

These estimates include any time spent by separately incorporated subsidiaries and other entities affiliated with the ultimate parent companies that receive the information requests.

*Estimated Average Burden per Year Per Request:* 196 hours.

(a) Information requests to the four largest recipients<sup>6</sup> of the Commission's information request, at a per request average each year of 400 hours = 2,400 hours, cumulatively, per year; and

(b) Information requests to nine additional respondents, of smaller size, at a per request average each year of 60 hours = 540 hours, cumulatively, per year.

*Estimated Annual Labor Cost:* \$294,000.

*Estimated Capital or Other Non-Labor Cost:* de minimis.

#### Request for Comment

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, such as anyone's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any "trade secret or any commercial or financial information which . . . is privileged or confidential"—as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

**Josephine Liu,**

*Assistant General Counsel for Legal Counsel.*

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collection of information during that period, including . . . separately incorporated subsidiaries or affiliates.").

<sup>6</sup> There are two tobacco companies that receive both a cigarette Order and a smokeless tobacco Order. Thus, this would equate to six requests for burden analysis.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-21-0728; Docket No. CDC-2020-0096]

#### 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 Notifiable Diseases Surveillance System—Revision—Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC). The purpose of this data collection is to provide the official source of statistics in the United States for nationally notifiable conditions. Data will be used to monitor the occurrence and spread of nationally notifiable conditions. Data will be gathered through electronic submissions of case notifications to CDC from public health departments from 50 states, New York City, Washington DC, five U.S. territories, and three freely associated states.

**DATES:** CDC must receive written comments on or before December 22, 2020.

**ADDRESSES:** You may submit comments, identified by Docket No. CDC-2020-0096 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: 404-639-7118; Email: [omb@cdc.gov](mailto: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 (OMB Control No. 0920-0728, Exp. 04/30/2023)—Revision—Center for Surveillance, Epidemiology and Laboratory Services (CSELS), 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 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 04/30/2023). This Revision includes requests for approval to: (1) Receive case notification data for Multisystem Inflammatory Syndrome (MIS) associated with Coronavirus Disease 2019 (COVID-19); (2) receive new disease-specific data elements for Anthrax, Brucellosis, Campylobacteriosis, Cholera, Cryptosporidiosis, Hansen's Disease, Leptospirosis, Melioidosis, MIS associated with COVID-19, COVID-19, S. Paratyphi Infection, S. Typhi Infection, Salmonellosis, STEC, Shigellosis, and Vibriosis; and (3) Receive new vaccine-related data elements for all conditions.

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, five

U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and three 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 or emailed 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. Jurisdictions remove most personally identifiable information (PII) before data are submitted to CDC, but some data elements (e.g., date of birth, date of diagnosis, county of residence) could potentially be combined with other information to identify individuals. Private information is not 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](http://data.cdc.gov). Annual summaries of finalized nationally notifiable disease data are published on CDC WONDER and [data.cdc.gov](http://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 for the one-time burden for reporting jurisdictions are for the addition of case notification data for MIS associated with COVID-19; disease-specific data elements for Anthrax, Brucellosis, Campylobacteriosis, Cholera, Cryptosporidiosis, Hansen's Disease, Leptospirosis, Melioidosis, MIS associated with COVID-19, COVID-19, S. Paratyphi Infection, S. Typhi Infection, Salmonellosis, STEC, Shigellosis, and Vibriosis; and vaccine data elements for all diseases. The estimated annual burden for the 257 respondents is 18,954 hours. The cost of the information collection is \$830,400. The total burden hours increased from 18,414 to 18,954 since the last revision because there were more disease-specific data elements added in this revision as compared to the last revision.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
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	12	600
Territories	Weekly (Automated)	5	52	20/60	87
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.	5	1	12	60
Freely Associated States	Weekly (Automated)	3	52	20/60	52
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56
Freely Associated States	Annual	3	1	5	15

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hr)	Total burden (in hr)
Freely Associated States .....	One-time Addition of Diseases and Data Elements.	3	1	12	36
Cities .....	Weekly (Automated) .....	2	52	20/60	35
Cities .....	Weekly (Non-automated) .....	2	52	2	208
Cities .....	Weekly (NMI Implementation) .....	2	52	4	416
Cities .....	Annual .....	2	1	75	150
Cities .....	One-time Addition of Diseases and Data Elements.	2	1	12	24
<b>Total</b> .....	.....	.....	.....	.....	18,954

**Jeffrey M. Zirger,**

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

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifier: CMS-R-148]

**Agency Information Collection Activities: Proposed Collection; Comment Request**

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human 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 (the 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by December 22, 2020.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

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' website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

2. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William N. Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

*CMS-R-148 Limitations on Provider Related Donations and Health Care Related Taxes, Medicaid and Supporting Regulations in 42 CFR 433.68 Through 433.74*

Under the 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 requires federal agencies to publish a 60-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.

**Information Collection**

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Limitations on Provider Related Donations and Health Care Related Taxes, Medicaid and Supporting Regulations in 42 CFR 433.68 through 433.74; *Use:* States may elect to submit a waiver to CMS for the broad based and/or uniformity requirements for any health care related tax program which does not conform to the broad based and uniformity requirements. It is also the responsibility of each State to demonstrate that their tax program(s) do not violate the hold harmless provision. For a waiver to be approved and a determination that the hold harmless provision is not violated, States must submit written documentation which satisfies the regulatory requirements.