National Notifiable Diseases Surveillance System

Supporting Statement Section A

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National Notifiable Diseases Surveillance System - Request for Revision

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A. Justification

- **The National Notifiable Diseases Surveillance System (NNDSS) is the nation's public health surveillance system used to monitor the occurrence and spread of nationally notifiable conditions. 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.**
- **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. The data are also 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.**
- **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.**
- **The respondent population consists of 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).**
- **CDC publishes numbers of cases and incidence rates of nationally notifiable conditions based on NNDDS data on CDC WONDER and in other scientific journals.**

A1. Circumstances Making the Collection of Information Necessary

CDC requests a three year approval for the revision of the National Notifiable Diseases Surveillance System (NNDSS) Information Collection Request (ICR), OMB Control No. 0920-0728, expiration date January 31, 2019. This application is the second revision to the previous application for 0920-0728 (approved by OMB on January 15, 2014) which consolidated four other CDC applications for nationally notifiable diseases case notification: Control Nos. 0920-0128, (Congenital Syphilis Surveillance), parts of 0920-0819 (Nationally Notifiable Sexually Transmitted Disease (STD) Morbidity Surveillance), parts of 0920-0009 (National Disease Surveillance Program - I. Case Reports) and parts of 0920-0004 (National Disease Surveillance Program - II. Disease Summaries).

Key changes in this revision include requests for approval to:

- Expand the respondent population to include the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau (independent nations that operate under a Compact of Free Association with the United States of America that are commonly referred to as "freely associated states")
- Receive new laboratory data elements for all conditions
- Receive new data elements for all vaccine-preventable diseases (VPDs)

- Receive new data elements for the following conditions that are already approved: Congenital Rubella Syndrome (CRS), Salmonellosis, Shigellosis, Campylobacteriosis, Shiga toxin-producing Escherichia coli (STEC), Hepatitis, and Hantavirus Pulmonary Syndrome (HPS).
- Receive case notification data for histoplasmosis which is now under standardized surveillance
- Receive case notification data for Acute Flaccid Myelitis (AFM) which is now under standardized surveillance
- Receive case notification data for all enteric *Escherichia coli* (*E. coli*) infections should any of them become nationally notifiable or be placed under standardized surveillance. CDC already has approval to receive case notification data for STEC which is nationally notifiable

Background and Respondent Population

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 the Council of State and Territorial Epidemiologists (CSTE) officially designate as "nationally notifiable" or as under "standardized surveillance" (referred to in this application as nationally notifiable conditions). CSTE is an organization of member states and territories representing public health epidemiologists. The NNDSS currently facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 57 jurisdictions: health departments in every U.S. state, New York City, Washington DC, and 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands). CDC is requesting permission to expand the respondent population to include the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau (independent nations that operate under a Compact of Free Association with the United States of America that are commonly referred to as "freely associated states"). The respondent population for 0920-0819 (Nationally Notifiable Sexually Transmitted Disease (STD) Morbidity Surveillance) included freely associated states. When part of 0920-0819 was merged with this application (0920-0728, approved on January 15, 2014), the freely associated states were inadvertently left out of the respondent population. The addition of the freely associated states will increase the respondent population from 57 to 60.

The value of receiving data on health events of public health concern from the freely associated states became evident with the emergence of the Zika virus as a public health threat. In addition, CDC's National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention has determined that these areas

experience multiple challenges with viral hepatitis and STDs due to the combination of high disease burden, geographic location, a broadly dispersed population, and lack of local resources. This is exacerbated by insufficient and fragmented surveillance systems, laboratory and intervention capacity, and access to medications. These factors also present challenges for diagnosis, treatment, surveillance and control of the other notifiable conditions.

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 **[Attachment 1. Authorizing Legislation]**.

The collection of data for NNDSS which is included in this application is supported and administered by several programs at CDC in the 1) Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Division for Health Informatics and Surveillance (DHIS); 2) Centers within the Office of Infectious Diseases (OID); and the 3) Center for Global Health (CGH).

The 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. 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.

Each year, CSTE, supported by CDC, determines which reportable conditions should be designated nationally notifiable or under standardized surveillance and voluntarily submitted to CDC so that

information can be shared across jurisdictional boundaries and both surveillance and prevention and control activities can be coordinated at regional and national levels.

