National Notifiable Diseases Surveillance System Supporting Statement Section A OMB Control Number 0920-0728

January 21, 2016 Program Contact Umed Ajani

Associate Director for Surveillance, Division of Health Informatics and Surveillance

Center for Surveillance, Epidemiology and Laboratory Services

Centers for Disease Control and Prevention

Phone: 404-498-0258

E-mail: UAjani@cdc.gov

National Notifiable Diseases Surveillance System - Request for Revision

Table of Contents

Section

A. Justification

- 1. Circumstances Making the Collection of Information Necessary
- 2. Purpose and Use of the Information Collection
- 3. Use of Improved Information Technology and Burden Reduction
- 4. Efforts to Identify Duplication and Use of Similar Information
- 5. Impact on Small Businesses or Other Small Entities
- 6. Consequences of Collecting the Information Less frequently
- 7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
- 8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency
- 9. Explanation of Any Payment or Gift to Respondents
- 10. Protection of the Privacy and Confidentiality of Information Provided by Respondents
- 11. Institutional Review Board (IRB) and Justification for Sensitive Questions
- 12. Estimates of Annualized Burden Hours and Costs
- 13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers
- 14. Annualized Cost to the Federal Government
- 15. Explanation for Program Changes or Adjustments
- 16. Plans for Tabulation and Publication and Project Time Schedule
- 17. Reason(s) Display of OMB Expiration Date is Inappropriate
- 18. Exceptions to Certification for Paperwork Reduction Act Submissions

Exhibits

- Exhibit 12-A Estimates of Annualized Burden Hours
- Exhibit 12-B Estimates of Annualized Burden Costs
- Exhibit 14-A Estimated Annualized Cost to the Government

Attachments

- 1. Authorizing Legislation
- 2a. 60-day Federal Register Notice (FRN)
- 2b. Public Comment
- 3. List of Nationally Notifiable Conditions
- 4. Core Data
- 5. Laboratory Data
- 6. Vaccine Data
- 7. Disease-Specific Data
- 8. DHIS Data Processing and Security Procedures for NND Data
- 9. Consultants List
- 10. DW PIA
- 11. MVPS PIA
- 12. BOT PIA

- 13. LEDS PIA
- 14. ArboNET PIA
- 15. COVIS PIA
- 16. STDNet PIA
- 17. NNDSS Research Determination
- 18. OID Research Determinations

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 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 publishes numbers of cases and incidence rates of nationally notifiable conditions based on NNDDS data in the Morbidity and Mortality Weekly Report (*MMWR*) and other scientific journals.

A1. Circumstances Making the Collection of Information Necessary

CDC requests a three year approval for a Revision for the National Notifiable Diseases Surveillance System (NNDSS), OMB Control No. 0920-0728, Expiration Date January 31, 2017. This application is a revision to the previous application for 0920-0728 (approved by OMB on January 15, 2014) which consolidated four other CDC applications to OMB 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:

- Replace "Hepatitis C virus, past or present" and "Hepatitis C, acute" with "Hepatitis C" on the List of Nationally Notifiable Conditions
- Replace all listed Arboviral conditions with an inclusive category, "Arboviral Diseases" on the List of Nationally Notifiable Conditions
- Receive case notification data for Hantavirus infection, non-Hantavirus Pulmonary Syndrome

- Receive case notification data for Acute Flaccid Myelitis should it become nationally notifiable
- Receive case notification data for Amebic Encephalitis should it become nationally notifiable
- Receive new laboratory and vaccine data elements for all conditions
- Receive new disease-specific data elements for Mumps, Pertussis, Varicella, Arboviral Diseases, and Sexually Transmitted Diseases (STD)

Background

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 designated as "nationally notifiable" (referred to in this application as nationally notifiable conditions). CSTE is an organization of member states and territories representing public health epidemiologists. The NNDSS 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). 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 <u>reportable conditions</u>, 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 <u>nationally notifiable</u> 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 are a few changes to the List of Nationally Notifiable Conditions that were not included in the previously approved Information Collection Request (ICR). CSTE issued a position statement in 2015 that replaced "Hepatitis C virus, past or present" and "Hepatitis C, acute" with "Hepatitis C"

