Dated: February 5, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–13–0848]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Laboratory Medicine Best Practices Project (LMBP) (0920–0848, exp. 5/31/2013)—Extension—Office of Surveillance, Epidemiology and Laboratory Services (OSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC is seeking approval from the Office of Management and Budget (OMB) to collect information from healthcare organizations in order to conduct a systematic review of laboratory practice effectiveness. The purpose of information collection is to include completed unpublished quality improvement studies/assessments carried out by healthcare organizations (laboratories, hospitals, clinics) in systematic reviews of practice effectiveness. CDC has been sponsoring the Laboratory Medicine Best Practices (LMBP) initiative to develop new systematic evidence reviews methods for making evidence-based recommendations in laboratory medicine. This initiative supports the CDC's mission of improving laboratory practices.

The focus of the Initiative is on pre- and post-analytic laboratory medicine practices that are effective at improving health care quality. While evidence-based approaches for decision-making have become standard in healthcare, this has been limited in laboratory medicine. No single-evidence-based model for recommending practices in laboratory medicine exists, although the number of laboratories operating in the United States and the volume of laboratory tests available certainly warrant such a model.

The Laboratory Medicine Best Practices Initiative began in October 2006, when DLS convened the Laboratory Medicine Best Practices Workgroup (Workgroup), a multidisciplinary panel of experts in several fields including laboratory medicine, clinical medicine, health services research, and health care performance measurement. The Workgroup has been supported by staff at CDC and the Battelle Memorial Institute under contract to CDC.

To date, the Laboratory Medicine Best Practices (LMBP) project work has been completed over three phases. During Phase 1 (October 2006–September 2007) of the project, CDC staff developed systematic review methods for conducting evidence reviews using published literature, and completed a proof-of-concept test. Results of an extensive search and review of published literature using the methods for the topic of patient specimen identification indicated that an insufficient quality and number of studies were available for completing systematic evidence reviews of laboratory medicine practice effectiveness for multiple practices, and hence for making evidence-based recommendations. These results were considered likely to be generalizable to most potential topic areas of interest.

A finding from Phase 1 work was that laboratories would be unlikely to publish quality improvement projects or studies demonstrating practice effectiveness in the peer reviewed literature, but that they routinely conducted quality improvement projects and had relevant data for completion of evidence reviews. Phase 2 (September 2007–November 2008) and Phase 3 (December 2008—September 2009), involved further methods development and pilot tests to obtain, review, and evaluate published and unpublished evidence for practices associated with the topics of patient specimen identification, communicating critical value test results, and blood culture contamination. Exploratory work by CDC supports the existence of relevant unpublished studies or completed quality improvement projects related to laboratory medicine practices from healthcare organizations. The objective for successive LMBP evidence reviews of practice effectiveness is to supplement the published evidence with unpublished evidence to fill in gaps in the literature.

Healthcare organizations and facilities (laboratory, hospital, clinic) will have the opportunity to voluntarily enroll in an LMBP network and submit readily available unpublished studies; quality improvement projects, evaluations, assessments, and other analyses relying on unlinked, anonymous data using the LMBP Submission Form. LMBP Network participants will also be able to submit unpublished studies/data for evidence reviews on an annual basis using this form. There will be no charge to respondents for their participation. The total estimated annualized burden hours for this information collection request are 100 hours.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Healthcare Organizations	150	1	40/60

Dated: February 5, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–12PZ]

Agency Forms Undergoing Paperwork Reduction Act Review

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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 follow Proficiency Testing (PT) and Good Laboratory Practices (GLPs), to identify ways that PT and GLPs could be better promoted, and to identify populations that would benefit from receiving information on PT GLPs. The Association of Public Health Laboratories (APHL) and Centers for Disease Control and Prevention (CDC) hope to learn more about the perceived benefits and burden of performing PT. This information may be helpful to the CDC as the Clinical Laboratory Improvement Amendments (CLIA) regulations for PT are revised. 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 CLIA. Many of these laboratories also use their PT results internally to further improve laboratory quality at no additional cost.

The first phase of this project was conducted by the APHL through focus group research in 2011. The research explored how clinical and public health laboratories perceived commercial PT programs and explored the ways in which the laboratories used PT to assure and improve the quality of their testing. This second phase of the project will be administration of a survey to build on the preliminary findings from the focus group research and help identify the types of laboratories that would benefit from learning about additional uses for PT. This information will be helpful to disseminate PT and GLPs to laboratories in a strategic and targeted way based on findings from this survey.

The goal is to achieve an 80% response rate (29,840 out of 37,300 laboratories). 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 surveyed will be all Certificate of Compliance and Certificate of Accreditation laboratories listed in the Centers for Medicare and Medicaid Services (CMS) Online Survey, Certification and Reporting (OSCAR) database. The OSCAR database contains demographic information and relevant characteristics including laboratory specialty and laboratory type for each laboratory.

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 provide 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.

There are no costs to respondents other than their time.

The annualized estimated burden is 9,947 hours.

Estimated Annualized Burden Hours:

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs)
Laboratorians	Laboratory Practices	29,840	1	20/60

Dated: February 5, 2013.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–13–12PE]

Agency Forms Undergoing Paperwork Reduction Act Review

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Proposed Project

Interventions to Reduce Shoulder MSDs in Overhead Assembly—New—National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The mission of the National Institute for Occupational Safety and Health (NIOSH) is to promote safety and health