notice will be summarized for, and included with, the OGE Generic Clearance request. The comments will also become a matter of public record.

Approved: June 11, 2024.

Shelley K. Finlayson,

Acting Director, U.S. Office of Government Ethics.

[FR Doc. 2024–13189 Filed 6–14–24; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–24–1310; Docket No. CDC–2024–0051]

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 proposed and/or 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 Antimicrobial Resistance and Fungal Threats. This data collection is designed to allow CDC to test and characterize, antimicrobial resistant bacteria and fungal isolates.

DATES: CDC must receive written comments on or before August 16, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2024–0051 by either 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 Antimicrobial Resistance and Fungal Threats (OMB Control No. 0920–1310, Exp. 5/31/2026)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

State and Local laboratory testing capacity is 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, the National Strategy of September 2014 and to implement the National Action Plan of October 2020 for Combating Antibiotic Resistant Bacteria. Data collected throughout this network is also authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

The Antimicrobial 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 as described. Carbapenemase-producing organisms: equipped to detect and characterize carbapenem-resistant Enterobacterales (CRE), carbapenem-resistant *Pseudomonas aeruginosa* (CRPA), and carbapenem-resistant *Acinetobacter baumannii* (CRAB) isolates and detect carbapenemase-producing organisms (CPOs) from screening swabs. Characterization of these resistant bacteria, which are typically identified in clinical laboratories, is often limited despite the fact they are becoming more prevalent, particularly in healthcare settings. The proposed laboratory testing will allow for additional testing and characterization, including use of validated high-quality 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 (*e.g.,* whole genome sequencing [WGS]) to identify the resistance mechanism(s). Screening swabs will undergo molecular testing to identify carbapenemase genes 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, participating jurisdictional public health laboratories will also participate in reference

identification of *Candida* spp. A subset of these laboratories will also conduct testing on Candida isolates and screening swabs, and *Aspergillus fumigatus.* The capacity to test for fungal pathogens at local clinical and public health laboratories is limited, and therefore the proposed laboratory testing will truly build infrastructure and ensure that validated high-quality methodologies are used. Fungal isolate characterization includes identification, antifungal testing to determine susceptibility to new drugs of therapeutic and epidemiological importance. Screening swabs will undergo the same series of validated tests, after *Candida* spp. are grown from the swab. Results from this laboratory testing will be used locally to: (1) support infection control, efforts; (2) monitor resistance; (3) characterize geographical distribution of resistance; and (5) provide data that informs state and local public health surveillance and prevention activities and priorities.

A subset of jurisdictions will perform routine antimicrobial susceptibility testing for *N. gonorrhoeae.* Also, a subset of local and state public health laboratories in the AR Lab Network will be using validated agar dilution and/or gradient strip diffusion assays to assess the levels of susceptibility in gonococcal isolates to 10 different antimicrobial agents. Several identified resistance isolates will undergo high-quality whole genome sequencing. AST and WGS data are critical for public health actions and for gonorrhea control efforts including gonococcal antimicrobial resistance surveillance, and to curtail the spread of antimicrobial-resistant *N. gonorrhoeae.*

In addition to the testing that is done throughout the AR Lab Network, performance measures are collected from each laboratory, to ensure that participating laboratories are making progress. The purpose of collecting performance measures is to facilitate informed decision-making for the AR Lab Network, to improve the technical assistance provided to the participating AR Lab Network partners, and to measure progress across the AR Lab Network.

CDC's AR Lab Network supports nationwide lab capacity to rapidly detect antimicrobial resistance and inform local public health responses to prevent spread and protect people. It closes the gap between local laboratory capabilities and the data needed to combat antimicrobial resistance by providing comprehensive lab capacity and infrastructure for detecting antimicrobial-resistant pathogens (germs), advanced 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 antimicrobial-resistant threats in healthcare, food, and the community, mount a comprehensive local response, and better understand these deadly threats to quickly contain them.

Funded State and Local Public Health Laboratories will provide the following information to the Division of Healthcare Quality Promotion (DHQP) Program Office at CDC about carbapenemase-producing organisms:

1. Annually, participating laboratories will submit a summary report describing testing methods and volume. These reports will be submitted through REDCap. And are to be used by DHQP 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 Performance Measures data through the Epidemiology and Laboratory Capacity performance measures portal. 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: (1) provide data for state and local infection prevention programs; (2) identify new types of antimicrobial resistant organisms; (3) identify new resistance mechanisms in targeted organisms; (4) describe the spread of targeted resistance mechanisms; and (5) identify geographical distribution of antimicrobial resistance or other epidemiological trends. Participating laboratories will utilize secure public health messaging protocols to transfer results 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 Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) Mycotics Program Office at CDC:

1. Annually, participating laboratories will provide Performance Measures data through the Epidemiology and Laboratory Capacity performance measures portal. 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 Health Level 7 (HL7) using an online web-portal transmission. This information will be used to: (1) identify and track antifungal resistance and emerging fungal pathogens; and (2) 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, 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.

