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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-17-17BAN; Docket No. CDC-2017-0081]

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 to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on "Strengthening United States Response to Resistant Gonorrhea (SURRG)." The goal of the study is to strengthen the U.S response to resistant gonorrhea by enhancing state and local public health surveillance and program infrastructure, build capacity to support rapid detection and public health response to antibiotic-resistant gonorrhea, and advance the understanding of epidemiological factors contributing to antibiotic-resistant gonorrhea.

DATES: Written comments must be received on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2017-0081 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, 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: 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, 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

Strengthening U.S. Response to Resistant Gonorrhea (SURRG) – New – National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The purposes of *Strengthening U.S. Response to Resistant Gonorrhea (SURRG)* are to: (1) improve national capacity to detect, monitor, and respond to emerging antibiotic-resistant gonorrhea; (2) understand trends in and factors contributing to antibiotic-resistant gonorrhea; and (3) build a robust evidence base for public health action. This information collection is important because: (1) effective treatment of gonorrhea is critical to gonorrhea control and prevention; (2) untreated or inadequately treated gonorrhea can cause serious reproductive health complications, such as infertility; (3) *Neisseria gonorrhoeae* (the bacterium that causes gonorrhea) has consistently demonstrated the ability to develop resistance to the antibiotics used for treatment and may be developing

resistance to the last remaining treatment option recommended by the CDC; and (4) antibiotic-resistant gonorrhea is extremely difficult to detect without enhanced surveillance and public health activities, such as SURRG, because healthcare providers rarely perform or have access to resistance testing for individual patients.

SURRG will support rapid detection of resistant gonorrhea and get actionable information into the hands of healthcare providers (to support appropriate treatment of individual patients) and local health departments (to support rapid public health response to slow the spread of resistant infections).

Jurisdictions participating in SURRG applied as part of a competitive process and will participate voluntarily. As an overview of SURRG, healthcare providers at participating clinics (sexually transmitted disease [STD] clinics affiliated with a single public health department or other participating non-STD clinic sites) will collect specimens for *N. gonorrhoeae* culture testing from men and women seeking care for possible gonorrhea. Specimens that demonstrate *N. gonorrhoeae* (called "isolates") will undergo antibiotic resistance testing within several days at the local public health laboratory. Laboratory results demonstrating resistance be rapidly communicated by the laboratory to the healthcare provider and designated health department staff member, who will initiate a field

investigation.

Researchers will interview the patient (from whom the resistant specimen was collected) about risk factors and recent contacts, and will re-test to ensure cure. The health department will interview recent contacts and test them for gonorrhea. The participating health departments will collect and transmit to CDC, demographic and clinical data about persons tested for and diagnosed with gonorrhea in the participating clinics, results of local antibiotic resistance testing, and information about field investigations.

None of the data transmitted to CDC will contain any personally identifiable information. CDC will use the data to monitor resistance, understand risk factors for resistance, and identify new approaches to prevent the spread of resistance. CDC will receive transmitted data through its Secure Access Management Services (SAMS).

SAMS is an approved federal information technology system that provides authorized and validated users secure and encrypted access to CDC file transfer applications. The encrypted data will be stored in a secure CDC server with strictly controlled and restricted access rights.

Researchers will ship isolates each month to one of four Antibiotic Resistance Regional Laboratory Network (ARLN) laboratories for confirmatory antibiotic susceptibility testing

and molecular characterization.

Under the SURRG protocol, the local SURRG data managers from each of the funded jurisdictions will abstract STD clinic data for patients tested for gonorrhea, receive data from non-STD clinic healthcare sites about persons tested for gonorrhea, receive resistance testing laboratory results from local public health laboratories, abstract data about field investigations, and will merge the data. Every two months, the local SURRG data manager will clean the data, remove personally identifiable information, and transmit the data to CDC. We estimate these data processes will take 16 hours every two months. Annually, the local SURRG data manager will send a final cumulative data file. Seven data transmissions/responses will occur.

Every two months, data managers at each of the participating non-STD clinic health centers will abstract and clean data and securely transmit the data to the local SURRG data manager. We estimate that it will take three hours each time data managers at each non-STD SURRG location abstract, clean, and transmit SURRG data.

Microbiologists at public health laboratories from each of the nine SURRG funded jurisdictions will conduct antibiotic resistance testing on all *N. gonorrhoeae* isolates from all STD clinic sites and non-STD clinic sites participating in SURRG. Each test takes approximately 10 minutes of staff time, and

testing of control strains will also be conducted approximately twice per week at each laboratory. On average, each jurisdiction will conduct approximately 600 resistance tests per year for patient care, plus 100 control strains per year for quality assurance. Thus, each grantee will perform approximately 700 tests per year. Every two months, a laboratory data manager will abstract test results and securely send the data file to the local SURRG data manager. We estimate that laboratory data managers will spend approximately one hour each time they abstract, clean, and transmit project data.

Health department staff will interview any person diagnosed with antibiotic-resistant gonorrhea or have a case of gonorrhea of public health significance index case, a diagnosed person's social and sexual contacts, and the sexual contacts of the index case's sexual contacts.

On average, each jurisdiction will identify four drug-resistant isolates each month. These isolates will spur field investigations, which will result in six additional interviews each month. We estimate 120 interviews will occur annually at each site (annual 1,080 interviews for the 9 sites). Each interview will take 30 minutes.

The total estimated annual burden hours are 2,976. Respondents receive federal funds to participate in this

project. There are no additional costs to respondents other than their time.

Estimate of Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (Hours)	Total Burden Hours
Local SURRG data manager	Facility, Laboratory and field Elements	9	7	16	1,008
Data manager at non-STD clinic health centers	Non-STD clinic Elements	18	6	3	324
Public Health Laboratory Microbiologist	Laboratory Testing	9	700	10/60	1,050
Public Health Laboratory Data Manager	Laboratory Elements	9	6	1	54
Gonorrhea Patients, Social and Sexual Contacts	Field Investigation Elements	1,080	1	30/60	540
Total					2,976

Leroy A. Richardson,

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