

Respondents/Affected Entities: Private sector.

Respondent's Obligation to Respond: Mandatory per 48 CFR 1552.211.

Estimated Number of Respondents: 337 (total).

Frequency of Response: Monthly.

Total Estimated Burden: 97,056 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total Estimated Cost: \$9,074,736 (per year), includes \$0 annualized capital or operation & maintenance costs.

Changes in Estimates: There is an increase of 19,650 hours (97,056 – 77,406) in the total estimated respondent burden compared with the ICR currently approved by OMB because there are approximately 337 contracts and orders requiring response in 2018 instead of only 266 in 2014. This figure has increased to 337 due in part to shorter-value and shorter-length contracts being awarded due to budget uncertainty; e.g., continuing funding resolutions, sequestration budget cuts.

Dated: May 24, 2018.

Pamela D. Legare,

Deputy Director, Office of Acquisition Management.

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BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-18-0728; Docket No. CDC-2018-0047]

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 the National Notifiable Diseases Surveillance System (NNDSS). The NNDSS is the nation's public health surveillance system that monitors the occurrence and spread of diseases and

conditions that are nationally notifiable or under standard surveillance.

DATES: CDC must receive written comments on or before August 13, 2018.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2018-0047 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 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

National Notifiable Diseases Surveillance System—Revision—Center for Surveillance, Epidemiology and Laboratory Services (CELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Public Health Services Act (42 U.S.C. 241) authorizes CDC to disseminate nationally notifiable condition information. The National Notifiable Diseases Surveillance System (NNDSS) is based on data collected at the state, territorial and local levels as a result of legislation and regulations in those jurisdictions that require health care providers, medical laboratories, and other entities to submit health-related data on reportable conditions to public health departments. These reportable conditions, which include infectious and non-infectious diseases, vary by jurisdiction depending upon each jurisdiction's health priorities and needs. Each year, the Council of State and Territorial Disease Epidemiologists (CSTE), supported by CDC, determines which reportable conditions should be designated nationally notifiable or under standardized surveillance.

CDC requests a three-year approval for a Revision for the NNDSS, OMB Control No. 0920-0728, Expiration Date 02/28/2021. This Revision includes requests for approval to: (1) Receive case notification data for Salmonella enterica serotype Paratyphi (S. Paratyphi) A, B, or C Infections should they become nationally notifiable or be placed under standardized surveillance; (2) receive case notification data for Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE) which is now nationally notifiable; (3) receive case notification data for Candida auris (C. auris) which is now under standardized surveillance; and (4) receive disease-specific data elements for CP-CRE.

The NNDSS currently facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 60 jurisdictions: Public health departments in every U.S. state,

New York City, Washington DC, 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and 3 freely associated states (Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau). This information is shared across jurisdictional boundaries and both surveillance and prevention and control activities are coordinated at regional and national levels.

Approximately 90% of case notifications are encrypted and submitted to NNDSS electronically from already existing databases by automated electronic messages. When automated transmission is not possible, case notifications are faxed, emailed, uploaded to a secure network or entered into a secure website. All case notifications that are faxed, emailed, and uploaded are done so in the form of an aggregate weekly or annual report, not individual cases. These different mechanisms used to send case notifications to CDC vary by the jurisdiction and the disease or

condition. Private personally identifiable information (PII) is collected from automated electronic messages and information can be retrieved by PII. In addition, some combinations of submitted data elements could potentially be used to identify individuals. Private information is not be disclosed unless otherwise compelled by law. All data are treated in a secure manner consistent with the technical, administrative, and operational controls required by the Federal Information Security Management Act of 2002 (FISMA) and the 2010 National Institute of Standards and Technology (NIST) Recommended Security Controls for Federal Information Systems and Organizations. Weekly tables of nationally notifiable diseases are available through CDC WONDER and *data.cdc.gov*. Annual summaries of finalized nationally notifiable disease data are published on CDC WONDER and *data.cdc.gov* and disease-specific data are published by individual CDC programs.

The burden estimates include the number of hours that the public health

department uses to process and send case notification data from their jurisdiction to CDC. Specifically, the burden estimates include separate burden hours incurred for automated and non-automated transmissions, separate weekly burden hours incurred for modernizing surveillance systems as part of NNDSS Modernization Initiative (NMI) implementation, separate burden hours incurred for annual data reconciliation and submission, and separate one-time burden hours incurred for the addition of new diseases and data elements. The burden estimates also include the one-time burden for reporting jurisdictions for the addition of case notification data for CP-CRE and C. auris and disease-specific data elements for CP-CRE. The estimated annual burden for the 233 respondents is 18,619 hours. The cost of the information collection is \$787,846. The total burden hours increased from 18,529 to 18,619 since the last revision because of the addition of diseases and disease-specific data elements.

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)
States	Weekly (Automated)	50	52	20/60	867
States	Weekly (Non-Automated)	10	52	2	1,040
States	Weekly (NMI Implementation)	50	52	4	10,400
States	Annual	50	1	75	3,750
States	One-time Addition of Diseases and Data Elements.	50	1	10	485
Territories	Weekly (Automated)	1	52	20/60	17
Territories	Weekly, Quarterly (Non-Automated)	5	56	20/60	93
Territories	Weekly (NMI Implementation)	5	52	4	1,040
Territories	Annual	5	1	5	25
Territories	One-time Addition of Diseases and Data Elements.	1	1	10/60	1
Freely Associated States	Weekly, Quarterly (Non-Automated)	3	56	20/60	56
Freely Associated States	Annual	3	1	5	15

Jeffrey M. Zirger,

Acting 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

Food and Drug Administration

[Docket No. FDA-2016-D-2285]

Medical Product Communications That Are Consistent With the Food and Drug Administration-Required Labeling—Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is

announcing the availability of a guidance for industry entitled “Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers.” This guidance provides information for manufacturers, packers, and distributors and their representatives (collectively “firms”) of drugs and medical devices for humans, including those that are licensed as biological products, and animal drugs (collectively “medical products”), about how FDA evaluates their medical product communications that present information that is not contained in the FDA-required labeling for the product but that may be