Supporting Statement for the Post Clinical Laboratory Survey Questionnaire (CMS-668B/OMB # 0938-0653) and Supporting Regulations in 42 CFR 493.1771, 493.1773, and 493.1777

Background

42 U.S.C. 263a contains the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) concerning certification requirements for any facility that performs tests on human specimens. The law also includes requirements for approval of accreditation bodies and State licensure bodies, inspections, sanctions, judicial review, fees and disclosure of information to the public. Subject to specified exceptions, a laboratory must have a current unrevoked and unsuspended certificate to be eligible for reimbursement in the Medicare or Medicaid programs or both.

The law provides for an onsite inspection on an announced or unannounced basis during regular hours of laboratory operation. In conducting such inspections, all records and information having a bearing on whether the laboratory is being operated in accordance with the law can be requested by the surveyor. These inspections are conducted on a biennial basis.

Implementing CLIA regulations are found in 42 CFR Part 493.

The Post Laboratory Survey Questionnaire, Laboratory, CMS-668B, was approved for the first time on August 23, 1994. Since the initial approval, there have been several changes to both the instrument and its focus.

For this current extension of the CMS-668B, we have made no revisions to the instrument since the last approval. The purpose of the current extension is to give laboratories receiving a CLIA survey by CMS or CMS' agent a mechanism for expressing their satisfaction with the CLIA survey process. We will not use this form to make any program adjustments and will continue to use an outside entity to collect the form. Completion of this form will be voluntary. All information will be kept confidential. Each calendar year, we will perform an overview evaluation of the completed forms and will release only a summary of the information collected to the State Agencies (SAs) and CMS Regional Offices (ROs).

We continue to receive anecdotal evidence that CLIA laboratories need a mechanism to relay their feelings and concerns about their recent CLIA survey. CMS's Division of Laboratory Services is requesting OMB to extend the approval the Post Laboratory Survey Questionnaire-Laboratory Form, CMS-668B. This form asks the laboratory to provide, after their compliance survey, information concerning their satisfaction with the CLIA survey process. This form will allow the laboratory an opportunity to comment and to express their

concerns about their recent CLIA survey.

A. Justification

1. Need and Legal Basis

The information collected on this survey form is used in the administrative pursuit of the Congressionally-mandated program with regard to regulation of laboratories participating in CLIA.

Legislative authority for this activity is 42 U.S.C. 263a; regulatory authority, 42 CFR 493.

The CMS Form 668B has been developed to assess the survey process from the viewpoint of the laboratory. The document has been designed to obtain information succinctly and give the laboratories the opportunity to report their satisfaction with the survey process. The CMS Form 668B will require an estimated 15 minutes to complete.

The SA or CMS RO will have surveyors leave this form with all laboratories that receive either an onsite survey or the alternate quality assessment survey (i.e., paper survey of quality indicators). The laboratory will be asked to complete this form; however, completion is voluntary. CMS Central Office will perform an overview evaluation of the completed forms. Each calendar year, a summary of the information collected will be sent to the SA and RO.

2. Information Users

CMS form 668B will be used by the laboratory to express its satisfaction with the survey process and will allow the laboratory the opportunity to make recommendations for improvement.

3. Use of Information Technology

This form is electronically available on the Internet at http://www.cms.hhs.gov/CMSForms/. This collection is not currently available for completion electronically.

4. Duplication of Efforts

This form will be the only means of collecting this information.

5. Small Business

This information collection does not significantly affect small businesses that

operate as laboratories that are regulated under CLIA. We have designed this form to collect only the information necessary to address the laboratory's satisfaction with the CLIA survey process. We have attempted to minimize the burden by shortening this form to one page.

6. Less Frequent Collection

Under CLIA, laboratories are required to be surveyed once every 2 years. If this information would be collected less frequently, the findings of this questionnaire would not be timely and not correspond to the laboratory's actual survey.

7. Special Circumstances for Information Collection

These requirements comply with all general information collection guidelines in 5 CFR 1320.6. There are no special circumstances associated with this collection.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on May 22, 2015. There were no comments received. No other outside consultation was sought.

9. Payments or Gifts to Respondents

There are no payments or gifts associated with this collection.

10. Confidentiality

We pledge privacy and will only display the data collected in an aggregate form.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this form.

12. Estimate of Burden

This form contains information that addresses a laboratory's satisfaction with the CLIA survey process. The time requirement for completion of this form is approximately 15 minutes. We based the number of laboratory respondents as 19,051. Using 15 minutes as the time for completion and basing the number of laboratories on 19,051, the following computation is appropriate.

Private Sector
17,648 (laboratories) (biennial review)/2 = 8824 laboratories per year
X 0.25 hours per response = 2,206 annual burden hours

State, Local or Tribal Government

1,319 (laboratories) (biennial review)/2 = 659.5 laboratories per year
X 0.25 hours per response = 165 annual burden hours

Federal Government
84 (laboratories) (biennial review)/2 = 42 laboratories per year
X 0.25 hours per response = 11 annual burden hours

Total
19,051 (laboratories) (biennial review)/2 = 9525.5 laboratories per year
X 0.25 hours per response = 2,382 annual burden hours

We estimate these information collection requirements will cost $6.88 (0.25 hrs X $27.50 per hour) for each form collected.

Private Sector
2,206 annual burden hours X $6.88 = $15,177.28

State, Local or Tribal Government
165 annual burden hours X $6.88 = $1,135.20

Federal Government
11 annual burden hours X $6.88 = $75.68

Total
2,382 annual burden hours X $6.88 = $16,388.16

13. Capital Costs

There is no capital cost associated with this collection.

14. Cost to Federal Government

Cost estimates are based on printing 20,000 forms that are a tri-fold, prepaid and self-addressed mailer; the estimated cost is $5,500 for printing and $9,800 for the return postage. We will also incur costs for the collection of these forms by an outside entity; we estimate that cost to be $35,000. The total cost is $50,300.

15. Changes in Burden/Program Changes

No program changes. The burden has been adjusted to account for the smaller number of respondents (20,486 in the 2012 estimate and 19,051 in this submission).

16. Publication and Tabulation Dates

There are no publication and tabulation dates associated with this collection.

17. Expiration Date

CMS would like an exemption from displaying the expiration date as these forms are used on a continuing basis. To include an expiration date would result in having to discard a potentially large number of forms.