ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Potential LA-PrEP users or Clients	Client Screening Survey & Consent Form	8,050	1	10/60
	C4P Client DCE Survey	1,610	1	25/60
Clinical providers who prescribe PrEP, in the United States.	Provider Screening Survey & Consent Form	1,150	1	10/60
	C4P Provider DCE Survey	230	1	20/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–1310; Docket No. CDC–2022–0119]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats. This collection will allow CDC to partner with public health laboratories and will help equip them to detect and characterize isolates.

DATES: CDC must receive written comments on or before December 12, 2022.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2022–0119 by any of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: *Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.*

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

Proposed Project

Public Health Laboratory Testing for Emerging Antibiotic Resistance and Fungal Threats (OMB Control No. 0920–1310, Exp. 12/31/2023)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This state and local laboratory testing capacity is being implemented by the Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) in response to the Executive Order 13676 of September 18, 2014 (Attachment 1a), the National Strategy of September 2014 (Attachment 1b) and to implement sub-objective 2.1.1 of the National Action Plan of March 2015 for Combating Antibiotic Resistant Bacteria (Attachment 1c). Data collected throughout this network is also authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

The Antibiotic Resistance Laboratory Network (AR Lab Network) is made up of jurisdictional public health laboratories (*i.e.,* all 50 states, five large cities, and Puerto Rico). These public health laboratories will be equipped to detect and characterize isolates of carbapenem-resistant Enterobacteriaceae (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), and carbapenem-resistant *Acinetobacter baumannii* (CRAB), as well as carbapenemase-positive organisms (CPOs) from colonization screening swabs. These resistant bacteria are

becoming more and more prevalent, particularly in healthcare settings, and are typically identified in clinical laboratories, but characterization is often limited. The laboratory testing will allow for additional testing and characterization, including use of gold-standard methods. Isolate characterization includes organism identification, antimicrobial susceptibility testing (AST) to confirm carbapenem resistance and determine susceptibility to new drugs of therapeutic and epidemiological importance, a phenotypic method to detect carbapenemase enzyme production, and molecular testing to identify the resistance mechanism(s). Screening swabs will undergo molecular testing to identify whether carbapenemase-producing organisms are present.

Results from this laboratory testing will be used to: (1) identify targets for infection control; (2) detect new types of resistance; (3) characterize geographical distribution of resistance; (4) determine whether resistance mechanisms are spreading among organisms, people, and facilities; and (5) provide data that informs state and local public health surveillance and prevention activities and priorities. Additionally, some jurisdictions will participate in reference identification of *Candida* spp. to aid in these pursuits using matrix-assisted laser desorption ionization/time-of-flight (MALDI–TOF) mass spectrometry or deoxyribonucleic acid (DNA) based sequencing.

CDC's AR Lab Network supports nationwide lab capacity to rapidly detect antibiotic resistance and inform local public health responses to prevent spread and protect people. It closes the gap between local capabilities and the data needed to combat antibiotic resistance by providing comprehensive lab capacity and infrastructure for detecting antibiotic-resistant pathogens, cutting-edge technology like DNA sequencing, and rapid sharing of actionable data to drive infection control responses and help treat infections. This infrastructure allows the public health community to rapidly detect emerging antibiotic-resistant threats in healthcare and the community, mount a comprehensive local response, and better understand these deadly threats to quickly contain them. A subset of jurisdictions will participate in detection and characterization of AR *Neisseria gonorrhoeae,* including antimicrobial susceptibility testing of *Neisseria gonorrhoeae.*

Funded state and local public health laboratories will provide the following information to the Program Office at CDC's Division of Healthcare Quality Promotion (DHQP):

1. Annually, participating laboratories will submit a summary report describing testing methods and volume. These reports will be submitted by email to *ARLN_DHQP@cdc.gov.* These measures are to be used by the DHQP Program Office to determine the ability of each laboratory to confirm and characterize targeted AR organisms and their overall capacity to support state healthcare-associated infection (HAI)/AR prevention programs.

2. Annually, participating laboratories will provide an Evaluation and Performance Measurement Report to CDC via email to *HAIAR@cdc.gov.* Data will be used to indicate progress made toward program objectives and challenges encountered.

3. Participating laboratories will report all testing results to CDC, at least monthly, by CSV or Health Level 7 (HL7) using an online web-portal transmission. This information will be used to: (a) provide data for state and local infection prevention programs; (b) identify new types of antibiotic resistant organisms; (c) identify new resistance mechanisms in targeted organisms; (d) describe the spread of targeted resistance mechanisms; and (e) identify geographical distribution of antibiotic resistance or other epidemiological trends. Participating laboratories will utilize secure public health messaging protocols to transfer data to CDC and submitting facilities and clinical laboratories. For messaging to CDC, these protocols will be based in Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS) platform. The AIMS platform is a secure environment that provides shared services to assist public health laboratories in the transport, validation and routing of electronic data. AIMS is transitioning to the use of HL7 messaging for data to be transmitted in real-time, allowing more frequent reporting or results while simultaneously lessening burden on public health laboratories.

4. Detection of targeted resistant organisms and resistance mechanisms that pose an immediate threat to patient safety and require rapid infection control, facility assessments, and/or additional diagnostics, an immediate communication to the local healthcare-associated infection program in the jurisdictional public health department and CDC is needed. The ''AR Lab Network Alerts'' encompass targeted AR threats that include new and rare plasmid-mediated (''jumping'') carbapenemase genes, isolates resistant to all drugs tested, and detection of human reservoirs for transmission. These alerts must be sent within one working day of detection. Participating laboratories will utilize REDCap to communicate these findings. The elements of these messages will include the unique public health laboratory specimen ID and a summary of its testing results to date.

