

Adding 2019 – Novel Coronavirus (2019-nCoV) to the National Notifiable Diseases Surveillance System

Request for OMB approval of a Revised Information Collection for
OMB Control Number 0920-0728

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Supporting Statement Section A

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**Adding 2019-nCoV to the National Notifiable Diseases Surveillance System
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- **Goal of the data collection:** We propose adding 2019 novel coronavirus (2019-n-CoV) to the National Notifiable Diseases Surveillance System (NNDSS). NNDSS is the nation’s public health surveillance system used to monitor the occurrence and spread of nationally notifiable conditions as well as some conditions under national standardized surveillance. NNDSS provides the official source of statistics in the United States for nationally notifiable conditions and CDC is the sole repository for these national, population-based data.
- **Intended use of the resulting data:** The data are used to monitor the occurrence of conditions and to plan and conduct prevention and control programs at the state, territorial, local and national levels. Data are used by CDC to describe cases, identify contacts, obtain travel histories and other epidemiologically important information to describe cases, manage outbreaks, and conduct public health follow-up to minimize the spread of disease.
- **Methods to be used to collect data:** Approximately 90% of case notifications are sent to CDC by automated electronic HL7 or NETSS messages. Some case notifications are still sent to CDC by non-automated mechanisms including email, secure file upload, and data entry to a secure website. These different mechanisms used to send case notifications to CDC vary by the jurisdiction and the disease or condition.
- **The subpopulation to be studied:** NNDSS is a case-based surveillance system meaning that the unit of reporting is a case – a person with a specific condition. The respondent population consists of 60 jurisdictions.
- **How data will be analyzed:** Public health departments at the state, territorial and local levels review, process and analyze reportable conditions data and voluntarily submit case notification data on nationally notifiable conditions to CDC. State and local health departments share data that they have already collected and stored in their own surveillance systems. The associated data might include clinical information, vaccine history, laboratory tests, patient characteristics, demographics, and epidemiologic variables such as exposures and risk factors.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC), National Center for Immunization and Respiratory Diseases (NCIRD), requests an emergency 180-day approval for the revision of the National Notifiable Diseases Surveillance System (NNDSS) Information Collection Request (ICR), OMB Control No. 0920-0728, to add 2019-Novel Coronavirus (2019-nCoV) to the NNDSS.

The Centers for Disease Control and Prevention (CDC) continues to closely monitor an outbreak of a 2019 novel coronavirus (2019-nCoV) in Wuhan City, Hubei Province, China that began in December 2019. CDC has established an Incident Management System to coordinate a domestic and international public health response.

Coronaviruses are a large family of viruses. Some cause illness in people; numerous other coronaviruses circulate among animals, including camels, cats, and bats. Rarely, animal coronaviruses can evolve and infect people and then spread between people such as has been seen with Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV).

Chinese authorities report most patients in the Wuhan City outbreak have been epidemiologically linked to a large seafood and animal market, suggesting a possible zoonotic origin to the outbreak. Chinese authorities additionally report that they are monitoring several hundred healthcare workers who are caring for outbreak patients; no spread of this virus from patients to healthcare personnel has been reported to date. Chinese authorities are reporting no ongoing spread of this virus in the community, but they cannot rule out that some limited person-to-person spread may be occurring. China has reported that two of the patients have died, including one with pre-existing medical conditions. Chinese health officials publicly posted the genetic sequence of the 2019-nCoV on January 12, 2020. This will facilitate identification of infections with this virus and development of specific diagnostic tests.

Thailand and Japan have confirmed additional cases of 2019-nCoV in travelers from Wuhan, China. It is possible that more cases will be identified in the coming days. This is an ongoing investigation and given previous experience with MERS-CoV and SARS-CoV, it is possible that person-person spread may occur. There is much more to learn about the transmissibility, severity, and other features associated with 2019-nCoV as the investigations in China, Thailand, and Japan continue. Additional information about this novel virus is needed to better inform population risk.

Addition of 2019-nCoV to the NNDSS is needed to facilitate a timely and effective public health response to this health threat. NNDSS data are used to monitor the occurrence of notifiable conditions and to plan and conduct prevention and control programs at the state, territorial, local and national levels. Data are used by CDC to trace cases and their contacts, obtain travel histories and other information to describe and manage outbreaks, and conduct public health follow-up to minimize the spread of disease and would be instrumental in effectively responding to 2019-nCoV cases.