(http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/2015PS/2015PSFinal/15-ID-03.pdf). This change is now reflected in bold. All specific Arboviral conditions were deleted and replaced with an inclusive category, "Arboviral Diseases" which was not included in the previously approved ICR and is listed in bold. After discussions with CDC and local, state, and territorial health departments, CSTE issued a position statement in 2004 that rendered all Arboviral Diseases nationally notifiable (http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PS/04-ID-01-FINAL.pdf). The following Arboviral conditions were deleted from Attachment 3:

- California serogroup virus neuroinvasive and non-neuroinvasive disease
- Dengue fever (DF), Dengue hemorrhagic fever (DHF), Dengue shock syndrome (DSS)
- Eastern equine encephalitis virus neuroinvasive and non-neuroinvasive disease
- Jamestown Canyon virus, neuroinvasive and non-neuroinvasive disease
- Powassan virus neuroinvasive and non-neuroinvasive disease

- St. Louis encephalitis virus neuroinvasive and non-neuroinvasive disease
- West Nile virus neuroinvasive and non-neuroinvasive disease
- Western equine encephalitis virus neuroinvasive and non-neuroinvasive disease
- Yellow fever

Hantavirus infection, non-Hantavirus Pulmonary Syndrome which was not included in the previously approved ICR, is now nationally notifiable and is also listed in bold in Attachment 3.

Additionally, there are two conditions, Acute Flaccid Myelitis and Amebic Encephalitis, that were not included in the previously approved ICR. A position statement was submitted at the CSTE Annual Meeting in June of this year specifying a standardized case definition for Acute Flaccid Myelitis (https://docs.google.com/document/d/1FecEviYjN_OSO-2KFg0kxMAVM-2vTI2x1EII_6lkN5s/edit). In 2012, CSTE approved a position statement establishing standardized case definitions for free-living amebae infections (http://wwwn.cdc.gov/nndss/conditions/free-living-amebae-infections/case-definition/2012/). CSTE has not yet issued a position statement for Amebic Encephalitis, a subset of free-living amebae infections, but a petition was started to make Primary Amoebic Meningoencephalitis (a specific Amebic Encephalitis caused by *Naegleria fowleri*) nationally notifiable (http://outbreaknewstoday.com/naegleria-fowleri-petition-calls-for-mandatory-reporting-of-pam-at-the-national-level-22962/). Acute Flaccid Myelitis and Amebic Encephalitis are not yet nationally notifiable but permission is being requested to receive case notification data should they become nationally notifiable in the near future.

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 4. Core Data].** All of these core data elements were included in the previously approved ICR.

A common set of laboratory and vaccine data elements submitted by public health departments not included in the previously approved ICR are included in this application. These data elements were added since they are necessary for routine surveillance and apply to a number of nationally notifiable conditions and can be standardized across these conditions for efficiency. Names, descriptions and value sets for the data elements are identified in two attachments [Attachment 5. Laboratory Data and Attachment 6. Vaccine 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 included in the previously approved ICR. Several disease-specific data elements not included in the previously approved ICR have been added to the disease-specific data elements (since they are necessary for routine surveillance) for the following conditions: Mumps, Pertussis, Varicella, Arboviral Diseases, and STD. Names, descriptions and value sets for the data elements are identified in bold in an attachment [Attachment 7. Disease-Specific Data].

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.

CDC uses NNDSS data also for weekly publication in the *Morbidity and Mortality Weekly Report* (*MMWR*) and for the annual summary presenting finalized official incidence data for these diseases in the *MMWR* series entitled *Summary of Notifiable Diseases*, *United States*. 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 *MMWR* and 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 (<u>http://wonder.cdc.gov/</u>) and through Data.Gov (<u>www.data.cdc.gov/</u>). 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.