Description of Data Elements Received

The nationally notifiable conditions received by CDC through NNDSS are listed in an attachment **[Attachment 3. List of Nationally Notifiable Conditions].** There is an additional list of new conditions "under standardized surveillance" (conditions in this category were previously referred to as "under national surveillance" and included in the list of nationally notifiable conditions in the ICR revision application approved by OMB on January 15, 2014) that CDC would like to receive case notification data for **[Attachment 4. List of Conditions Under Standardized Surveillance]**. This list was not included in the last ICR revision application approved by OMB on January 21, 2016 since there were no new conditions in this category. This list of conditions "under standardized surveillance" includes two conditions, histoplasmosis and AFM. Conditions are considered "under standardized surveillance" when CSTE publishes a position statement that specifies a standardized case definition but does not specify that the condition should be nationally notifiable. CSTE published a position statement in 2016 specifying a standardized case definition for histoplasmosis (http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/2016PS/16_ID_02.pdf). This position statement says that "if requested by CDC, jurisdictions (e.g. States and Territories) conducting surveillance according to these methods may submit case information to CDC." CDC requests permission to receive case notification data for histoplasmosis as it is now under standardized surveillance. CSTE also published a position statement in 2015 specifying a standardized case definition for AFM (http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/2015PS/2015PSFinal/15-ID-01.pdf). This position statement also says that "If requested by CDC, jurisdictions (e.g. States and Territories) conducting surveillance according to these methods may submit case information to CDC." CDC requests permission to receive case notification data for AFM as it is now under standardized surveillance

There are a few additional conditions that were not included in the previous ICR. CDC also requests permission to receive case notification data for all enteric *E. coli* infections (enterotoxigenic, enteropathogenic, enteroinvasive, enteroaggregative, or other pathogenic *E. coli*) should any of them become nationally notifiable or be placed under standardized surveillance. CDC already has approval to receive case notification data for Shiga toxin-producing *E. coli* (STEC) which has been nationally notifiable since 2013 (http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PS/13-ID-01.pdf).

Should any other enteric *E. coli* infections become nationally notifiable or placed under standardized surveillance, CDC will submit a non-substantive change request to OMB.

A common, core set of data elements is submitted by public health departments for all of the nationally notifiable conditions included in this ICR. The core data elements include the name of the condition, demographic data for the person with the condition, epidemiologic data, and administrative data. Names, descriptions and value sets for the data elements are identified in an attachment **[Attachment 5. Core Data].** All of these core data elements were included in the previously approved ICR.

A common set of laboratory data elements submitted by public health departments for all of the nationally notifiable conditions are also included in this ICR. Most of these laboratory data elements were included in the previously approved ICR. Nineteen new laboratory data elements that were not included in the previously reviewed ICR were added since they are necessary for routine surveillance and apply to a number of nationally notifiable conditions. These new laboratory data elements enable the program to identify the organism, specify the subtype of the organism, interpret laboratory results, and determine which drugs are effective or resistant to a particular organism. Names, descriptions and value sets for the data elements are identified in an attachment with the nineteen new data elements in bold **[Attachment 6. Laboratory Data]**.

A common set of vaccine data elements submitted by public health departments for all of the nationally notifiable conditions are also included in this ICR. All of these vaccine data elements were included in the previously approved ICR. Names, descriptions and value sets for the data elements are identified in an attachment **[Attachment 7. Vaccine Data]**.

A common set of VPD data elements submitted by public health departments, not included in the previously approved ICR, is included in this ICR. These data elements were added since they are necessary for routine VPD surveillance and apply to a number of nationally notifiable conditions (such as measles, rubella, congenital rubella syndrome, mumps, pertussis, varicella, tetanus, etc.) and can be standardized across these conditions for efficiency. Names, descriptions and value sets for the data elements are identified in **Attachment 8. Vaccine Preventable Disease Data**.

