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[FR Doc. 2014–29047 Filed 12–10–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–15–15GE]

Proposed Data Collections Submitted for Public Comment and Recommendations

The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. To request more information on the below proposed project or to obtain a copy of the information collection plan and instruments, call 404–639–7570 or send comments to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30333 or send an email to *omb@cdc.gov.*

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget (OMB) approval. 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; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. Written comments should be received within 60 days of this notice.

Proposed Project

Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics—Clinical and Laboratory Standards Institute—NEW—Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention is funding three 5-year projects collectively entitled ''Improving the Impact of Laboratory Practice Guidelines: A New Paradigm for Metrics''. An ''LPG'' is defined as written recommendations for voluntary, standardized approaches for medical laboratory testing that takes into account processes for test selection, sample procurement and processing, analytical methods, and results reporting for effective diagnosis and management of disease and health conditions. LPGs may be disseminated to, and used by, laboratorians and clinicians to assist with test selection and test result interpretation. The overall purpose of these cooperative agreements is to increase the effectiveness of LPGs by defining measures and collecting information to inform better LPG creation, revision, dissemination, promotion, uptake, and impact on clinical testing and public health. The project will explore how these processes and their impediments and facilitators differ among various intended users of LPGs. Through this demonstration project, CDC seeks to understand how to customize LPG creation and promotion to better serve these intended users of LPGs. An important goal is to help organizations that sponsor the development of LPGs create a sustainable approach for continuous quality improvement to evaluate and improve an LPG's impact through better collection of information.

The CDC selected three organizations that currently create and disseminate LPGs to support activities under a cooperative agreement funding mechanism to improve the impact of their LPGs. The American Society for Microbiology, the Clinical and Laboratory Standards Institute (CLSI), and the College of American Pathologists, will each use their LPGs as models to better understand how to improve uptake and impact of these and future LPGs. Only the CLSI submission will be described in this notice.

Specifically, the CLSI project will address two LPGs that are important to clinical testing and have a high public health impact: *POCT12, Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities* and *POCT13, Glucose Monitoring in Settings without Laboratory Support.* These LPGs provide guidance and recommendations for personnel monitoring patient glucose levels at sites that have access to a hospital laboratory as well as locations, such as physician offices or nursing homes that do not have an on-site moderate or high complexity laboratory. It is expected that as a result of sustained improvements in the process of creating and updating these clinical LPGs, public health, which depends upon accurate and appropriate laboratory testing guided by the use of LPGs, will also generally benefit. The intended users of the CLSI's *POCT12* and *POCT13* LPGs will include point-of-care coordinators, clinical laboratory directors, medical technologists, nurses, and medical doctors.

The CLSI plans to collect information using the same survey instrument, ''Fingerstick Glucose Survey'' (FGS), on three separate occasions. During the first information collection (FGS1), all targeted respondents will be asked to complete the survey. Respondents who indicate that they are not familiar with either *POCT12* or *POCT13* will be asked to provide an email address and offered a free copy of the applicable LPG. This subset of respondents will be asked to complete the same survey (FGS2) 4–6 months after receiving the free LPG. After analysis of the information collected during the first two surveys, CLSI will make improvements to *POCT12* and *POCT13,* such as provision of educational materials or helpful products such as quality control logs, and may also alter their marketing campaigns to address issues related to awareness and use of CLSI documents.

The third survey (FGS3) will then be sent to all targeted respondents approximately 2.5 years after the first survey to obtain information that can be used to evaluate the impact of these improvements. Respondents that received a free copy of *POCT12* or *POCT13* following the first survey will also be contacted by email and asked to take the third survey.

A link to the survey will be distributed to all targeted respondents either by email or postcard. The CLSI

will solicit participation from physician office laboratories, Department of Defense laboratories, and hospitals that offer point-of-care glucose testing. Participants will be recruited by COLA, the Joint Commission and a Point-of-Care Coordinator network, who have agreed to distribute links to the survey through their membership mailing lists. In addition, participants will also be solicited through mailing lists purchased by CLSI from Clinscan and the American Hospital Association. Clinical sites offering point-of-care glucose testing in the Department of Defense medical system will also be asked to participate through the Department of Defense Clinical Laboratory Improvement Program (CLIP). In order to obtain the needed number of respondents for a statistically valid study, additional laboratories, selected at random from a database of Clinical Laboratory Improvement Amendment (CLIA) certificate holders, will also be solicited. The survey will contain instructions to direct it to the individual in each laboratory responsible for the development or revision of procedures for fingerstick glucose testing. Directing the survey to the individual with this specific responsibility will help to ensure that only one response will be obtained from each participating laboratory. Respondents include point-of-care coordinators, clinical laboratory directors, managers, and supervisors, medical technologists, nurses, and medical doctors.

The CLSI hopes to achieve an 80% response rate with their laboratory information collections, or 24,000 out of about 30,000 potential respondents. The second survey will occur approximately 4–6 months after the initial survey and will only target responders from the first survey that received a complimentary copy of one of the LPG documents. CLSI anticipates that approximately 12,000 participants will be asked to take the second survey. Approximately two and a half years after the initial survey, the same survey will be sent to the same laboratories as the first survey (*i.e.* we will solicit approximately 30,000 potential respondents and expect about 24,000 individuals to take the survey). The third survey will measure the impact of the modifications to the documents and marketing strategy made based on the data collected from the first 2 surveys. The response rate for all surveys will be maximized by repeated reminders using the same channel that will be used to distribute the survey. All targeted laboratories will receive an email or postcard approximately one month before distribution of the survey. This letter will describe the survey and our purpose for collecting information. Another email or post card with a link to the survey will be sent to the same targeted laboratories. We also plan to resend the link to the survey to all targeted laboratories approximately one month later to remind them of the survey.

The CLSI believes completion of the survey will take approximately 15 minutes. The survey will be pilot tested with 9 or fewer respondents before deployment to assure that they require 15 minutes or less to take.

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 hours)	Total burden hours
Point-of-Care Coordinators	FGS1	500	1	15/60	125
	FGS2	250	1	15/60	63
	FGS3	500	1	15/60	125
Laboratory Directors	FGS1	4,276	1	15/60	1,069
	FGS2	2,138	1	15/60	535
	FGS3	4,276	1	15/60	1,069
Laboratory Managers	FGS1	4,276	1	15/60	1,069
	FGS2	2,138	1	15/60	535
	FGS3	4,276	1	15/60	1,069
Laboratory Supervisors	FGS1	4,276	1	15/60	1,069
	FGS2	2,138	1	15/60	535
	FGS3	4,276	1	15/60	1,069
Medical Technologists	FGS1	7,800	1	15/60	1,950
	FGS2	3,900	1	15/60	975
	FGS3	7,800	1	15/60	1,950
Nurses	FGS1	5,000	1	15/60	1,250
	FGS2	2,500	1	15/60	625
	FGS3	5,000	1	15/60	1,250
Medical Doctors	FGS1	3,500	1	15/60	875
	FGS2	1,750	1	15/60	438
	FGS3	3,500	1	15/60	875
Total					18,520

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[FR Doc. 2014–29036 Filed 12–10–14; 8:45 am]

BILLING CODE 4163–18–P