



**Center for Clinical Standards and Quality/Survey & Certification Group**

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**Admin Info: 15-43-CLIA**

**DATE:** July 24, 2015

**TO:** State Survey Agency Directors

**FROM:** Director  
Survey & Certification Group

**SUBJECT:** FY 2016 Clinical Laboratory Improvement Amendments (CLIA) Budget Call Letter

**Memorandum Summary**

- **FY 2016 CLIA Budget Call Letter:** Enclosed is a copy of the FY 2016 CLIA Budget Call Letter.
- State workload targets are determined based on the staff required to survey each State's laboratory population. **State budgets should reflect the cost to perform the workload shown in this budget call.**
- Comments on the CLIA Budget Letter are due to the Centers for Medicare & Medicaid Services (CMS) Central Office (CO) by **July 31, 2015.**

**Background**

This memorandum provides information and guidelines for determining FY 2016 State Survey Agency (SA) CLIA budgets and projected workloads. While CLIA is a self-funded program, the authority to obligate funds is subject to an annual apportionment from the Office of Management and Budget (OMB). Although we have not received an apportionment for FY 2016 from OMB, all States within your regions should prepare FY 2016 budgets to reflect the workload and funding levels provided in this package. The State budget submissions should cover the period from October 1, 2015 through September 30, 2016. All budget documents must be prepared, transmitted, and certified utilizing the Automated Survey and Certification/CLIA Reporting System (ASCCRS). **Hardcopy budget forms should not be utilized.**

The CMS is continuing the "Waived Lab Survey" initiative to conduct on-site surveys of two percent of all laboratories holding a Certificate of Waiver (CW) and a follow-up survey of all labs receiving a Statement of Deficiencies or a Letter of Recommendation. Again for FY2016, States should be reminded that all CW survey activity planned (whether for full or partial year) should **not be included** in this budget submission – **a separate budget award for waived labs would apply for any waived lab activity either concurrent with or subsequent to the date of this instruction.**

While CW surveys will be budgeted separately from all other SA surveys, this should not prevent States from integrating the CW workload into the day- to-day survey operations to attain program efficiencies and other economies in the State's survey activity.

States preparing to apply for exemption of the State's laboratory program from CLIA should prepare budget proposals to avoid potential gaps in program funding and survey performance. States already having approval are not subject to this letter.

For FY 2016, the CMS CO will continue to monitor survey activity closely and provide periodic summary reports of national and State survey levels and statistics. Please continue to give careful attention to each State's progress in meeting negotiated workload targets, as well as the minimum national productivity standard of 120 surveys per surveyor full-time equivalents (FTEs) per year (112 initial/recertification and 8 follow-up surveys).

The proposed funding level for each State is based on the premise that the State is performing at the minimum national productivity standard. Those States indicating that they cannot perform the targeted workload within the suggested budget levels should be encouraged to bring productivity up to the minimum national standards. Continued under performance by any State(s) in your jurisdiction should be addressed prior to budget approval. However, the CMS CO recognizes there may be unique demographic and/or staffing situations that may prevent a State from meeting the minimum. We encourage you to identify those situations and notify us so that we can adjust accordingly.

### **Refinement to the Budget Process**

In addition to focusing on surveyor productivity and surveys completed, the CMS CO is continuing to refine the CLIA budget process to more accurately reflect State resource requirements for their workload. The FY 2016 instructions incorporate several significant changes and/or updates from the FY 2015 budget call, including:

- Updates the computation of budget amounts based on national survey performance times as recorded through the HCFA-670 survey reporting form (approximately 16,755 on-site initial/recertification and 492 on-site follow-up surveys from the period 10/1/12 through 9/30/14 were used in the calculation of the actual times required to perform laboratory surveys);
- Updates the total hours required to perform surveys within each State for FY 2016 by the amount of the State's variation from the national average travel time for initial /recertification and onsite follow-up survey hours (2.83 and .26 hours respectively). This methodology recognizes that while all States should perform surveys at the national average hours for each lab class, travel times vary by geographic location;
- Updates the formula for calculating funding required for proficiency testing (PT) monitoring. In the budget call for FY 2015 we estimated that approximately 3.3 percent of laboratories nationwide would experience at least one unsuccessful PT rating during each of the three yearly review cycles, with an average of 2.6 test failures per lab. For FY 2016 (based on actual PT results reported by the approved PT organizations for calendar

year 2014) the estimate of unsuccessful ratings increased to 4.3 percent while the test failures per lab estimate decreased to 2.5 percent;