For many conditions submitted to CDC, participating public health departments also submit data elements which are specific to each condition. With the coordination with other CDC programs conducting surveillance on nationally notifiable conditions, as noted above, this application includes disease-specific tables for 68 diseases**.** Most of these data elements were either included in the previously approved ICR or approved through a non-substantive change request. 143 new data elements that were not included in the previously reviewed ICR or approved through a non-substantive change request were added for CRS, Salmonella, Shigellosis, Campylobacteriosis, STEC, Hepatitis, and HPS. Names, descriptions, value sets, and justification for the addition of these new data elements are in **Attachment 9. Justification for the Addition of Disease-Specific Data Elements**. Names, descriptions and value sets for all of the data elements are in an attachment **[Attachment 10. Disease-Specific Data]** with the new data elements identified in bold.

A.2. Purpose and Use of the Information Collection

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.Gov (www.data.cdc.gov/). Shared data are summary statistics of aggregate data produced after personal identifiers have been removed (Section A.16,

below). Surveillance programs in OID and 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.

A.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 National Electronic Telecommunications System for Surveillance (NETSS) messages. However, NETSS messages are not based on industry standards. Some case notification messages are still sent to CDC by non-automated mechanisms including fax, 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.

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 has been represented in the burden table as "NMI Implementation."

A.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.

A.5. Impact on Small Businesses or Other Small Entities

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

A.6. Consequences of Collecting the Information Less Frequently

Public health departments that use automated methods to send case notifications to CDC send case notifications at least weekly. Most public health departments that use non-automated methods to send case notifications to CDC also send them at least weekly and some (territories and freely associated states) send them 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.

A.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.

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

A.8.A.

A 60-day Federal Register Notice was published in the *Federal Register* on December 22, 2016, Vol. 80, No. 92, pp. 93939-93940 **[Attachment 2a. 60-Day FRN].** One non-substantive comment **[Attachment 2b. Public Comment]** was received and the standard CDC response was sent.

A.8.B.

Through cooperative agreements, two independent external peer review panels conducted reviews of NNDSS. The report from the first panel was issued in December 2011 and focused on the results of an assessment of systems, frameworks and processes for infectious diseases within CDC. The report from the second panel was issued in April 2013 and focused on the results of a review of state and local systems, frameworks and processes for reportable conditions and for submission of information on notifiable infectious diseases to CDC. External consultants to the second independent external peer review panel, conducted by CSTE, are listed in the attachment **[Attachment 11. Consultants List]**.

A.9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts provided to respondents.

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

NNDSS data are stored in multiple information systems at CDC. The systems at CDC that store case notification data include the following: Data Warehouse (DW), Message Validation, Processing, and Provisioning System (MVPS), Botulism Database (BOT), Laboratory based Enteric Disease Surveillance (LEDS), National West Nile Surveillance System (ArboNET), Cholera and Other Vibrio Illness Surveillance

System (COVIS), and STDNet. The Privacy Act is applicable to some of these information systems as noted on their Privacy Impact Assessments (PIAs) **[Attachments 12 through 18]**. The Privacy Act System of Records Notice (SORN) 09-20-0136 "Epidemiologic Studies and Surveillance of Disease Problems" is noted in the PIA for COVIS. The SORN 09-20-0113 "Epidemic Investigation Case Records" is noted in the PIA for BOT. Private personally identifiable information (PII) is collected and information can be 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 technologies (computers and servers) that use national public health standards for messaging systems which provide security mechanisms for jurisdictions to use when submitting data. Most 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 notifications are faxed, emailed, uploaded to a secure network or entered into a secure website. 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 and Data.CDC.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 Certification

and Accreditation process, in which the CDC WONDER constraints are examined and validated by the CDC's Office of the Chief Information Security Officer (OCISO). While there are no such constraints on NNDSS data published on Data.CDC.gov, only public use, non-PII data 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.

A.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 and program evaluation), not research **[Attachment 19. NNDSS Research Determination; Attachment 20. OID Research Determinations]**.

Sensitive Questions

The NNDSS does not ask questions of a sensitive nature, but information is submitted about sensitive topics, including whether a patient has sexually transmitted diseases and sexual and drug-using behaviors. The NNDSS must receive information about sensitive notifiable diseases in order to monitor the occurrence of the diseases so that effective prevention and control programs can be planned and implemented.

