DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-15-15CK]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond,

including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 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 (ASM), the Clinical and Laboratory Standards Institute (CLSI), 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 Hematology (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 information 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 evaluation using a survey and/or focus group. 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 2668 out of 3335 potential respondents for the IHC LPG. 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 Centers for Medicare and Medicaid Services Part B reimbursement claims for IHC testing. The response rate for the baseline IHC survey was approximately 70% and more focused promotion is planned. We have identified a total of 3335 (2885

CAP-PT customers + 450 non-CAP-PT customers) laboratories that will be targeted by the IHC post-dissemination survey. Both populations represent laboratories that are CAP-accredited and non-CAP-accredited.

Laboratories that are enrolled in CAP IHC PT programs will receive surveys with their PT mailings. Non-CAP-PT-customer laboratories will be surveyed via the US postal system, with a fax-back mechanism. Only one response per laboratory will be accepted.

The CAP will need to collect both baseline and post-guideline dissemination information 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 information 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. The online survey will be hosted by Survey Monkey.

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 CAP-PT customer laboratories by sending reminders through the PT program. The CAP will also try to maximize response rates for the ALA survey by advertising it through various channels and sending an email reminder.

For burden calculation, we assume one response per laboratory for the IHC survey to 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 may include multiple responses within a laboratory of 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 is expected to take 20 minutes to

complete. The ALA baseline survey is expected to take an average of 25 minutes to complete. The maximum times observed during pilot testing were 30 and 45 minutes, respectively. Results from the pilot tests were used to revise both surveys.

The total Estimated Annualized Burden Hours for this ICR is 1,570. There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Type of Respondents	Form Name	No. of Respondents	No. of Responses per Respondent	Avg. Burden per Response (in hrs.)
Pathologists	IHC	834	1	20/60
	ALA	1,045	1	25/60
Laboratory Directors	IHC	834	1	20/60
Laboratory Managers	IHC	1,667	1	20/60
Hematologists	ALA	55	1	25/60

Leroy A. Richardson,
Chief, Information Collection Review Office,
Office of Scientific Integrity,
Office of the Associate Director for Science,
Office of the Director,
Centers for Disease Control and Prevention.

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