- Maintains the State staffing ratio for clerical support at 1 clerical FTE to every 3 surveyor FTEs. Data indicates that, on a State by State basis, the additional need for clerical support for waived and provider perform microscopy procedure (PPMP) labs is small and continues to be partially offset by a drop in required clerical support for initial/recertification surveys;
- Addresses the National Cytology PT program and its impact on the CLIA workload and State budgets;
- Continues to reflect the current survey policy **suspending** Alternate Quality Assessment Survey (AQAS) surveys from October 1, 2004 indefinitely. **No States should be using the AQAS until otherwise notified;**
- Updated schedule and listing of CLIA course offerings for surveyors; and,
- Updates computer equipment requirements to support State hardware and software upgrade and/or procurement plans.

The requirement for State validation surveys of accredited labs remains at the FY 2015 level of 5 percent per survey cycle to reflect the continued need for enhanced oversight in this area. Additional funds have been included in the individual State budgets to accommodate this activity level.

We continue to attain a reasonable level of surveyor performance and productivity as shown by the changes in these parameters during FY 2014:

- Surveyor performance (efficiency): the national average hours to perform an initial or recertification survey (includes labs surveyed prior to termination) increased slightly this year from 12.03 to 12.26 hours. This measure remains **acceptably** below the national guideline “not to exceed 14 hours per survey;” and,
- Surveyor productivity (effectiveness): national average surveyor productivity, defined as the number of initial or recertification surveys per surveyor per year (includes labs surveyed prior to terminations), measured 92 surveys (a decrease from 93 for FY 2013). This performance remains **below** the targeted national yearly minimum of 112 initial/recertification surveys per surveyor. During FY 2014 thirty-four (34) States met or exceeded the 112 minimum initial/recertification productivity requirements. For FY 2016 the surveyor performance and productivity target will remain unchanged.

The survey workload continues the recent shift in laboratory registrations from compliance certification to the waived category. The FY 2016 national survey workload reflects a decrease of approximately 173 surveys (encompassing initials, validations, complaints, and follow-up surveys) from FY 2015 budget levels.

As a result, the nationwide FTEs ceiling for surveyors will decrease to 85.4 FTEs from 86.9 FTEs in FY 2015. State workload targets are determined based on the staff required to survey each State's laboratory population. **State budgets should reflect the cost to perform the workload shown in this budget call.**

Please inform the CMS CO Budget Staff if a State's request exceeds the amount in the call letter after negotiations, or if the State has data that is not consistent with what is reflected in this letter. State hiring plans, program driven efficiencies and number of surveys per surveyor should be closely evaluated in deciding a State's ability to meet survey targets. Attachments H1 and H2 should be used to identify those States that need to bring surveyor productivity into alignment with national performance standards.

### **Budget Negotiations**

Each State is required to submit a CLIA annual activity plan. This plan should build upon the FY 2016 budget and detail how the State expects to structure its laboratory surveyor program to complete the designated workload. Based on current workload assumptions, we estimate national staffing for FY 2016 at 85.4 State surveyor FTEs, a slight decrease nationwide from FY 2015. We are maintaining the ratio of 1 clerical to 3 surveyors. State budget submissions should reflect the number of positions (supervisory, surveyor, non-surveyor professional and clerical staff) currently authorized as well as planned new hires/attrition including data/justification for the additions. This should be stated both in the number of employees and FTEs. The submission should also address the State's plan for training surveyors and monitoring their performance. Finally, State plans should provide assurance that proposed CLIA FTE charges and all other CLIA funds allotted to SA's are used only for CLIA-related tasks as required by CLIA law. All cost estimates should be based on State specific hourly rates. Please notify the RO if SA salaries increase during the year, so that the State budget can be adjusted accordingly.

To assist in the budget negotiations with the States we have attached four charts that present projected State workload and funding levels for each State by region. These charts array projected State funding requirements for certificate and complaint/follow-up surveys of accredited and compliance laboratories. All amounts are calculated based on the unit cost methodology as described in the current user fee regulation. In addition, we are providing workloads arrayed by laboratory type (compliance or accredited) and by size (i.e., schedules LVA through J) for each State. A chart identifying the potential performance based survey population is attached to assist regions and States in determining their workload.