A.12. Estimates of Annualized Burden Hours and Costs

As stated in A.1 above, this application is the second 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 the applications for 0920-0728 that were approved on January 15, 2014 and January 31, 2016 inadvertently included the number of hours that the public health department used to conduct routine disease surveillance for their jurisdiction. The burden estimates included the number of hours used to receive and process case reports from the clinician or laboratory and the number of hours used to process and send case notification data from the jurisdiction to CDC. The number of hours used to receive and process case reports should not have been included in the burden estimates as these hours are incurred by the jurisdiction for routine surveillance

whether they send case notification data to CDC or not. The burden estimates from the previous applications were corrected to include only the number of hours that the public health department uses to process and send case notification data from their jurisdiction to CDC. These corrected estimates also include separate burden hours incurred for automated and non-automated transmissions, separate weekly burden hours incurred for modernizing surveillance systems as part of NMI implementation, separate burden hours incurred for annual data reconciliation, and separate one-time burden hours incurred for the addition of new diseases and data elements. These estimates are based on information from CDC employees that manage the NMI effort and conduct site visits to provide technical assistance to help the public health departments modernize their surveillance systems.

The burden estimates in Table A12A below are based on the corrected burden estimates and also include the estimates of burden hours for the key changes in this revision including: 1) the additional burden hours that the freely associated states will incur when they are added to the NNDSS respondent population; 2) the one-time increase in burden hours that states and cities will incur to process and send 19 new laboratory data elements for all conditions; 3) the one-time increase in burden hours that states and cities will incur to process and send 13 new data elements for VPDs; 4) the one-time increase in burden hours that states and cities will incur to process and send 143 new data elements for CRS, Salmonellosis, Shigellosis, Campylobacteriosis, STEC, Hepatitis, and HPS and 5) the one-time increase in burden hours that states, territories, and cities, will incur to send case notification data for histoplasmosis and AFM.

The burden estimates are shown for four types of respondents: states, territories, freely associated states, and cities.

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 send weekly automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours. 10 states send weekly non-automated case notification data to CDC for at least one disease or condition and their average burden is 2 hours. All 50

states perform weekly activities to modernize their surveillance systems as part of NMI implementation and their average burden is 4 hours. All 50 states reconcile and send annual case notification data to CDC and their average burden is 75 hours. All 50 states modify their surveillance systems and automated case notification messages to accommodate new data elements and diseases and their one-time average burden is 8 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. One territory sends weekly automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours. All 5 territories send weekly and quarterly non-automated case notification data to CDC for at least one disease or condition and their average burden per response is 20/60 hours. All 5 territories perform weekly activities to modernize their surveillance systems as part of NMI implementation and their average burden is 4 hours. All 5 territories reconcile and send annual case notification data to CDC and their average burden is 5 hours. One territory modifies their surveillance system and automated case notification message to accommodate new data elements and diseases and their one-time average burden is 10/60 hours.

Freely Associated States

Freely associated states incur burden by: 1) sending weekly and quarterly non-automated case notification data to CDC, and 2) reconciling and sending annual case notification data to CDC. All 3 freely associated states send weekly and quarterly non-automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours. All 3 freely associated states reconcile and send annual case notification data to CDC and their average burden is 5 hours. These estimates are the same as the estimates for the territories since the volume of case notifications and the methods that the freely associated states use to send case notification data to CDC are nearly the same as the territories.

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 2 cities send weekly automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours. Both of the 2 cities send weekly non-automated case notification data to CDC for at least one disease or condition and their average burden per response is 2 hours. Both of the 2 cities perform weekly activities to modernize their surveillance systems as part of NMI implementation and their average burden is 4 hours. Both of the 2 cities reconcile and send annual case notification data to CDC and their average burden is 75 hours. Both of the 2 cities modify their surveillance systems and automated case notification messages to accommodate new data elements and diseases and their one-time average burden is 8 hours.

