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 hrs.)
Petitioners	Form A, 42 CFR 83.9	2	1	3/60	6/60
	Form B, 42 CFR 83.9	5	1	5	25
Petitioners using a submission format other than Form B (as permitted by rule).	42 CFR 83.9	1	1	6	6
Petitioners Appealing final HHS decision (no specific form is required).	42 CFR 83.18	2	1	5	10
Claimant authorizing a party to submit petition on his/her behalf.	Authorization Form, 42 CFR 83.7	3	1	3/60	9/60
Total					41

Jeffrey M. Zirger,

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

[FR Doc. 2019–14304 Filed 7–3–19; 8:45 am]

BILLING CODE 4163–18–P

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 September 3, 2019.

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 NE, 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 NE, MS–D74, Atlanta, Georgia 30329; phone: 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; 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	2,688
Public Health Laboratories	ARLN Alerts	56	34	6/60	190
Total					3,108

Jeffrey M. Zirger,

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

[FR Doc. 2019–14299 Filed 7–3–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–19–0770; Docket No. CDC–2019–0054]

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 National HIV Behavioral Surveillance System (NHBS). CDC is requesting approval for a revision to the previously approved project to continue collecting standardized HIV-related behavioral data from persons at risk for HIV, selected from up to 25 Metropolitan Statistical Areas (MSAs) throughout the United States.

DATES: CDC must receive written comments on or before September 3, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0054 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 NE, 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, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 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; 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

National HIV Behavioral Surveillance System (NHBS)—(OMB Control No. 0920–0770, Exp. 05/31/2020)—Revision—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purpose of this data collection is to monitor behaviors of persons at high risk for infection that are related to Human Immunodeficiency Virus (HIV) transmission and prevention in the United States. The primary objectives of the NHBS are to obtain data from samples of persons at risk to: (a) Describe the prevalence and trends in risk behaviors; (b) describe the prevalence of and trends in HIV testing and HIV infection; (c) describe the prevalence of and trends in use of HIV prevention services; (d) identify met and unmet needs for HIV prevention services in order to inform health departments, community based organizations, community planning groups and other stakeholders.

By describing and monitoring the HIV risk behaviors, HIV seroprevalence and incidence, and HIV prevention experiences of persons at highest risk for HIV infection, NHBS provides an important data source for evaluating progress towards national public health goals, such as reducing new infections, increasing the use of condoms, and targeting high-risk groups.

The Centers for Disease Control and Prevention requests approval for a three-year revision of this information collection. Data are collected through anonymous, in-person interviews conducted with persons systematically selected from up to 25 Metropolitan Statistical Areas (MSAs) throughout the United States; these 25 MSAs are chosen based on having high HIV prevalence. Persons at risk for HIV infection to be interviewed for NHBS include men who have sex with men (MSM), persons who inject drugs (IDU), and heterosexually active persons at increased risk of HIV infection (HET). A brief screening interview will be used to determine eligibility for participation in the behavioral assessment.

The data from the behavioral assessment will provide estimates of (1) behavior related to the risk of HIV and other sexually transmitted diseases, (2) prior testing for HIV, (3) and use of HIV prevention services.

All persons interviewed will also be offered an HIV test, and will participate in a pre-test counseling session. No other federal agency systematically collects this type of information from persons at risk for HIV infection. These data have substantial impact on prevention program development and monitoring at the local, state, and national levels.

CDC estimates that NHBS will involve, per year in up to 25 MSAs, eligibility screening for 100 persons and eligibility screening plus the behavioral assessment with 500 eligible respondents, resulting in a total of 37,500 eligible survey respondents and