

respondents other than their time. The total estimated annualized burden hours are 38.

## ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State Public Health Director .....	Interview Guide .....	6	1	75/60
State Public Health Manager .....	Interview Guide .....	11	1	75/60
State Medicaid Director .....	Interview Guide .....	6	1	75/60
State Medicaid Manager .....	Interview Guide .....	6	1	75/60

**Leroy A. Richardson,**

Chief, Information Collection Review Office,  
Office of Scientific Integrity, Office of the  
Associate Director for Science, Office of the  
Director, Centers for Disease Control and  
Prevention.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-18-0307; Docket No. CDC-2018-0019]

#### 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 "Gonococcal Isolate Surveillance Project (GISP)". The purpose of GISP is to monitor trends in antimicrobial resistance in *N. gonorrhoeae* strains in the United States in order to establish a scientific basis for the selection of gonococcal therapies and to allow proactive changes to treatment guidelines before widespread resistance and failures of treatment occur.

**DATES:** CDC must receive written comments on or before April 6, 2018.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2018-0019 by any of the following methods:

- *Federal eRulemaking Portal:*

*Regulations.gov.* Follow the instructions for submitting comments.

- *Mail:* Leroy A. Richardson, 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 Leroy A. Richardson, 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

Gonococcal Isolate Surveillance Project (OMB Control Number 0920-0307, Expiration 2/28/2019)—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 Gonococcal Isolate Surveillance Project (GISP) was created in 1986 to monitor trends in antimicrobial susceptibilities of *N. gonorrhoeae* strains in the United States. Data from GISP are used to establish a scientific basis for the selection of gonococcal therapies and to allow pro-active changes to treatment guidelines before widespread resistance and failures of treatment occur. To increase capacity to detect and monitor resistant gonorrhea and improve the specificity of GISP, this submission is a revision to include collection of additional isolates and data elements.

The Centers for Disease Control and Prevention has designated *N. gonorrhoeae* as one of three "urgent" antibiotic resistance threats in the United States. The CDC is requesting a three-year OMB approval for this revision, which directly responds to the

National Strategy for Combating Antibiotic Resistant Bacteria by improving and strengthening surveillance of antimicrobial resistance

through GISP. Additionally, data from GISP will also allow CDC to monitor and evaluate the effectiveness of public health interventions conducted to

support the National Strategy for Combating Antibiotic Resistant Bacteria. There are no costs to respondents other than their time.

#### 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)
Sentinel site conducting core surveillance.	Demographic/Clinical Data .....	20	240	11/60	880
Sentinel site conducting enhanced surveillance.	Demographic/Clinical Data .....	10	840	12/60	1,680
Regional laboratory .....	Antimicrobial Susceptibility Testing Results.	4	3,300	40/60	8,800
Regional laboratory .....	Control Strain Susceptibility Testing	4	48	5/60	16
Total .....	.....	.....	.....	.....	11,376

**Leroy A. Richardson,**

*Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-18-0773]

#### Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled National Surveillance for Severe Adverse Events Among Persons on Treatment of Latent Tuberculosis Infection to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 22, 2017 to obtain comments from the public and affected agencies. CDC received one substantive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) 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 submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

#### Proposed Project

National Surveillance for Severe Adverse Events Associated with Treatment of Latent Tuberculosis Infection—(0920-0773, expiration 01/31/2018)—Extension—Division of Tuberculosis Elimination (DTBE), National Center for HIV, Viral Hepatitis, STD, and TB Prevention NCHHSTP), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

This project seeks a three-year extension to continue the passive reporting system for severe adverse events (SAEs) associated with therapy for Latent Tuberculosis Infection (LTBI). The system will rely on medical chart review and/or onsite investigations by TB control staff. In 2004, CDC began collecting reports of SAEs associated with any treatment regimen for LTBI. For surveillance purposes, an SAE was defined as any drug-associated reaction resulting in a patient's hospitalization or death after at least one treatment dose for LTBI. Reports of SAEs related to rifampicin plus pyrazinamide (RZ) and isoniazid (INH) INH have prompted a need for this project a national surveillance system of such events.

The objective of the project is to determine the annual number and temporal trends of SAEs associated with any treatment for LTBI in the United States. Surveillance of such events will provide data to support periodic evaluation or potential revision of guidelines for treatment of persons with LTBI.

Potential respondents are any of the 60 reporting areas for the national TB surveillance system (the 50 states, the District of Columbia, New York City, Puerto Rico, and 7 jurisdictions in the Pacific and Caribbean). Data will be collected using the data collection form for SAEs associated with LTBI treatment. The data collection form is completed by healthcare providers and health departments for each reported hospitalization or death related to treatment of LTBI and contains demographic, clinical, and laboratory information. Reporting of SAEs will be conducted through telephone, email, or during CDC site visits.