DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60 Day-19-19AYV; Docket No. CDC-2019-0048]

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 State and Local Public Health Laboratory Antibiotic

Resistance Testing. This collection will assist public health

laboratories to improve detection and characterization of two

urgent antibiotic resistant threats in healthcare-associated

infections, carbapenem-resistant Enterobacteriaceae (CRE) and

carbapenem-resistant Pseudomonas aeruginosa (CRPA).

DATES: CDC must receive written comments on or before **[INSERT**

DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0048 by any of the following methods:

- Federal eRulemaking Portal: 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, N.E., MS-D74, Atlanta, Georgia 30329.

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

Please note: Submit all comments through the Federal eRulemaking portal (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, of the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: 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; and

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.

5. Assess information collection costs.

Proposed Project

State and Local Public Health Laboratory Antibiotic Resistance

Testing – Existing Collection in use without an OMB Control

Number - 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 collection

is being implemented by the Department of Health and Human

Services (HHS), Centers for Disease Control and Prevention (CDC)

in response to Executive Order 13676, with the National Strategy

of September 2014, and to implement sub-objective 2.1.1 of the

National Action Plan of March 2015 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 Antibiotic Resistance Laboratory Network (AR Lab

Network) is made up of 56 jurisdictional public health

laboratories (i.e. all 50 states, five large cities, and Puerto

Rico). These 56 laboratories will be equipped to detect and

characterize carbapenem-resistant Enterobacteriaceae (CRE) and

Pseudomonas aeruginosa (CRPA). These resistant bacteria are

becoming more and more prevalent, particularly in healthcare

settings, and are typically identified in clinical laboratories.

However, characterization is often limited. The laboratory

testing will allow for additional testing and characterization,

including use of gold-standard methods. 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). Results from this laboratory testing will be used

to (1) identify targets for infection control, (2) detect new

types of resistance, (2) characterize geographical distribution

of resistance, (3) determine whether resistance mechanisms are

spreading among organisms, people, and facilities, and (4)

provide data that informs state and local public health

surveillance and prevention activities and priorities.

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 (germs), 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.

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

1. A summary report describing testing methods and volume. These reports will be submitted by email to ARLN_DHQP@cdc.gov.

2. Evaluation and Performance Measurement Reports to CDC via email to HAIAR@cdc.gov.

3. A report for all testing results to CDC using an online web-portal transmission. For messaging to CDC, these messaging protocols will be provided by the Association of Public Health Laboratories (APHL) Informatics Messaging Services (AIMS) platform.

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, and an immediate
communication to the local healthcare-associated infection
program in the jurisdictional public health department and
CDC

The estimated annualized burden hours were determined as
follows. There are 56 laboratories within this framework. A
"respondent" refers to a single participating testing
laboratory. A "response" is defined as the data
collection/processing and laboratory processing associated with
an individual isolate from an individual patient.

The average burden per response for the Annual Summary of
testing methods was evaluated to be approximately six minutes.
The average burden per response for the Annual Evaluation and
Performance Measurement Report was evaluated to be four hours
per report.

Based on previous laboratory experience in analyzing
CRE/CRPA isolates, the estimated time for each participating
public health laboratory for Monthly Testing Results Report is
four hours per response. Because of the need to add more data
collection points as new drugs are developed, new susceptibility
testing methods are made available, new resistance mechanisms
emerge, and new pathogens are prioritized as threats, the

Monthly Data Report includes some placeholder elements in expectation of evolving needs.

The use of ARLN Alerts encompass targeted AR threats that include new and rare plasmid-mediated ("jumping") carbapenemase genes, isolates that are non-susceptible to all drugs tested, and detection of novel resistance mechanisms. These alerts must be sent within one working day of detection. The elements of these messages include the unique public health laboratory specimen ID and a summary of specimen testing results generated to date. With the conversion to HL7 messaging of these data will be transmitted in real-time, thus eliminating the need to send alerts. Until that time, REDCap will be utilized to communicate alerts. CDC estimates that public health laboratories send an average of 34 ARLN Alerts per lab each year, with an estimated burden per response of 0.1 hours.

The total estimated annualized burden across all AR Lab Network labs and activities for DHQP is 3108 hours. Public Health laboratories receive federal funds through CDC's Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) mechanism to participate in this project.

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	Annual Report of Testing Methods	56	1	6/60	6
Public Health Laboratories	Annual Evaluation and Performance Measurement Report	56	1	4	224
Public Health Laboratories	Monthly Testing Results Reports	56	12	4	2688
Public Health Laboratories	ARLN Alerts	56	34	6/60	190
Total					3108

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[FR Doc. 2019-14299 Filed: 7/3/2019 8:45 am; Publication Date: 7/5/2019]