Effective/Implementation Dates: 04-18-08)

In order to discourage resignation of an employee for whom there has been a considerable expenditure for formal training, some States require the employee to sign an agreement that she/he will remain on the job for a certain length of time (e.g., six months) after completing the training. If State regulation or practice provide for such agreements, the SA has the selected employee sign such an agreement after having obtained CMS approval for the activity.

6546 - Miscellaneous - SA Procedure
(Rev. 1, 05-21-04)

Items illustrative of this category, for example, are:

- Bonding and public liability;
- Equipment rental;

- SA cost (not employee's share) of workmen's compensation;
- Group insurance;
- Unemployment insurance; and
- Proportionate share of merit system of civil service charges.

Multi-program pro ration of costs always applies.

6546.1 - Bonding

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

Where a new bond or an amendment to an existing bond is required in relation to receiving and handling CLIA funds, the cost of the bond, when borne by the State, or the additional cost attributable to an amended bond, is a proper charge.

6546.2 - Public Liability

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

An appropriate share of the cost to protect against financial responsibility for injury to person or property is properly charged to CMS when such expenses are in the form of premiums for public liability or property damage insurance. The cost of awards, judgments, or settlements arising from injury to person or property are not chargeable to CMS.

The share of public liability and property damage insurance costs properly chargeable to CMS, in the case of motor pool or personally-owned vehicles used in the discharge of SA official business, is proportionate to that share of all travel of personnel of the agency which is devoted to activities directly concerned with the CLIA program.

The other items mentioned above may be prorated or charged directly as appropriate. If prorated, the method of prorating should be appropriate and acceptable to the State and to CMS. Thus, the costs of workmen's compensation, group insurance, or unemployment insurance would usually be charged directly for employees whose salary costs are prorated in the same ratio as the salary costs.

6548 - Goods, Facilities, Services From Other Staff or Local Agencies

(Rev. 1, 05-21-04)

6548.1 - Definition

(Rev. 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”*.

6548.2 - Centralized State Services

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

In some States services of an administrative nature (including certain commodities) such as accounting, printing, civil service, or central purchasing are furnished to various operating agencies of the State by specialized service departments outside the health department or other agency having an agreement or State plan with DHHS under §§1864 or 1903 of the Act. The SA allocates an equitable part of such charge to the State CLIA program if the services are necessary and are ones from which the program derives a benefit similar to that accruing to other units of the agency, and provided:

- The pro-rata charge to the CLIA program does not include costs attributable to the general expense of State government in carrying out the coordinating, fiscal, and administrative functions of government;
- The charge is based on reasonable cost; and
- The costs are extra, identifiable, and readily ascertainable either by segregation or as a prorated share of the cost of such facilities or services.

The SA describes the basis of the service agency’s charge, including the method of proration and the services provided and submits it for prior approval. The SA identifies such costs separately in the CLIA budget submittal.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R199SOM</u>	01/17/2020	Revisions to State Operations Manual (SOM) Chapter 6 - Special Procedures for Laboratories and Chapter 9 Exhibits	01/17/2020	N/A
<u>R195SOM</u>	11/15/2019	Revisions to State Operations Manual (SOM) Chapter 6 - Special Procedures for Laboratories and Chapter 9 Exhibits- Rescinded and replaced by Transmittal 199	11/15/2019	N/A
<u>R45SOM</u>	05/08/2009	Revisions to Chapter 6 - "Special Procedures for Laboratories	05/08/2009	N/A
<u>R35SOM</u>	04/18/2008	Revisions to Chapter 6 - "Special Procedures for Laboratories	04/18/2008	N/A
<u>R01SOM</u>	05/21/2004	Initial Issuance of Pub 100-07	N/A	N/A