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

A. 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 for use through September 1996. For the first approval, this form provided an avenue for the laboratory to make the Centers for Medicare & Medicaid Services (CMS) aware of any operational changes the laboratory made in response to CLIA and allowed the laboratory to assess the survey process. The Office of Management and Budget (OMB) approved this form with the understanding that this stand-alone survey effort as it was designed was inadequate for evaluating satisfaction with the CLIA survey process, for the laboratory universe or a specific subgroup of laboratories.

Between September 1, 1995 to February 1, 1996, CMS's Division of Laboratory Services (DLS), who is responsible for the administration of the CLIA program, conducted a pilot study to validate concerns addressed in the original approval. A pilot of the CMS-668B was conducted in the Chicago Regional Office (RO) and the Kansas City RO. Of the 600 CMS-668B forms given to surveyed CLIA laboratories in the pilot, only 122 forms were returned for evaluation (response rate of 20%). The responses were representative of each type of laboratory in the CLIA database and at the same approximate frequency. After summarizing the responses, it was determined that OMB's concerns were valid.

On February 13, 1996, the CLIA program launched a performance-based survey process for all providers of laboratory testing, entitled the "Alternate Quality

Assessment Survey" (AQAS). The AQAS is a self-survey form that is a paper survey of quality indicators and is used in lieu of an onsite survey. Laboratories that were surveyed under the CLIA program and found to have exceptional performance; i.e., no or minor deficiencies and satisfactory proficiency testing, are potential candidates for the AQAS. In addition, no laboratory will go longer then 4 years without an onsite survey and CMS also surveys a five percent sample of the self-assessed laboratories to verify the effectiveness of the program.

Based upon information obtained in the pilot study and the launch of AQAS process, DLS decided to redesign the Post Laboratory Survey Questionnaire-Laboratory, CMS Form 668B in 1996. We redesigned this form and included comments received from CLIA surveyors in the ROs and State Agencies (SAs). The focus of the redesigned form was to only address a laboratory's satisfaction with the survey process and its objective was to evaluate laboratory satisfaction with the CLIA survey process on a nationwide basis. Due to the response rate seen in the pilot of this form, all laboratories being surveyed under CLIA, by either the onsite process or the AQAS process, would receive this form. To adjust for biases due to CMS's role in regulating laboratories, we decided that this would be a voluntary form, all information would be kept confidential and only summarized information would be given to the SAs and ROs.

Once this form was redesigned, a small sample was piloted in each RO during December 1996. The purpose of this second pilot was to ensure that the form's instructions were clear and understandable and that laboratories would find this form easy to answer. In addition, a form design expert in the Health Standards and Quality Bureau of CMS evaluated this form. The CMS Form 668B was modified using all suggestions.

The 1996-redesigned CMS-668B form was approved by OMB on July 22, 1997 for use through July 2000. This form was approved with the understanding that CMS must submit a plan to OMB for achieving a response rate adequate to support inference to the entire laboratory population and subgroup of interest, and that CMS must explain how it will evaluate non-response bias and its follow-up procedures that minimize bias and maximize response rate. OMB clarified that if CMS cannot invest in appropriate follow-up for the universe of laboratories, it may consider once again sampling but with a larger universe than in the last fielding.

Since DLS did not have either the financial or staffing resources to invest in a follow-up of each laboratory that would receive this instrument, we decided to continue to sample but included a larger universe. Our universe included all laboratories that received a CLIA compliance survey across that nation; however, the following were not included in our sampling:

- Laboratories in States that were currently using a post survey

satisfaction questionnaire;

- Laboratories in States that were exempt from the requirements of CLIA;
- Laboratories in States with limited resources; and,
- Laboratories that received a complaint survey.

This sampling was implemented on September 1, 1998 and continued until July 31, 2000.

We presented preliminary findings from the first three quarters of this sampling to the Clinical Laboratory Improvement Advisory Committee (CLIAC) on September 22, 1999. Since most responses received to this questionnaire were positive, CLIAC recommended using an outside entity to collect the data.

For the 2000 extension (approved for use through August, 2003), we made a few minor changes to the CMS-668B instrument, used an outside entity to collect this data and modified the purpose of this form. The purpose of this form was changed to only giving laboratories that received a survey by CMS or CMS' agent a mechanism for expressing their satisfaction with the CLIA survey process. We did not use this form to make any program adjustments but used the information to suggest areas of the survey process that may need to be re-evaluated. In addition, we still kept this a voluntary form, kept all information confidential, and only released summarized information.

For the last two extensions and the current extension of the CMS-668B, we have made no revisions to either the instrument or its purpose and will continue to use an outside entity to collect the form. Since anecdotal evidence has suggested that CLIA laboratories continue to need a mechanism to relay their feelings and concerns about their recent CLIA survey, CMS's DLS 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 (onsite or AQAS), 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.

B. 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 AQAS (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 and send the forms to the RO. 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. Furthermore, the information gathered may be used to improve and possibly shorten the survey process.

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

A 60-day Federal Register notice for an extension of this currently OMB approved collection was published on 12/15/2008, attached. The publication of this notice was used to solicit outside consultation. 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 21,000. Using 15 minutes as the time for completion and basing the number of laboratories on 21,000, the following computation is appropriate.

Private Sector
19,291 (laboratories) (biennial review)/2 = 9,645.5 laboratories per year
X 0.2499 hours per response = 2,410.41 annual burden hours

State, Local or Tribal Government
1,620 (laboratories) (biennial review)/2 = 810 laboratories per year
X 0.2499 hours per response = 202.419 annual burden hours

Federal Government
89 (laboratories) (biennial review)/2 = 44.5 laboratories per year
X 0.2499 hours per response = 11.12055 annual burden hours

Total
21,000 (laboratories) (biennial review)/2 = 10,500 laboratories per year
X 0.2499 hours per response = 2,623.95 annual burden hours

13. Capital Costs

There is no capital cost associated with this collection.

14. Cost to Federal Government

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

Private Sector
19,291 (laboratories) (biennial review)/2 = 9,645.5 laboratories per year
X $6.88 = $66,361.04

State, Local or Tribal Government
1,620 (laboratories) (biennial review)/2 = 810 laboratories per year
X $6.88 = $5,572.80

Federal Government
89 (laboratories) (biennial review)/2 = 44.5 laboratories per year
X $6.88 = $306.16

Total
21,000 (laboratories) (biennial review)/2 = 10,500 laboratories per year
X $6.88 = $72,240.00

Cost estimates are based on printing 29,000 forms that are a tri-fold, prepaid and self-addressed mailer; the estimated cost is $5,200 for printing and $12,180 for mailing. We will also incur costs for the collection of these forms by an outside entity; we estimate that cost to be $30,000.

15. Changes in Burden/Program Changes

There is no change in burden since the number of respondents has remained the same since our last collection.

There are no program changes that affect this form.

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.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

There are no statistical methods employed in this information collection.