Billing Code:

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-12-12PZ]

Proposed Data Collections Submitted for

Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-7570 or send comments to Kimberly S. Lane, at 1600 Clifton Road, MS D74, Atlanta, GA 30333 or send an email to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on

respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Proficiency Testing in US Clinical Laboratories: Perception, Practices and Potential for Expanded Utility –NEW-the Office of Surveillance, Epidemiology and Laboratory Services (OSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The primary focus of this project is to conduct a systematic analysis in order to understand which types of laboratories would be likely to follow Proficiency Testing (PT) Good Laboratory Practices (GLPs). The Association of Public Health Laboratories (APHL) and CDC (Centers for Disease Control and Prevention) hope to learn more about which laboratories are not following Clinical Laboratory Amendments of 1988(CLIA) PT guidelines and the reasons why. Our survey population frame is 20,500 Certificate of Compliance laboratories and 16,800 Certificate of Accreditation laboratories. All of these laboratories are required to perform PT in accordance with the

CLIA. Many of these labs also use their PT results internally for laboratory quality improvement (PT GLPs).

In addition, Centers for Medicaid and Medicare Services (CMS) and CDC are currently collaborating to revise the CLIA regulations to update the list of non-microbiological tests (analytes) for which PT is required, and to update the requirements for microbiology PT. Both of these changes are expected to have some impact on clinical and public health laboratories, but CDC has very little data to estimate the impact. This information is needed to complete the regulatory impact analysis. The Department of Health and Human Services knows very little about which analytes are tested in the affected laboratories other than those for which PT is required by CLIA regulations. This survey will ask laboratories whether they offer testing for candidate analytes, and how the regulatory changes would impact their costs and PT practices in their laboratory. Similarly for microbiology laboratories, CMS and CDC are considering whether to remove the levels of service model for PT enrollment. Therefore the survey will ask a sample of microbiology laboratories how this and other potential changes would impact their costs, PT practices, and perceived risk of failing PT.

The goal of this project is to complete a needs assessment to identify the populations that would benefit from receiving information on PT GLPs. Since laboratories already pay for these PT materials, information provided to further use PT for quality improvement purposes has the potential to further improve laboratory quality at no additional cost to US clinical laboratories.

The first phase of this project was conducted by Association of Public Health Laboratories (APHL) through focus group research in 2011. The focus groups explored how clinical and public health laboratories perceived commercial PT programs, and explored the ways in which the laboratories used PT (GLPs) to assure and improve the quality of testing in their own laboratories. This second phase of the project will be administration of a survey to help identify laboratories that would benefit from learning additional uses for PT and providing information on how to disseminate them to laboratories in a strategic and targeted way.

The goal is to achieve an 80% response rate (29,840 out of 37,300 labs). APHL and CDC will strive to ensure a high response rate by promoting the survey through advertisements in laboratory trade publications, at professional meetings, and

possibly through programs and laboratory accreditation organizations.

The cohort of laboratories will be all laboratories listed in the Centers for Medicare and Medicaid (CMS) Online Survey, Certification and Reporting (OSCAR) database. The OSCAR database contains demographic information and practice characteristics for all laboratories included in the database.

The survey will be administered through a web-based survey system, specifically Survey Monkey. APHL will send each laboratory a postmarked letter explaining the survey and providing them with a link to log in to the survey with a unique identifier on their address label. Two weeks afterwards, APHL will follow-up with a postcard reminder which will also include that unique identifier on the address label.

Approximately 37,300 clinical laboratories will be targeted and solicited to take the on-line survey. Each laboratory is permitted to submit only one completed survey. Preliminary pilot testing indicates completion of the on-line survey will take approximately 15 minutes. Assuming a 80% response rate, there would be 29,840 respondents.

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hrs)	Total Burden (in hrs)
Laboratorians	Laboratory Practices	29,840	1	20/60	9947
				Total	9947

Date: July 31, 2012

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Ron A. Otten, Ph.D.
Director, Office of Scientific Integrity (OSI)
Office of the Associate Director for Science (OADS)
Office of the Directors
Centers for Disease Control and Prevention

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