Sites participating in detection and characterization of AR *Neisseria gonorrhoeae,* including antimicrobial

susceptibility testing of *Neisseria gonorrhoeae* will provide the following to the Division of STD Prevention (DSTDP), STD Laboratory Reference and Research Branch (SLRRB) at CDC:

1. Annually, participating laboratories will provide Performance Measures data through the Epidemiology and Laboratory Capacity performance measures portal. 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'' 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 Health Level 7 (HL7) using an online web-portal transmission. This information will be used to: (1) identify and track antimicrobial resistant pathogens and emerging patterns of resistance; and (2) aid public health departments and healthcare facilities in timely responding to antimicrobial 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 a Revision to the data collection that with an increase in burden due to the building and maintaining of HL7 and CSV data feeds. Additionally, there has been a significant increase of AR threats identified through the AR Lab Network, and the addition of laboratories testing and taking on screening testing are reflected in this submission. OMB approval is requested for an estimated 57,993 annual burden hours of data collection. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Average number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Public Health Laboratories.	I.1—ROUTINE TESTING BY GENERA IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.2—EXPANDED DRUG SUSCEPTIBILITY TESTING (ExAST) IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.3—CANDIDA SPECIES IDENTIFICATION IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.4—HAIAR WHOLE GENOME SEQUENCING (WGS) OF GRAM-NEGATIVE AR THREATS IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.5—C. AURIS COLONIZATION SCREENING IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.6—CARBAPENEMASE-PRODUCING ORGANISM (CPO) SCREENING IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.7—AZOLE RESISTANCE IN CLINICAL ASPERGILLUS FUMIGATUS ISOLATES—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.8—N. GONORRHOEAE WHOLE GENOME SEQUENCING (WGS)—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.9—GONOCOCCAL (GC) ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.10—WHOLE GENOME SEQUENCING (WGS) OF S. PNEUMONAIE—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.11—CLOSTRIDIOIDES DIFFICILE (C. DIFFICILE) TESTING IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.12—ANTIFUNGAL RESISTANT TINEA DERMATOPHYTES—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Average number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Public Health Laboratories.	I.13—ANTIMICROBIAL SUSCEPTIBILITY TESTING (AST) OF INVASIVE HAEMOPHILUS INFLUENZAE (H. INFLUENZAE) IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.14—MYCOPLASMA GENTALIUM (MG)—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.15—MOLECULAR Mtb TESTING—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.16—C. AURIS WHOLE GENOME SEQUENCING (WGS) IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.17—MONITORIING CRE CRPA IN COMPANION ANIMALS TO FROM HUMANS—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.18—HEALTHCARE WASTEWATER-BASED SURVEILLANCE—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.19—COMMUNICATION AND COORDINATION OF ACTIONABLE EPI LAB DATA IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	I.20—CHARACTERIZATION OF THE CLINICAL LABORATORY NETWORK IN JURISDICTION—Annual Evaluation and Performance Measurement Report.	56	1	6/60	6
Public Health Laboratories.	Annual Report of Bacterial Specimen Testing Methods for Carbapenemase-producing Organisms.	56	1	2	112
Public Health Laboratories.	Monthly Data Report Form for Carbapenemase-producing Organisms.	56	1,302	20/60	24,304
Public Health Laboratories.	Carbapenemase-producing Organisms Alert Form.	56	214	3/60	599
Public Health Laboratories.	Alert and Monthly Data Report Form for *Candida*.	Up to 56	1,671	20/60	31,192
Public Health Laboratories.	AR Lab Network Form for Phylogenetic Tree-level Mycotics Reporting.	Up to 56	30	6/60	168
Public Health Laboratories.	AR Lab Network Form for Isolate/Specimen-level Mycotics Testing.	Up to 56	30	6/60	168
Public Health Laboratories.	AR Lab Network Alert and Monthly Data Report Form for *Neisseria gonorrhoeae*.	Up to 56	202	6/60	1,131
Public Health Laboratories.	HL7 Messages updates—IT Maintenance	32	4	20/60	43
Public Health Laboratories.	Implementation of new HL7 messages—IT Initial Set up.	11	4	3	132
Public Health Laboratories.	CSV files updates for Carbapenemase-producing organisms—IT Maintenance.	24	1	1	24
Total	.....	.....	.....	.....	57,993

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Public Health Ethics and Regulations, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2024–13227 Filed 6–14–24; 8:45 am]

BILLING CODE 4163–18–P