The NNDSS is the nation's public health surveillance system that enables all levels of public health (local, state, territorial, federal and international) to monitor the occurrence and spread of the diseases and conditions that CDC and the Council of State and Territorial Epidemiologists (CSTE) officially designate as "nationally notifiable" or as under "standardized surveillance." CSTE is an organization of member states and territories representing public health epidemiologists. CDC and CSTE determine which diseases and data elements should be monitored as part of national surveillance. The NNDSS program creates the infrastructure for the surveillance system and facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 60 jurisdictions.

The NNDSS also facilitates relevant data management, analysis, interpretation and dissemination of the information. The data are used to monitor the occurrence of notifiable conditions and to plan and conduct prevention and control programs at the state, territorial, local and national levels. CDC is responsible for the reporting and dissemination of nationally notifiable conditions' information, as authorized by the Public Health Service Act (42 USC 241) of January 4, 2012.

Authorizing Legislation comes from Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment 1).

2. Purpose and Use of the Information Collection

The purpose of adding 2019-nCoV to the NNDSS is to facilitate efforts to prevent and control the spread of nCoV in the U.S., monitor the impact of this emerging virus, and track the epidemiology of the virus so CDC can provide timely, evidence-based guidance to states and the public. Case-based notification includes information critical to a public health response, including data regarding laboratory confirmation. Adding 2019-nCoV would allow for data collection in 60 jurisdictions that would require reporting of this condition and core data elements. Public health departments send case notifications to CDC at least weekly.

The NNDSS is a reporting platform for states and territories to voluntarily share with CDC the data that they collect from health care providers, medical laboratories and other related entities pursuant to state, territorial and local legislation and regulations. These locally reportable conditions, which include infectious and non-infectious diseases, vary by jurisdiction depending upon each jurisdiction's health priorities and needs (as such, not all jurisdictions send CDC information on all conditions). These data at the state, territorial, and local levels are used to identify and monitor health impact of the reportable conditions in those communities, measure trends, identify populations or geographic areas at high risk, plan prevention and control programs and policies, allocate resources appropriately, and evaluate the effectiveness of programs and policies. Infectious disease agents and environmental hazards often cross geographical boundaries. The primary burden on the jurisdiction associated with this information collection stems from the initial cost of programming new conditions and data elements into the local jurisdiction's reporting system for those diseases and conditions that the jurisdiction has made locally reportable.

Conditions are included in the NNDSS when CDC and CSTE agree that the condition is of sufficient public health significance to warrant the states and territories submitting case-based surveillance data to CDC to allow monitoring on a national level. Each year, CSTE, supported by CDC, determines which reportable conditions should be designated nationally notifiable or under standardized surveillance. When states decide whether to make a condition reportable and when the CSTE membership and CDC decide whether to make a condition nationally notifiable, they consider the following issues: severity, incidence, communicability, preventability, impact on the community or society and need for public health action. CSTE position statements must be sponsored by a CSTE Active Member, specifically, a person engaged in the practice of epidemiology for a government public health authority at the local, tribal, state, and territorial level. The position statements are discussed and then reviewed at the CSTE national office. Next, a technical review by a select group of subject matter experts is done. The national office then shares the position statement with appropriate CSTE Executive Board members. The national office then circulates the draft position statement among voting members and the position statement is voted on at the Annual CSTE Conference. The final approved position statement is then published on the CSTE website. When CSTE approves a position statement placing a condition under standardized surveillance, this establishes standardized case definitions and surveillance methods for use by jurisdictions conducting surveillance for this condition and recommends that jurisdictions conducting surveillance share the case data with CDC if it is requested by the relevant CDC program. When CSTE takes the additional step of making a

condition nationally notifiable, this expresses the consensus of the CSTE membership that all states and territories should enact laws or regulations to make this condition reportable in their jurisdictions and should voluntarily submit the data to CDC so that information can be shared across jurisdictional boundaries and so that surveillance and prevention and control activities can be coordinated at regional and national levels. CSTE, in conjunction with CDC, makes annual recommendations for additions and deletions to the list of conditions under standardized surveillance and nationally notifiable diseases.

