

leadership; update of Legislation Relating to the Evidence Based Policy Commission; update on National Health and Nutrition Examination Surveys Reports and Activities; update on Division of Health Care Statistics Reports and Activities; update on Vital Statistics activities; and update on International Activities of NCHS.

Requests to make oral presentations should be submitted in writing to the contact person listed below. All requests must contain the name, address, telephone number, and organizational affiliation of the presenter. Written comments should not exceed five single-spaced typed pages in length and must be received by December 26, 2017. Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

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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 January 16, 2018.

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 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

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,

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 Medicare & Medicaid
Services**

[Document Identifier: CMS-10237]

**Agency Information Collection
Activities: Submission for OMB
Review; Comment Request**

AGENCY: Centers for Medicare &
Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by December 18, 2017.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR, Email: OIRA_submission@omb.eop.gov.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at Web site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT:

William Parham at (410) 786-4669.

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. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits; *Use:* This information collection includes the process for organizations wishing to provide healthcare services under MA and/or MA-PD plans must complete an application annually, file a bid, and receive final approval from CMS. The application process has two options for applicants that include: Request for new MA product or request for expanding the service area of an existing product. This collection process is the only mechanism for MA and/or MA-PD organizations to complete the required application process. CMS utilizes the application process as the means to review, assess and determine if applicants are compliant with the

current requirements for participation in the Medicare Advantage program and to make a decision related to contract award. *Form Number:* CMS-10237 (OMB control number: 0938-0935); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other For-profits and Not-for-profit institutions); *Number of Respondents:* 380; *Total Annual Responses:* 380; *Total Annual Hours:* 6,246. (For policy questions regarding this collection contact Stacy Davis at 410-786-7813.)

Dated: November 13, 2017.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**
**Centers for Medicare & Medicaid
Services**

[Document Identifiers: CMS-10401]

**Agency Information Collection
Activities: Submission for OMB
Review; Comment Request**

AGENCY: Centers for Medicare &
Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected; and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by December 18, 2017.