According to the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2016 National Occupational Employment and Wage Estimates, the estimated mean hourly wage for Computer Systems Analysts is $44.05 (https://www.bls.gov/oes/current/oes_nat.htm#15-0000) and the estimated mean hourly wage for Epidemiologists is $37.37 (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 and annual data reconciliation. These wage estimates were used because these two occupations represent the category of occupations held by the respondents that perform these activities. Using $44.05 as an average hourly wage rate for Computer Systems Analysts and using $37.37 as an average hourly wage rate for Epidemiologists, it is estimated that the average national annual burden for weekly and annual reporting is 18,529 hours at a national cost of $780,553.

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 Diseases and Data Elements	50	1	8	400
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
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	8	16

Total					**18,529**

A12B. Estimates of Annualized Cost Burden

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Respondent Cost
States	Weekly (Automated)	50	52	20/60	867	$44.05	$38,191
States	Weekly (Non-automated)	10	52	2	1,040	$37.37	$38,865
States	Weekly (NMI Implementation)	50	52	4	10,400	$44.05	$458,120
States	Annual	50	1	75	3,750	$37.37	$140,138
States	One-time Addition of Diseases and Data Elements	50	1	8	400	$44.05	$17,620
Territories	Weekly (Automated)	1	52	20/60	17	$44.05	$749
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93	$37.37	$3,475
Territories	Weekly (NMI Implementation)	5	52	4	1,040	$44.05	$45,812
Territories	Annual	5	1	5	25	$37.37	$934
Territories	One-time Addition of Diseases and Data Elements	1	1	10/60	1	$44.05	$44
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56	$37.37	$2,093
Freely Associated States	Annual	3	1	5	15	$37.37	$561
Cities	Weekly (Automated)	2	52	20/60	35	$44.05	$1,542
Cities	Weekly (Non-automated)	2	52	2	208	$37.37	$7,773
Cities	Weekly (NMI Implementation)	2	52	4	416	$44.05	$18,325
Cities	Annual	2	1	75	150	$37.37	$5,606
Cities	One-time Addition of	2	1	8	16		

	Diseases and Data Elements					$44.05	$705
Total							**$780,553**

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

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

A.14. Annualized Cost to the Federal Government

Item	NNDSS Estimated Cost to Federal Government		
	FY 17	FY 18	FY 19
Personnel - Software development, support, and management (intramural)	$6,848,455	$6,848,455	$6,848,455
Contracts – Program and web support	$10,488,556	$10,488,556	$10,488,556
Cooperative Agreements with States for NNDSS case notification and management (extramural)	$9,243,323	$10,474,636	$10,474,636
Total	$26,580,334	$27,811,647	$27,811,647

The estimated annualized cost to the government for NNDSS is $27,401,209 (average of three years).

A.15. Explanation for Program Changes or Adjustments

Changes to NNDSS in this revision include the expansion of the respondent population to include the freely associated states (the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau); receipt of new laboratory data elements for all conditions, receipt of new data elements for all VPDs; receipt of new data elements for the following conditions that are already approved: CRS, Salmonellosis, Shigellosis, Campylobacteriosis, STEC, Hepatitis, and HPS; receipt of case notification data for histoplasmosis which is now under standardized surveillance; receipt of case notification data for AFM which is now under standardized surveillance, and receipt of case notification data for all enteric *E. coli* infections should any of them become nationally notifiable or be placed under standardized surveillance. Should any enteric *E. coli* infection become nationally notifiable or placed under standardized surveillance, CDC will submit a non-substantive change request to OMB.

The total burden decreased since the last submission because of corrections and updates to the burden table. Going forward, there will be a one-time increase in the burden estimates each time new data elements or new conditions are added. The one-time increase in the burden estimates for adding new data elements will be reflected as a separate line in the burden table in an ICR revision or a non-substantive change request.

A.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 will not be published in the *MMWR* but will be available through CDC WONDER and data.cdc.gov. The *MMWR Summary of Notifiable Diseases, United States, 2015*, will be the last summary of finalized notifiable disease data to be published by *MMWR*. Going forward and beginning with 2016 data, finalized notifiable disease data will be published on CDC WONDER and data.cdc.gov and disease-specific data will be published by individual CDC programs. This transition to using CDC WONDER and CDC.data.gov as the primary forums for presentation of weekly tables will allow 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.

A.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 21. PRA Burden Statement Screenshot.**

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.