### **Program Goals**

State budget submissions should be reviewed closely to ensure that national CLIA annual and biennial goals are addressed. Thorough and well-structured action plans for addressing these goals and objectives must be included to ensure that the State has developed an effective strategy for achieving their performance targets. States should identify how national goals are being translated into individual performance objectives. Activity plans should be closely reviewed to ensure that these items are addressed.

## **General Budget Formulation Guidelines**

The State Operations Manual (SOM) contains information relevant to the budgetary process. You may also refer to the Code of Federal Regulations (CFR) Title 2, Part 200 “Uniform Requirements, Cost Principals and Audit Requirements for Federal Awards” which provides direction in determining the allowable costs of programs administered by State Governments under grants from, and contracts with, the Federal Government.

## **Budget Approved Forms**

We will continue to utilize the ASCCRS for our FY 2016 budget development and certification processes. (CLIA budget reporting formats CMS 102, CMS 105, 1465A, and 1466 are part of the complete CLIA budget package.) Using ASCCRS States will electronically prepare and certify budgets and, subsequent to RO and CO review, re-certify final budget approval packages. (For those States where the proposed budget is approved as submitted no re-certification will be necessary.) The following **development and reporting process steps must be followed:** Specifically, on a State by State basis, the following must occur:

- State develops, inputs and certifies its proposed FY 2016 budget into the ASCCRS;
- State notifies the region that its budget has been certified and is ready for review;
- Region reviews State’s electronic budget submission and negotiates with the State, as necessary, to reach agreement on final budget amounts;
- Following the State and RO budget negotiations (but prior to RO approval), the region notifies CO that the State’s budget proposal is ready for review;
- CO reviews and concurs/non-concurs with the proposed budget;
- CO notifies the RO of the approved funding level; and,
- RO approves budget (or notifies the State to recertify in the event of non-concurrence with requested funding levels).

The above process will be followed for each State within each RO. Please note that the ASCCRS includes report features which enable each RO to easily track (by year) the dates that the CMS-102 has been certified and approved.

## **Budget Assumptions**

The following assumptions underlie the guidance being provided in this package:

- Approximately 251,637 laboratories (includes 8,211 State exempt labs) are registered with the CLIA program. Surveys should be scheduled in the most efficient manner, independent of cycle status and effective dates, except that surveys cannot be conducted greater than twelve months prior to certificate expiration date or later than two years from this date. However, surveys should not be scheduled, wherever possible, until applicable fees are paid. We estimate that approximately 18,546 laboratories will hold compliance certificates (a decrease of approximately 340 labs from the prior year estimate) and 16,430 labs will hold certificates of accreditation (an increase of 301 from the prior year estimate). These counts exclude VA and State exempt labs.

- We have categorized the State biennial survey workload of approximately 20,507 total surveys as follows: 18,344 onsite compliance laboratory surveys (excludes Federal and State operated laboratories subject to regional office survey); 1,284 complaint/ follow up surveys of compliance laboratories; 879 validation surveys (including accredited complaint/follow-up visits).
- For FY 2016, we project a workload of approximately 9,172 compliance initial and recertification surveys, 642 complaint/follow-up onsite laboratory surveys (we estimate approximately 174 of the 642 will be complaint surveys), and 438 validations of accredited laboratories surveys. Laboratories that can provide documentation of accreditation by an approved accrediting organization, or those properly documented in our system as accredited, should not be surveyed except those selected for validation or as a result of a complaint.

### **Non-Accredited/Accredited Workload**

*Attachment A* represents the accredited and non-accredited survey workload and associated funding for each State in FY 2016. For every 14 initial or recertification surveys we are budgeting one follow-up survey. A follow-up survey (offsite and/or onsite) will be required for all condition level deficiencies. Offsite review of condition level deficiencies is encouraged with onsite revisits being reserved for more serious offenders or those that cannot be documented in another manner.

Complaints that cannot be resolved by an offsite investigation will continue to require an onsite survey. Cytology complaints should be forwarded to CMS CO cytology staff. Accredited laboratory complaints are to be coordinated through the RO and can be followed up by the State agency or forwarded to the appropriate accrediting organization with appropriate communication and coordination of all affected entities. Transfusion related fatality investigations must be performed by the State Agency or the regional office and may require collaboration with hospital or other provider programs and surveyors. All complaints will be entered into the ASPEN complaint tracking system. (From January 1, 2014 through December 31, 2014 approximately 280 complaints were entered into ACTS-CLIA of which 174 had surveys.)

