This document is scheduled to be published in the
Federal Register on 04/20/2016 and available online at
http://federalregister.gov/a/2016-09190, and on **FDsys.gov**

BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-16-1067]

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 projects or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice 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 (OMB Control No. 0920-1067) – Revision – 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 (CDC) funded the College of American Pathologists (CAP) as one of three professional organizations in 5-year cooperative agreement 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. 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.

One of the awardees is the College of American Pathologists (CAP). This revision request concerns additional information collection relating to the CAP's LPG for immunohistochemistry (IHC) testing, for which a post dissemination survey was approved under OMB Control No. 0920-1067 and has been completed. We are requesting a revision to the OMB-approved 0920-1067 package by adding two information collections: telephone interviews and focus groups as a follow-up to the completed IHC LPG post survey to further explore the survey findings that are being analyzed now. The questions to be used for the telephone interviews and focus groups are based on the questions and results of the IHC post survey, to help CAP and CDC

better understand the impediments and facilitators that affect uptake of the IHC LPG. The intended participants in the proposed telephone interviews and focus groups will be selected from the IHC post survey respondents which include pathologists, pathology chairs, clinical laboratory directors, laboratory managers overseeing the IHC staining department, laboratory supervisors, and histotechnologists.

This revision request represents a decrease in burden. The proposed telephone interviews will explore the impediments and facilitators that affect uptake and use of the CAP IHC LPG, both generally and concerning specific recommendations. This will be followed by two focus groups, arranged into two peer groups of pathologists (composed of pathologists, pathology chairs, and laboratory directors) and non-pathologist laboratory professionals (composed of laboratory managers, laboratory supervisors, and histotechnologists for the purpose of estimating burden), which will allow us to collect information on the current usage of CAP's tools and resources (toolkit) to facilitate implementation of the IHC guideline for its future improvement.

For this request, the CAP will collect information via 40 telephone interviews (20 pathologists, 10 laboratory directors, and 10 laboratory managers). The telephone interview questions are scripted to be completed within 20 minutes by each respondent (0.33 hour per respondent or ~13 hours total). Because the CAP anticipates that approximately 121 laboratory individuals (41 pathologists, 40 laboratory directors, and 40 laboratory managers) will need to be

contacted to reach 40 individuals who will voluntarily participate, and the burden for those individuals who will not go on to participate (81) in the telephone interview is one minute, the total burden for individuals who decline participation is 81 minutes (1.35 hours.

In addition, the CAP will conduct two focus group sessions and invite 12 participants to each of the sessions, composed of the following respondent types: (4) pathologists, (4) pathology chairs, (4) laboratory directors, (4) laboratory managers, (4) laboratory supervisors, and (4) histotechnologists. Each of the focus groups will last no more than 60 minutes (1.0 hour) which is based on standard focus group planning instructions, inclusive of time required to complete informed consent (24 hours or 1,440 minutes total burden). It is anticipated that 200 individuals will be contacted to determine their availability to participate in one of the two focus group sessions and each will take no longer than 5 minutes to read and respond to the invitation letter (~17 hours or 1000 minutes total). The 200 individuals contacted will be composed of the following respondent types: (34) pathologists, (33) pathology chairs, (33) laboratory directors, (34) laboratory managers, (33) laboratory supervisors, and (33) histotechnologists.

This revision includes three types of laboratory professionals who were not included in the original OMB-approved submission: pathology chairs, laboratory supervisors, and histotechnologists. Because the OMB-approved IHC post-survey has been completed, this

request for approval of additional data collection (telephone interviews and focus groups) is a reduction of burden. The total new burden for this revision request will be ~58 hours which is a reduction of 1,512 hours from the previously approved submission. A total of 321 respondents (121 invited to take the telephone interview and 200 invited to participate in focus groups), is a reduction of 4,114 respondents with an approved burden of 1,570 hours and 4,435 respondents).

There are no costs to respondents other than their time.

Estimated Annualized Burden Hours

Form Name	Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)
IHC telephone interview-contacted	Pathologists	41	1	1/60
	Laboratory Directors	40		
	Laboratory Managers	40		
IHC telephone interview	Pathologists	20	1	20/60
	Laboratory Directors	10		
	Laboratory Managers	10		
IHC focus group invitation	Pathologists	34	1	5/60
	Pathology Chairs	33		
	Laboratory Directors	33		
	Laboratory Managers	34		
	Laboratory Supervisors	33		
	Histotechnologists	33		
IHC focus	Pathologists	4	1	1

group	Pathology Chairs	4		
	Laboratory Directors	4		
	Laboratory Managers	4		
	Laboratory Supervisors	4		
	Histotechnologists	4		

_____

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.

[FR Doc. 2016-09190 Filed: 4/19/2016 8:45 am; Publication Date: 4/20/2016]