DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15CK]

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 (LPGs): A New Paradigm for Metrics- College of American Pathologists – 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, and the College of American Pathologists (CAP), will each use their LPGs as models to better understand how to improve uptake and impact of these and future LPGs. Only the CAP submission will be described in this notice.

The CAP project will address two LPGs that are important to clinical testing: immunohistochemistry test validation (IHC) and an algorithm for diagnosing acute leukemia (ALA). The ALA LPG is being co-developed with the American Society of Hematologists (ASH). The intended users of the CAP's IHC LPGs will include pathologists, clinical laboratory directors, and laboratory managers overseeing the IHC staining department. For the CAP's ALA LPG the intended users are pathologists and hematologists overseeing testing for acute leukemia. Thus, all these professionals will be surveyed by CAP.

Prior to entering into this cooperative agreement project with the CDC, the CAP had already completed a baseline IHC LPG information collection from laboratories that used IHC testing. Subsequent to this data collection, the CAP created and disseminated an IHC LPG in a peer reviewed journal. Because of this prior baseline assessment, the CAP will only need to collect post-dissemination data. For their ALA LPG CAP/ASH Algorithm for Initial Work-Up of Acute Leukemia, the CAP will conduct both a baseline and a post-dissemination survey. Because there are uncertainties concerning the specific focus group probes for the IHC LPG and the ALA LPG, this notice only provides a description of our collection of post-dissemination information for the IHC LPG and the baseline ALA LPG.

The CAP hopes to achieve an 80% response rate, or 2,668 out of 3,335 potential respondents. This represents laboratories known to be currently performing IHC testing based upon their participation in CAP's IHC proficiency testing (PT) program and 450 additional laboratories identified by CDC using previous CMS Part B reimbursement claims for IHC testing. The response rate for the baseline IHC survey was approximately 70% but through more focused promotion the CAP hopes to increase participation. We have identified a total of 3,335 (2,885 CAP-accredited + 450

non-CAP-accredited) laboratories that will be targeted by the IHC post-dissemination survey.

CAP-accredited laboratories that are enrolled in IHC PT will receive surveys with their PT mailings. Non-CAP-accredited laboratories will be surveyed via the US postal system, with a fax-back mechanism.

The CAP will need to collect both baseline and post-guideline dissemination data for the ALA LPG. CAP will allow only one response per computer internet protocol address. The CAP has a database of pathologists who have indicated specialization in hematopathology; these hematopathologists will be invited to participate. The CAP hopes to achieve an 80% response rate with their individual data collections, or 880 (80% x 1100 pathologists listed in the CAP database).

The baseline survey for the ALA guideline includes questions about individual practices for diagnosing various types of acute leukemia and individual and laboratory reporting practices. The link to the baseline survey for the ALA guideline will be disseminated via email to hematopathologists in CAP's database, who will be provided a link to the Qualtrics site that hosts the survey.

The CAP and CDC will strive to ensure a high response rate for their IHC and ALA surveys. CAP plans to advertise both surveys. Similarly, the CAP plans to maximize response rates for non-CAP-accredited laboratories by sending reminders through the US postal system. The CAP will also try to maximize response rates for the ALA survey by advertising it through various channels.

For burden calculation, we assume one response per laboratory. We assume respondents for the IHC survey will include 1) pathologists, 2) laboratory directors, and 3) other laboratory managers of IHC laboratories, which may consist of graduate level scientists (PhDs and Masters level), approximately in a 25%:25%:50% distribution, respectively. We assume respondents for the ALA surveys will include pathologists and hematologists that sign out cases, approximately in a 95%:5% distribution, respectively.

The IHC baseline survey, which was conducted prior to this CAP-CDC cooperative agreement, took 15 minutes to complete. The IHC post-dissemination survey and the ALA baseline survey are also expected to take 15 minutes. Each survey will be pilot tested with nine or fewer respondents before deployment to

assure that they require 15 minutes or less to complete. CDC is requesting a one-year OMB approval to collect the information. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Pathologist	IHC	834	1	15/60	209
	ALA	1,045	2	15/60	523
Laboratory Directors	IHC	834	1	15/60	209
Laboratory Managers	IHC	1,667	1	15/60	417
Hematologist	ALA	55	2	15/60	28
Total					1,386

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