Procedures for receiving, securing, provisioning, publishing, and releasing nationally notifiable infectious diseases data received at CDC by information systems administered by DHIS are described in an attachment [Attachment 8. DHIS Data Processing and Security Procedures for NND Data]. These procedures were developed in 2014 and recently revised in January 2015. 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.3. Use of Improved Information Technology and Burden Reduction

A new NNDSS initiative that focuses, in part, 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. The NMI is an effort to enhance the surveillance capabilities of NNDSS to provide more comprehensive, timely, and higher quality data for public health decision making. Key NMI activities include standardizing message content and format for NNDSS data received by CDC from health departments and developing a new system to validate, process, and provision that data to CDC programs. Through NMI, subject matter experts provide guidance to the reporting jurisdictions for submitting their data using interoperable, standardized data and exchange mechanisms in a consistent format. These improvements will allow more of the information requested by CDC programs to be sent in the NNDSS message, reducing the need for supplemental data submissions through non-automated routes. Introduction of the templates for laboratory and vaccine data elements described in section A.1 above are important steps toward harmonizing frequently requested data, making implementation more efficient for submitters. Use of standardized data elements and values ensures that public health data

collection is in agreement with the information collected in the health care sector, reducing the need for data transformation by the public health agencies that submit the NNDSS data. These improvements in information technology will eventually decrease the burden on the health departments that submit NNDSS data.

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 to allow state and local health departments to Submit more nationally notifiable disease data to CDC, both the duplication of reporting to CDC by state and local health departments and the burden to state and local 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

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

As explained in Section A.6, rapid submission of national data to NNDSS is essential to the early identification of disease epidemics, more timely and complete understanding of disease trends, and evaluation of prevention and control efforts.

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

A 60-day Federal Register Notice was published in the *Federal Register* on May 13, 2015, Vol. 80, No. 92, pp. 27315-27316 [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 9. 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 10 through 16]**. 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 diseasespecific data related to a case of a nationally notifiable condition. The security of private information during electronic 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 records 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. Once in DHIS, the electronic 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. When electronic transmission is not possible or when public health departments prefer, weekly case counts are provided by telephone, fax, mail, and email, primarily to meet weekly deadlines for publication in the *MMWR*.

For some conditions in NNDSS, CDC programs do not receive data electronically. Case report forms are mailed or faxed to CDC by state, local and territorial health departments. In certain circumstances, such as outbreak situations, reports are first made by telephone, and then followed by a written report. On occasion, reports are emailed by state health departments via secure email systems. These data are entered into electronic databases. In some instances, weekly case counts are provided by telephone, fax, mail, and email, primarily to meet weekly deadlines for publication in the *MMWR*. All hard copy materials are stored in locked cabinets in restricted access areas in buildings that require card key access.

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 (<u>http://wonder.cdc.gov/</u>. NNDSS data are also published on Data.CDC.gov (<u>https://data.cdc.gov/</u>) and DATA.GOV (<u>http://www.data.gov/</u>). 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 17. NNDSS Research Determination; Attachment 18. 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 consolidates Control No. 0920-0128, parts of 0819, 0009, and 0004, into Control No. 0920-0728. Fifty-seven (57) reporting jurisdiction (50 states, 5 territories, and 2 cities) submit data to NNDSS on a weekly basis. The average burden per response is based on the burden tables from all of the consolidated applications and has not changed. The burden on the states and cities is estimated to be 10 hours per response and the burden on the territories is estimated to be

5 hours per response. The one new nationally notifiable condition (Hantavirus infection, non-Hantavirus Pulmonary Syndrome), will not increase the burden since it has a very low incidence. Acute Flaccid myelitis is also a low incidence condition and will not increase the burden if it becomes nationally notifiable. The addition of new vaccine, laboratory, and disease-specific data elements will not add any additional burden because the states, territories, and cities already collect those data elements. There will be no increase in burden for the states, territories, and cities to send those data elements to CDC since most case notifications are submitted electronically from already existing databases via automated electronic transfers.