Please note that we used adjusted actual survey times to compute the survey funding levels. National statistics on actual survey times were extracted from CMS-670 survey information and represent historical survey experience. The data have been adjusted by the amount of the State's variation from national travel time to reflect State specific geographies.

At this time, laboratory programs in Washington State and New York State (non-physician office laboratories) are exempt from CLIA. Workloads for these States have been either fully or partially excluded from the budget call and State funding has been adjusted to reflect the cessation of all or part of their surveys. When a State achieves CLIA exempt status the laboratories in the State covered by the exemption become the responsibility of the State and CMS provides no CLIA funding. **States applying for Exempt Status must prepare a budget and continue to perform CLIA surveys and other related CLIA functions until the exemption is approved and the Exempt State fee payment is received by CMS.**

States that have decided not to renew their CLIA exempt status should prepare their FY 2016 budget in accordance with instructions outlined in this call letter.

### **Supervisory and Clerical Support**

*Attachment B* represents funding, by State, for supervisory and clerical support. **States should be encouraged to continue to reduce the level of supervision whenever possible.** The supervisory ratio for FY 2016 remains unchanged at one (1) supervisory FTE to every seven (7) surveyor FTEs. We have also priced-out an allowable level of non-surveyor professional support staffing consistent with one (1) support FTE to every six (6) surveyor FTEs (unchanged from FY 2015). This ratio continues to recognize a State's need to operate in-house quality control and other administrative functions. These specific functions include, but are not limited to:

- Working with CO and RO on implementation of Individualized Quality Control Plan (IQCP);
- Responding to correspondence; data entry of new CLIA applications and related changes and evaluating lab director qualifications for all except certificate of waiver new applications;
- Addressing inquiries regarding technical survey findings/regulation interpretations;
- Identifying data needs and resolving data issues; analyzing data reports; making data system changes as notified;
- Formulating and executing State budgets;
- Enhancing laboratory education and public information;
- Developing internal survey policy, procedures, and guidelines in accordance with CMS policy;
- Hearing and appeals preparation; and other CLIA related enforcement matters;
- Supporting CLIA claims, denials, and certificate fee inquiries;
- Developing and sharing best practices;
- Participating in the development and implementation of surveyor guidelines, forms, SOM and all Survey and Certification administrative letters;
- Assisting in administrative responsibilities including documentation and productivity;
- Participating on workgroups and special projects as new issues and needs arise;
- Developing and monitoring records of SA CLIA activities of complaints;
- Coordinating with Program Integrity activities for laboratories and identifying and implementing an effective State Agency Performance Review (SAPR) program and evaluating the effectiveness of corrective actions taken in response to the CLIA SAPR and FMS;
- Facilitating orientation of new surveyors;
- Identifying and reporting to RO immediate jeopardy situations promptly;
- Making enforcement recommendations to RO;
- Attending and participating at CLIA CO/RO trainings and meetings as applicable;
- Ensuring Cytology PT enrollment and performance follow-up;
- Assisting with PT referral and direct-to-consumer testing investigations;
- Coordinating, assisting with the planning of, and attending annual mandatory CLIA Consortia Meetings;

For FY 2016, the CMS CO is maintaining the clerical ratio at one (1) clerical FTE to every three (3) surveyor FTEs. Maintaining the ratio will enable States to manage the workload associated with servicing the lab population of waived, microscopy and accredited laboratories as well as respond to the non-surveyable lab population during the year.

The clerical workload will include, but not be limited to:

- Continued workloads associated with inquiries arising from enrollment, fees, certificate issuance, reissuance, certificate status changes, billing and payment denials;
- Laboratory correspondence associated with surveys (e.g., announced surveys);
- Maintenance of the CLIA database and assimilation to new database processes and reporting systems;
- Preparation of data requests, reports and laboratory correspondence related to proficiency testing reviews;
- Telephone and other inquiry responses, including inquiries from some of the 28,000 waived/ microscopy labs receiving their 2016 renewal fees; and,
- Other data entry functions and laboratory communications.