For each nationally notifiable condition or condition under standardized surveillance that a state, territorial, or local jurisdiction chooses to report to CDC, a common, core set of data elements is requested for each case. The core data elements include the name of the condition, demographic data for the person with the condition, epidemiologic data, and administrative data. All of these core data elements were included in the previously approved ICR and can be found in attachment 4.

In addition to the core data elements that are required for a structurally valid case notification message, the core data elements are optional since the jurisdiction may not collect these data elements or the jurisdiction may not have the information for a particular case. If any one of required data elements is not present in the message, the message cannot be processed by CDC and an error message will be generated. The creation of a core set of data for each disease case report was an important accomplishment of NNDSS. It not only standardized case data coming into CDC, but it promoted standardization across states as well. Other CDC surveillance programs are now incorporating the core data elements into their systems so that data at CDC will be interoperable and more shareable. And, during a public health emergency, it makes data collection and exchange timelier.

CDC and HHS are committed to minimizing the disease collection and submission burden for jurisdictions. This is accomplished by:

- Helping jurisdiction focus their surveillance efforts by providing guidance on which data elements are most important for disease monitoring and control;
- Not requiring jurisdictions to send data elements that are not available for an individual, not included in the jurisdiction's surveillance system, or not a priority for collection in the jurisdiction; and
- Receiving this data through NNDSS, an existing infrastructure that supports automated messaging and that is already in use by public health jurisdictions to transmit case-based surveillance data from their jurisdiction surveillance systems to CDC.

Once case notification data are received by NNDSS, CDC data analysts conduct quality control assessments, including evaluating the information submitted against an established case definition. Analysts standardize the data and then share the data with CDC subject matter experts who have responsibility for prevention and control of those diseases. Data are used by CDC subject matter experts to monitor the occurrence of the conditions, identify populations or geographic areas at high risk, plan prevention and control programs and policies, allocate resources appropriately, and evaluate the effectiveness of programs and policies. In addition,

information is collected that allows CDC to trace cases and their contacts and their travel histories, or other linkages necessary to describe and manage outbreaks or conduct public health follow-up to minimize the spread of disease.

NNDSS provides the official source of statistics in the United States for nationally notifiable conditions and CDC is the sole repository for these national, population-based data. CDC also uses the notifiable condition data to publish surveillance summaries and other reports in scientific, public health and medical journals.

Data are also shared with jurisdictions and with the public. For certain nationally notifiable conditions, CDC releases national data to the public through CDC's web-based query system known as WONDER (<http://wonder.cdc.gov/>) and through Data.CDC.gov (<https://data.cdc.gov/>). Shared data are summary statistics of aggregate data produced after personal identifiers have been removed (Section A.16, below). Surveillance programs under the Deputy Director for Infectious Diseases (DDID) and the Center for Global Health (CGH) receive nationally notifiable condition data for infectious diseases from DHIS and use, release and/or share their programs' data according to guidance established by CDC, their Centers and programs.

3. Use of Improved Information Technology and Burden Reduction

An NNDSS initiative that focuses on using improved information technology is the NNDSS Modernization Initiative (NMI). NMI is part of the CDC Surveillance Strategy (<http://www.cdc.gov/ophss/docs/cdc-surveillance-strategy-final.pdf>) released in February 2014. NMI seeks to improve the use of information technology by implementing health information exchange industry standards for messaging and vocabulary. Since the epidemiology of some notifiable conditions has changed over time, new clinical information (e.g., laboratory tests and results, vaccination information, and treatment information) is needed for surveillance. Implementing these industry standards including Health Level 7 (HL7) electronic messaging allows the receipt of such information in a case notification message.

Approximately 90% of case notifications are sent to CDC by automated electronic HL7 or NETSS messages. However, NETSS messages are not based on industry standards. Some case notifications are still sent to CDC by non-automated mechanisms including email, secure file upload, and data entry to a secure website. These different mechanisms used to send case notifications to CDC vary by the jurisdiction and the disease or condition. As NMI advances, all public health departments will exclusively use HL7 messages to send case notification messages to CDC for all diseases and conditions. CDC continues to develop message mapping guides (MMGs) to describe and standardize the data content needed for electronic HL7 case notification.