According to the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates, the mean hourly wage for Epidemiologists is \$35.63 (<u>http://www.bls.gov/oes/current/oes_nat.htm#19-0000</u>). This rate is used as the hourly wage rate for respondents that submit notifiable disease data weekly and annually to CDC because it represents the category of occupations held by the respondents and was used in the consolidated applications. Using \$35.63 as an average hourly wage rate, it is estimated that the average national annual burden for weekly and annual reporting is 28,340 hours at a national cost of \$1,009,754.

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 and Annual	50	52	10	26,000
Territories	Weekly and Annual	5	52	5	1, 300
Cities	Weekly and Annual	2	52	10	1,040
Total					28,340

A12A. Estimates of Annualized Burden Hours

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 and Annual	50	52	10	26,000	\$35.63	\$926,380
Territories	Weekly and Annual	5	52	5	1,300	\$35.63	\$46,319
Cities	Weekly and Annual	2	52	2	1,040	\$35.63	\$37,055
Total							\$1,009,754

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. <u>Annualized Cost to the Federal Government</u>

Item	NNDSS Estimated Cost to Federal Government				
	FY 16	FY 17	FY 18		
Personnel - Software development, support, and	\$8,605,792	\$8,105,792	\$8,105,792		
management (intramural)					
Cooperative Agreements with States for NNDSS case	\$10,474,636	\$10,474,636	\$10,474,636		
notification and management (extramural)					
Total	\$19,080,428	\$18,580,428	\$18,580,428		

The estimated annualized cost to the government of the NNDSS systems (both CDC developed and federal support to the states) is \$18,747,095 (average of three years).

A.15. Explanation for Program Changes or Adjustments

Changes to NNDSS in this revision include the replacement of "Hepatitis C virus, past or present" and "Hepatitis C, acute" with "Hepatitis C" on the List of Nationally Notifiable Conditions; the replacement of all listed Arboviral conditions with an inclusive category, "Arboviral Diseases" on the List of Nationally Notifiable Conditions; receipt of case notification data for Hantavirus infection, non-Hantavirus Pulmonary Syndrome; receipt of case notification data for Acute Flaccid Myelitis and Amebic Encephalitis should they become nationally notifiable; receipt of new laboratory and vaccine data elements for all conditions since they are necessary for routine surveillance and apply to a number of nationally notifiable conditions and can be standardized across these conditions for efficiency; and the receipt of new disease-specific data elements for Mumps, Pertussis, Varicella, Arboviral Diseases and STD since they are necessary for routine surveillance for these particular conditions. As stated above, these changes will not add to the burden since states, territories, and cities already collect this information and there is no increase in burden to send these data elements to CDC. Most case notifications are submitted electronically from already existing databases via automated electronic transfers. Additionally, CSTE, local, state, and territorial health departments and CDC work jointly to decide which conditions are nationally notifiable and added to NNDSS.

A.16. Plans for Tabulation and Publication and Project Time Schedule

CDC tabulates and publishes provisional counts of nationally notifiable conditions each week. The data are published in the *MMWR* and are available at <u>http://wonder.cdc.gov/mmwr/mmwrmorb.asp</u>. The *MMWR* weekly tables of nationally notifiable diseases are also available on the *MMWR* web site (<u>http://www.cdc.gov/mmwr/mmwr_wk/wk_cvol.html</u>) within the "Notifiable Disease and Mortality Tables" section of each week's publication. In August, finalized case counts by jurisdiction of nationally notifiable conditions for the previous year are published in *MMWR* Early Release tables. Then, in spring of the following year, the final annual data tables are published in the *MMWR Summary of Notifiable Diseases, United States*, available at this location: <u>http://www.cdc.gov/mmwr/mmwr_nd/index.html</u>. A limited number of hard copies of the Annual Summary are available and are also distributed. These summaries are for use by local, state, and federal health agencies, schools of medicine and public health, communications media, and other agencies or persons interested in notifiable disease surveillance and epidemiology in the United States. In addition, CDC programs publish routinely 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

CDC requested approval to not display the expiration date for OMB approval on information collection forms in the previous revision application. Approval was granted on January 15, 2014.

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

There are no exceptions to the certification.