



Center for Clinical Standards and Quality/Survey & Certification Group

Admin Info: 16-30-CLIA

DATE: September 02, 2016

TO: State Survey Agency Directors

FROM: Director
Survey & Certification Group

SUBJECT: Fiscal Year (FY) 2017 Clinical Laboratory Improvement Amendments (CLIA)
Budget Call Letter

Memorandum Summary

- **FY 2017 CLIA Budget Call Letter:** Enclosed is a copy of the FY 2017 CLIA Budget Call Letter.
- State staffing targets are determined based on the workload required to survey each State's laboratory population. **State budgets should reflect the cost to perform the workload shown in this budget call.**
- State Budget submittals are due to the Centers for Medicare & Medicaid Services (CMS) Central Office (CO) by **September 21, 2016.**

Background

CMS is providing information and guidelines for determining FY 2017 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 2017 from OMB, all States should prepare FY 2017 budgets to reflect the workload and funding levels provided in this package. The State budget submissions should cover the period from October 1, 2016 through September 30, 2017. 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.**

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) with a follow-up survey of all labs receiving a Statement of Deficiencies or a Letter of Recommendation. All CW survey activity planned should **not be included** in this budget submission – **a separate budget award for waived labs will apply for any waived lab activity either at the date of this instruction or after.** This separate budget should not preclude 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.

For FY 2017, CMS will continue to monitor survey activity closely and provide periodic summary reports of national and State survey levels and statistics. Each State should continue to work toward meeting the 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 eight follow-up surveys).

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 are encouraged to bring productivity up to the minimum national standards. The CMS Regional Offices (ROs) should address continued under performance by any State(s) prior to budget approval.

Key Points for FY 2017

- The State staffing ratio for clerical support is maintained at one clerical FTE to every three surveyor FTEs.
- The requirement for State validation surveys of accredited labs remains at the level of five percent per survey cycle.
- The supervisory ratio for FY 2017 remains unchanged at one supervisory FTE to every seven surveyor FTEs.
- The allowable level of non-surveyor professional support staffing is one support FTE to every six surveyor FTEs (unchanged from FY 2016).
- The number of survey hours should not exceed 14 per survey.
- The number of initial/recertification surveys remains at a minimum of 112 per surveyor.
- The nationwide FTE ceiling for surveyors will decrease from 85.4 to 84.2.
- 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 as both the number of employees and the number of FTEs.
- The budget submission should address the State's plan for training surveyors and monitoring their performance.
- 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 (notify the RO if SA salaries increase during the year, so that the State budget can be adjusted accordingly).
- 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.

Budget Process

Each State is required to submit a CLIA annual activity plan. This plan should build upon the FY 2017 budget and detail how the State expects to structure its laboratory surveyor program to complete the designated workload. For FY 2017, we project a workload of approximately 9,032 compliance initial and recertification surveys, 632 complaint/follow-up onsite laboratory surveys (we estimate approximately 175 of the 632 will be complaint surveys), and 438 validations of accredited laboratories surveys.

We will continue to utilize the ASCCRS for our FY 2017 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, on a State by State basis:**

- State develops, inputs and certifies its proposed FY 2017 budget into the ASCCRS;
- State notifies the region that its budget has been certified and is ready for review;
- RO 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.

All State budget packages must be prepared electronically using the ASCCRS – **no hard copy documents will be accepted**. The RO will be responsible for notifying CO when the State and the RO 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 Division of Survey & Certification and CLIA Budget (DSCB). Once we have received notice, the proposals entered into the ASCCRS will be considered the official State budget-funding request for FY 2017.

The instructions and guidelines in this package are to be used as the basis for negotiation of FY 2017 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.

Attachment G (**Guidelines and Program Emphases to be followed by States in Preparing FY 2017 CLIA Budgets**) provides detailed information on budget preparation for the States.

Additional References:

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 Principles 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.

Contact: If you have any questions or need further clarification pertaining to information provided in the budget call letter, please contact the Director, DSCB, Jeffrey Pleines at (410) 786-0684 or Herb Goodrich (410) 786-3234.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 5 days of this memorandum.

/s/

David R. Wright

Attachment (s):

- Attachments A1-A4: FY 2017 Accredited and non-accredited survey workload, hours, and associated funding for each State.
- Attachment B: FY 2017 State funding for supervisory, clerical and non-surveyor professional support.
- Attachment C: FY 2017 State allowances for funding proficiency testing (PT).
- Attachment D: FY 2017 Total budget estimates for each State.
- Attachment E: FY 2017 Surveyor staffing levels per State.
- Attachment F: Alternative Quality Assessment Surveys Notice
- Attachment G: Guidelines and Program Emphases to be followed by States in Preparing FY 2017 CLIA Budgets
- Attachment H: FY 2017 National HCFA-670 data for standard surveys and revisits, survey travel times.
- Attachment I: FY 2017 Changes in survey able laboratory population on State/Regional level.

cc: Survey and Certification Regional Office Management