All NNDSS jurisdictions receive funding through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) cooperative agreement (<https://www.cdc.gov/ncezid/dpei/epidemiology-laboratory-capacity.html>) and some of that funding is used to implement electronic integrated surveillance systems. Several of the territories are at some stage of implementing the National Electronic Disease Surveillance System (NEDSS) Base System (NBS) as their electronic integrated surveillance system that they will use

to send automated HL7 case notifications to CDC. NBS is a CDC-developed integrated information system that helps local, state, and territorial public health departments manage reportable disease data and send notifiable disease data to CDC.

As NMI moves forward, opportunities exist to decrease the burden for public health departments that send case notification data to CDC. Implementation of more MMGs will reduce the burden since public health departments will not have to use different mechanisms that vary by disease or condition to send case notification messages to CDC. In addition, CDC is developing a dashboard that will display case notification data sent by jurisdictions. The dashboard will include the details of messages received and processed by CDC, as well as warnings and errors on messages that were submitted by jurisdictions but did not pass the structural, content, and business rules validation. As a result, jurisdictions will be able to use the dashboard to verify the number of messages received by CDC and to assist with the reconciliation of data throughout the year. This will decrease the burden from the annual data reconciliation effort. As the new messaging standards are developed through NMI implementation, there is a burden to the jurisdictions as they incorporate these new standards, although the end result is expected to reduce the overall burden. The limited duration effort required to implement the new standards is represented in the burden table as “NMI Implementation.”

4. Efforts to Identify Duplication and Use of Similar Information

No other Federal agency funds or conducts this type of surveillance, based on information on reportable conditions received by state, territorial, and local public health departments and notifications submitted by public health departments to CDC. Information obtained and maintained in NNDSS serves as a unique, centralized, integrated source of information about nationally notifiable conditions in the U.S. and the information is not available from any other source. As the DHIS NNDSS electronic systems are developed through NMI implementation to allow state and local public health departments to submit more nationally notifiable disease data to CDC, both the duplication of reporting to CDC by state and local public health departments and the burden to state and local public health departments may be reduced.

5. Impact on Small Businesses or Other Small Entities

This submission of information does not involve small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

Public health departments send case notifications to CDC at least weekly. Some territories and freely associated states send notifications at least quarterly. The timeliness of these data is one of the most critical factors in the notification process. Rapid disease notification is an indispensable tool for public health officials at local, state, territorial and national levels, who use the data to monitor the occurrence and prevent the spread of the diseases. Less frequent notification does not allow timely assessment, particularly for emerging disease threats. Changes in disease distribution are continuously monitored so that appropriate investigations or interventions may be rapidly undertaken. In addition, rapid notification is also necessary to allow the United States to meet its obligations under the revised 2005 International Health Regulations to report

important events that meet the criteria to be considered a public health emergency of international concern to the World Health Organization.

We are not aware of any legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Collection of case notification data is conducted in a manner consistent with the guidelines in 5 CFR 1320.5. CDC requests that public health departments send case notification messages at least weekly if possible, as justified under section A6.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Because this is a request for an emergency clearance, CDC asks that the 60-day comment period be waived. However, a 60-day Federal Register notice will be submitted to make the public aware of this investigation.

B. The efforts to consult outside the agency are outlined below:

NCIRD has consulted with local, state, Federal, and international public health partners.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts provided to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

NNDSS data are stored in the Data Warehouse (DW), Data Message Brokering (DMB) and the Message Validation, Processing, and Provisioning System (MVPS). HL7 case notifications that use older MMGs are processed by DMB, and HL7 messages that use newer MMGs are processed by MVPS. NETSS case notifications are processed in the DW which ultimately stores all electronic case notifications. The Privacy Act is applicable as personally identifiable information (PII) is collected and information can be retrieved by PII. However, data are not retrieved by PII. In addition, some combinations of submitted data elements could potentially be used to identify individuals. Private information will not be disclosed unless otherwise compelled by law. No assurance of confidentiality has been obtained.

