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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15DA]

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"- American Society for Microbiology – 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, 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 ASM submission will be described in this notice.

The ASM project will address four LPGs that are important to clinical testing and have a high public health impact: reducing blood culture contamination (BCC), rapid diagnosis of blood stream infections (BSI), proper collection and transport of urine (UT), and microbiological practices to improve the diagnosis and management of patients with *Clostridium difficile* (*C. difficile*) infection (CDI). The BCC LPG was published and it includes recommendations for the use of: (1) venipuncture over catheters as the preferred technique for sample collection in a

clinical setting, and (2) phlebotomy teams over non-phlebotomist staff for collecting blood for culture. The BSI report examines the effectiveness of rapid diagnostic tests to promote more accurate and timely administration of targeted antibiotic therapy for patients with bloodstream infections. This report will be published and recommendations will be developed based on additional information collected. Practices related to the collection, storage and preservation of urine for microbiological culture that improve the diagnosis and management of patients with urinary tract infections were analyzed and approved recommendations will be published. Microbiological practices related to improving diagnosis and management of patients with *C. difficile* infection will be collected and analyzed, and recommendations will also be developed and published.

The intended respondents of ASM's surveys will include microbiology supervisors, laboratory directors, and laboratory managers. For this request for OMB approval of a new information collection, we will be requesting approval to collect baseline and post-dissemination information for the BCC LPG. Because the BSI, UT and CDI reports are not yet published, ASM will conduct a baseline survey to determine current practices prior to dissemination of the LPGs.

On behalf of the ASM and the CDC, the Laboratory Response Network (LRN), which was founded by the CDC, will recruit laboratories that perform the kinds of testing affected by these LPGs to take the surveys. Messages regarding ASM surveys will be worded as an invitation, not as a coercive request. Some states may opt not to recruit LRN laboratory participation, but because the issues are important to clinical and public health, we expect good participation by most states. This mechanism will assure the best response rate of all the options we considered.

The CDC LRN Coordinator will email a letter to the Laboratory Director of the LRN Reference Laboratories, (i.e., 50 State Public Health Laboratories, the New York City Public Health Laboratory and the Los Angeles County Public Health Laboratory). These 52 LRN Reference Laboratory Directors will be asked to then email the sentinel laboratories, which include hospital and independent laboratories, in their states, and provide a hyperlink to access the survey tool on-line via a landing page provided by ASM through their Clinical Microbiology portal. Survey Monkey will be used as the data collection instrument and responses will be collected and maintained by ASM. We anticipate that a maximum of 4,200 sentinel laboratories will be contacted and asked to complete the survey on-line. ASM anticipates achieving an 80% response rate with their

information collections, or 3,360 out of ~4,200 aggregate responses for each of the 5 different surveys.

For burden calculations, we assume one respondent per laboratory and we also assume respondents will include microbiology supervisors, laboratory directors, and laboratory managers, approximately in a 50%:25%:25% distribution, respectively. According to ASM, the burden hours per respondent who will be invited to participate in the BCC baseline and post-dissemination surveys and the BSI, UT and CDI baseline surveys will be 20 minutes. This time frame was specified based on ASM's previous experiences conducting laboratory surveys. Each survey will be pilot tested with 9 or fewer respondents before dissemination to assure that completing the surveys does not extend past 20 minutes.

CDC is requesting a three-year OMB approval to collect this 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	Avg. Burden per Response (in hrs.)	Total Burden (in hrs.)
Microbiology Supervisors	BCC	2,100	2	20/60	1,400
	BSI	2,100	1	20/60	700

	UT	2,100	1	20/60	700
	CDI	2,100	1	20/60	700
Laboratory Directors	BCC	1,050	2	20/60	700
	BSI	1,050	1	20/60	350
	UT	1,050	1	20/60	350
	CDI	1,050	1	20/60	350
Laboratory Managers	BCC	1,050	2	20/60	700
	BSI	1,050	1	20/60	350
	UT	1,050	1	20/60	350
	CDI	1,050	1	20/60	350
				Total	7,000

Leroy A. Richardson,
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