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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-13-0848]

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 and send comments to Ron Otten, 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

Laboratory Medicine Best Practices Project (LMBP), OMB Control Number 0920-0848, Expiration 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 systemic evidence reviews 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 The purpose of information collection is to include completed unpublished quality improvement studies/assessments carried out by healthcare organizations (laboratories, hospitals, clinics) in systematic reviews of practice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 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 CDC 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 registrant 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 registrants will also be able to submit unpublished studies/data for evidence reviews on an annual basis using this form. There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Respondents	No. of respondents	No. of Responses per respondent	Average Burden per response (in hrs)	Total Burden (in hours)*
Healthcare Organizations	150	1	40/60	100
Total				100

DATE: November 26, 2012

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