Sites participating in *Candida* identification testing will also provide the following to the Mycotics Program Office at CDC—Division of Foodborne, Waterborne, and Environmental Diseases (DFWED):

1. Annually, participating laboratories will provide an Evaluation and Performance Measurement Report to CDC via email to *ARLN@cdc.gov.* Data will be used to indicate progress made toward program objectives and challenges encountered.

2. Participating laboratories will report all testing results to CDC, requested at least monthly, by REDCap or HL7 using an online web-portal transmission. This information will be used to: (a) identify and track antifungal resistance and emerging fungal pathogens; and (b) aid public health departments and healthcare facilities in rapidly responding to fungal public health threats and outbreaks. Participating laboratories will utilize secure public health messaging protocols to transfer results data to CDC. For messaging to CDC, these messaging protocols will be based in REDCap or the AIMS platform. The REDCap and AIMS platforms are secure environments that provide shared services to assist public health laboratories in the transport, validation and routing of electronic data. AIMS is transitioning to the use of HL7 messaging for data to be transmitted in real-time, allowing more frequent reporting of results while simultaneously lessening burden on public health laboratories.

3. For those resistant organisms that pose an immediate threat to patient safety and require rapid infection control, facility assessments, and/or additional diagnostics, an immediate communication to the local healthcare-associated infection program in the jurisdictional public health department and CDC is needed. The ''AR Lab Network Alerts'' encompass targeted AR threats that include *C. auris,* which is rapidly emerging in healthcare settings. These alerts must be sent within one working day of detection. Participating laboratories will utilize REDCap and/or email to *ARLN_alert@cdc.gov* to communicate these findings. The

elements of these messages will include the unique public health laboratory specimen ID and a summary of specimen testing results to date.

Sites participating in detection and characterization of AR Neisseria gonorrhoeae, including antimicrobial susceptibility testing of *Neisseria gonorrhoeae* will provide the following to the STD Laboratory Reference and Research Branch (SLRRB) at CDC—Division of STD Prevention (DSTDP):

1. Annually, participating laboratories will provide an Evaluation and Performance Measure Report. Data will be used to indicate progress made toward program objectives and challenges encountered.

2. Participating laboratories will notify CDC DTSDP of any isolate(s) identified to demonstrate an ''alert'' MIC as defined by SLRRB within one working day. Laboratories will utilize REDCap to communicate these findings. The elements of these messages will include the unique public health laboratory specimen ID and a summary of specimen testing results to date.

3. Participating laboratories will report all testing results to CDC, requested at least monthly, by email, REDCap, or HL7 using an online web-portal transmission. This information will be used to: (a) identify and track antibiotic resistant pathogens and emerging patterns of resistance; and (b) aid public health departments and healthcare facilities in timely responding to antibiotic resistant public health threats and outbreaks. Participating laboratories will utilize secure public health messaging protocols to transfer results data to CDC, submitting facilities and clinical laboratories. For messaging to CDC, these messaging protocols will be based in REDCap or the AIMS platform. The REDCap and AIMS platforms are secure environments that provide shared services to assist public health laboratories in the transport, validation, and routing of electronic data. AIMS is transitioning to the use of HL7 messaging for data to be transmitted in real-time, allowing more frequent reporting of results while simultaneously lessening burden on public health laboratories.

CDC requests OMB approval for an estimated 4,705 annualized burden hours. There is no cost to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Public Health Laboratories	Annual Report of Bacterial Specimen Testing Methods.	56	1	6/60	6
Public Health Laboratories	Annual Evaluation and Performance Measurement Report for Bacterial Specimen Testing.	56	1	4	224
Public Health Laboratories	Monthly Testing Results Reports—Bacterial Specimen Testing.	56	12	4	2688
Public Health Laboratories	AR Lab Network Alerts—Bacterial Specimen Testing.	56	34	6/60	190
Public Health Laboratories	Annual Evaluation and Performance Measurement Report (*Candida* identification).	Up to 56	1	2	112
Public Health Laboratories	Monthly Testing Results Reports—*Candida* identification.	Up to 56	12	2	1344
Public Health Laboratories	AR Lab Network Alerts—*Candida auris*.	Up to 56	13	6/60	73
Public Health Laboratories	Annual Evaluation and Performance Measurement Report (*Neisseria gonorrhoeae*).	Up to 56	1	1	56
Public Health Laboratories	Monthly Testing Results Reports—*Neisseria gonorrhoeae*.	Up to 56	1	6/60	6
Public Health Laboratories	AR Lab Network Alerts—*Neisseria gonorrhoeae*.	Up to 56	1	6/60	6
Total					4705

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3431–N]

Medicare Program; Virtual Meeting of the Medicare Evidence Development and Coverage Advisory Committee—December 7, 2022

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: This notice announces a virtual public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) (''Committee'') will be held on Wednesday, December 7, 2022. National Coverage Determinations resulting in coverage with evidence development (CED) can expedite earlier Medicare beneficiary access to innovative technology while ensuring that systematic patient safeguards are in place to reduce the risks inherent to new technologies, or to new