Case notifications include demographic, epidemiologic, administrative, vaccine, laboratory and disease-specific data related to a case of a nationally notifiable condition. The security of private information during automated transmission to NNDSS is maintained by the Department of Health and Human Services (HHS) standard encryption technologies (computers and servers) that use national public health standards for messaging systems which provide security

mechanisms for jurisdictions to use when submitting data. Case notifications are encrypted and submitted to NNDSS electronically from already existing databases via automated electronic transfers through a secure network. Electronic data are transmitted to and securely processed at CDC. When automated transmission is not possible, case counts are emailed or uploaded to a secure network or entered into a secure website. Information that is emailed or uploaded is in the form of an aggregate weekly or annual case counts. Once in DHIS, all case notification 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). These DHIS systems are also in compliance with more recent standards to protect information: the NIST Recommended Security Controls for Federal Information Systems and Organizations, Special Publication 800-53, Revised May 1, 2010.

As noted in A.2 above, for certain nationally notifiable conditions, CDC releases national data to the public through CDC's web-based query system known as CDC WONDER (<http://wonder.cdc.gov/>). NNDSS data are also published on Data.CDC.gov (<https://data.cdc.gov/>) and DATA.GOV (<http://www.data.gov/>). Privacy is protected in a number of ways. CDC WONDER, Data.CDC.gov, and DATA.GOV only provide summary statistics of aggregate data to their users. Data for CDC WONDER are produced by CDC programs, which have already stripped the data of all PII before providing these public-use data sets to CDC WONDER. Furthermore, CDC WONDER dynamically imposes privacy and suppression constraints on all query results sets produced by the CDC WONDER web application, in compliance with each data set's specific data use policy. CDC WONDER and Data.CDC.gov are also subject to and have met CDC's Security Assessment and Authorization (SA&A) process, in which the CDC WONDER constraints are examined and validated by the CDC's Office of the Chief Information Security Officer (OCISO). Only public use, non-PII data in the form of summary statistics are uploaded to Data.CDC.gov per OCISO policy. In addition, NNDSS data published on Data.CDC.gov are also published on DATA.GOV. Surveillance programs in OID and CGH have primary responsibility at CDC for surveillance of the infectious diseases and conditions covered by their Centers. Programs within these Centers receive nationally notifiable infectious disease data from DHIS and use, release and/or share their programs' data according to guidance established by CDC, their Centers and programs.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

This activity does not require Institutional Review Board (IRB) documentation as this activity is public health practice (surveillance), not research.

Justification for Sensitive Questions

The NNDSS does not ask questions of a sensitive nature, but information is submitted about sensitive topics. The NNDSS must receive sensitive information about notifiable conditions and conditions under standardized surveillance in order to monitor the occurrence of the diseases so that effective prevention and control programs can be planned and implemented.

12. Estimates of Annualized Burden Hours and Costs

As stated in A.1 above, this application is a revision to the previous application for 0920-0728 (approved by OMB on January 15, 2014) which consolidated Control No. 0920-0128, parts of 0819, 0009, and 0004, into Control No. 0920-0728.

The burden estimates in Table A12A below include the burden estimates for the one-time increase in burden hours that states, territories, and cities, will incur to send case notification data for the addition of 2019-nCoV. The burden estimates also 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 for the addition of case notification data for the addition of case notification data for 2019-nCoV. The estimated annual burden for the 257 respondents is 18,355 hours.

A12A. Estimates of 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 Disease and	50	1	2	100

	Data Elements				
States	One-time SO/GI Survey	12	1	5/60	1
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 Disease and Data Elements	5	1	2	10
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
Freely Associated States	One-time Addition of Disease and Data Elements	3	1	2	6
Cities	Weekly	2	52	20/60	35

	(Automated)				
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 Disease and Data Elements	2	1	2	4
Total					18,355

States

States incur burden by: 1) sending weekly automated case notification data to CDC, 2) sending weekly non-automated case notification data to CDC, 3) modernizing their surveillance systems as part of NMI implementation, 4) reconciling and sending annual case notification data to CDC, and 5) modifying their surveillance systems and automated case notification messages to accommodate new data elements and diseases. All 50 states (and D.C. and NYC) send weekly automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours.

Territories

Territories incur burden by: 1) sending weekly automated case notification data to CDC, 2) sending weekly and quarterly non-automated case notification data to CDC, 3) modernizing their surveillance systems as part of NMI implementation, 4) reconciling and sending annual case notification data to CDC and 5) modifying their surveillance systems and automated case notification messages to accommodate new data elements and diseases. All 5 territories send weekly automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours.