### **Proficiency Testing**

*Attachment C* represents State allowances for funding proficiency testing (PT). These funds reflect the workload anticipated in FY 2016. Actual data for calendar year (CY) 2014 (the most recent complete calendar year data) showed the laboratory failure rate increasing to 4.3 percent year over year while the average test failures per lab decreased to 2.5 tests per lab. Accordingly, for FY 2016, we are providing funding based on the assumption that 4.3 percent of laboratories holding a certificate of compliance will receive an unsatisfactory rating with an average of 2.5 failures (unsatisfactory/ unsuccessful performance) per lab in their proficiency testing. The FY 2016 budget reflects an increase of (26.5 percent) in PT funding over FY 2015 levels due to a large increase in actual lab failures. PT should necessitate an average two hour review of each failure by State surveyors or other staff. PT reviews performed during an on-site survey may be used to compliment, but not substitute for, ongoing PT monitoring. PT should be routinely monitored per the SAPR protocol. Policies and procedures outlined in the Survey and Certification proficiency testing administrative letter must be followed.

### **Funding by State**

*Attachment D* represents the total budget allowance for each State by its four component pieces (non-accredited surveys, accredited surveys, support costs and proficiency testing). **We ask that you stay within the total funding amount shown for each State when negotiating budgets.**

### **Surveyor FTEs**

*Attachment E* represents the FY 2016 surveyor staffing levels for each State. Please instruct your States to work within the FTE levels in this chart when developing initial budget requests. As noted earlier for FY 2016, we are decreasing the recommended surveyor staffing from the FY 2015 level of 86.9 FTEs to 85.4 FTEs. The workloads established in the chart are our best

efforts to apportion funds to support State staffing, and are based on data representative of the current laboratory population. Both CMS RO and CO must approve any budget requests for FTEs higher than those indicated in this chart.

Funding levels provided in this budget require that a State be able to meet the minimum performance level of 120 (112 initial/recertification and 8 follow-up) surveys per surveyor per year. States exceeding, or demonstrating the ability to exceed, this performance level should be held at their authorized funding and staffing levels. States failing to meet the minimum performance standard should address those actions it will take to increase survey performance before budgets are approved. You are encouraged to use attachments H1 and H2 in conjunction with Attachment E to identify specific States survey times.

### **Alternative Surveys -State Laboratory Counts**

*Attachment F* - Activity on indefinite hold.

### **National Guidelines**

*Attachment G* represents national program emphases, guidelines and assumptions that each State must follow when preparing their FY 2016 CLIA budgets. You may forward this information directly to your States in order to provide direction and assistance for budget preparation.

### **HCFA- 670 Data**

*Attachment H* represents the national HCFA-670 data for both standard surveys and revisits that were used to formulate the States' budgets, as well as State-by-State survey travel times (this attachment is for your information). Average State survey times are included for comparison to the national average.

### **New, Termination, and Pending Lab Counts**

*Attachment I* identifies changes in the surveyable lab population on a State and regional level. State budget requests based on projected increases (or decreases) in their lab population may be compared against the information in Attachment I. While States may argue that new labs increase the workload, they need to evaluate the net difference between initial lab registrations, terminations and pending applications. Nationwide, during the one-year period ending January 31, 2015, a total of 741 new lab applications were either pending or approved for CLIA participation while 799 labs terminated CLIA.

### **Budget Packages**

All State budget packages must be prepared electronically using the ASCCRS – **no hard copy documents will be accepted**. The region will be responsible for notifying this office when the State and the region have come to agreement on the State proposals. (Notification should take place on or before the due date for budget submissions and directed to the attention of Herb Goodrich of the budget staff.) Once we have received notice, the proposals entered into the ASCCRS will be considered the official State budget-funding request for FY 2016.

The instructions and guidelines in this package are to be used as the basis for negotiation of FY 2016 CLIA workloads and funding levels with State agencies within each region. Please continue to maintain close liaison with us to address States' questions that may arise during budget negotiations.

**Contact:** If you have any questions or need further clarification pertaining to information provided in the budget call letter, please call David Escobedo at (410) 786-5401 or have your staff contact Herb Goodrich (410) 786-3234 of the budget staff.

**Effective Date:** Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment (s):

Attachment A1  
Attachment A2  
Attachment A3  
Attachment A4  
Attachment B  
Attachment C  
Attachment D  
Attachment E  
Attachment F  
Attachment G  
Attachment H1  
Attachment H2  
Attachment H3  
Attachment I

cc: Survey and Certification Regional Office Management