Freely Associated States

Freely associated states incur burden by: 1) sending weekly automated case notification data to CDC, 2) sending weekly and quarterly non-automated case notification data to CDC, 3) reconciling and sending annual case notification data to CDC and 4) modifying their surveillance systems and automated case notification messages to accommodate new data elements and diseases. All 3 freely associated states send weekly automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours.

Cities

Cities incur burden by: 1) sending weekly automated case notification data to CDC, 2) sending weekly non-automated case notification data to CDC, 3) modernizing their surveillance systems as part of NMI implementation, 4) reconciling and sending annual case notification data to CDC, and 5) modifying their surveillance systems and automated case notification messages to accommodate new data elements and diseases. Both of the two cities send weekly automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours.

According to the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2017 National Occupational Employment and Wage Estimates, the estimated mean hourly wage for Computer Systems Analysts is \$44.59 (https://www.bls.gov/oes/current/oes_nat.htm#15-0000) and the estimated mean hourly wage for Epidemiologists is \$36.65 (http://www.bls.gov/oes/current/oes_nat.htm#19-0000) The estimated hourly wage for a Computer Systems Analyst is used for weekly automated submissions and weekly NMI implementation activities and the estimated hourly wage for an Epidemiologist is used for weekly non-automated submissions, annual data reconciliation, and the one-time SO/GI survey. These wage estimates were used because these two occupations represent the category of occupations held by the respondents that perform these activities. Using \$44.59 as an average hourly wage rate for Computer Systems Analysts and using \$36.65 as an average hourly wage rate for Epidemiologists, it is estimated that the average national annual burden for weekly and annual reporting is 18,355 hours at a national cost of \$783,837.

13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other annual costs to respondents or record keepers.

14. Annualized Cost to the Federal Government

Item	
	FY 19
Personnel - Software development, support, and management (intramural)	\$6,156,238
Contracts – Program and web support	\$13,830,353
Cooperative Agreements with States for NNDSS case notification and management (extramural)	\$9,373,323
Total	\$29,359,914

The estimated annualized cost to the government for NNDSS is \$29,359,914.

15. Explanation for Program Changes or Adjustments

This revision adds 2019-nCoV to the NNDSS to facilitate receipt of case notification data and disease-specific data elements. This change is critical to facilitate a timely and effective public health response to the outbreak of 2019-nCoV in Wuhan, China. This virus poses a new and significant health risk and given previous experience with MERS-CoV and SARS-CoV, it is possible that person-person spread may occur. There is much more to learn about the transmissibility, severity, and other features associated with 2019-nCoV as the investigations in China, Thailand, and Japan continue. Addition of 2019-nCoV to NNDSS will provide critical information to better understand and control the spread of this novel virus.

The total burden hours reflects the addition of disease and disease-specific data elements.

16. Plans for Tabulation and Publication and Project Time Schedule

CDC tabulates and publishes provisional counts of nationally notifiable conditions each week. In the past, these data were published in the MMWR and were available through CDC WONDER and data.cdc.gov. Beginning in 2018, the weekly tables of nationally notifiable diseases have not been published in the MMWR but are available through CDC WONDER and data.cdc.gov. Finalized notifiable disease data are published on CDC WONDER and disease-specific data are published by individual CDC programs. This transition to using CDC WONDER and CDC.data.gov as the primary forums for presentation of weekly tables allows CDC to finalize and publish annual data more quickly. In addition, CDC programs routinely publish reports on specific notifiable conditions in the MMWR and in other scientific, medical and public health journals.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Since approximately 90% of case notifications are submitted to CDC electronically from already existing databases via automated electronic transfers, CDC requests approval to place the PRA burden statement and OMB expiration date on the NNDSS Data Collection and Reporting webpage. Respondents can navigate to the list of required data elements from this central location. A screenshot of the webpage is shown in Attachment 5. PRA Burden Statement Screenshot.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. Authorizing Legislation
2. 60-day FRN
3. Human Subjects Determination

4. Core Data Elements
5. PRA Burden Statement Screenshot