

National Notifiable Diseases Surveillance System (NNDSS)

Supporting Statement Section A

OMB Control Number 0920-0728, Revision

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NNDSS - Request for Revision

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Abstract

The Centers for Disease Control and Prevention (CDC) requests a three year approval for a Revision for the National Notifiable Diseases Surveillance System (NNDSS) [National Electronic Disease Surveillance System (NEDSS), OMB Control No. 0920-0728, Expiration Date 01/31/2014]. This request has been developed in coordination with four other CDC applications to OMB for nationally notifiable diseases case notification: Control Nos. 0920-0128, (Congenital Syphilis Surveillance), 0920-0819 (Nationally Notifiable Sexually Transmitted Disease (STD) Morbidity Surveillance), 0920-0009 (National Disease Surveillance Program - I. Case Reports) and 0920-0004 (National Disease Surveillance Program - II. Disease Summaries). This consolidation of 0128 and some parts of 0819, 0009 and 0004 into 0728, is an important step in implementing CDC's longer term strategy of developing a more coordinated and integrated infectious diseases surveillance system that reduces overlap and duplication; increases interoperability, integration and efficiency; and thereby reduces burden to state, territorial and local health departments that report infectious disease data to CDC. Due to the consolidation, this NNDSS application includes conditions and many additional data elements that were not previously included in OMB Control No. 0920-0728.

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

CDC requests a three year approval for a Revision for the National Notifiable Diseases Surveillance System (NNDSS) [National Electronic Disease Surveillance System (NEDSS), OMB Control No. 0920-0728, Expiration Date 01/31/2014]. This request has been developed in coordination with four other CDC applications to OMB for nationally notifiable diseases case notification: Control Nos. 0920-0128, (Congenital Syphilis Surveillance), 0920-0819 (Nationally Notifiable Sexually Transmitted Disease (STD) Morbidity Surveillance), 0920-0009 (National Disease Surveillance Program - I. Case Reports) and 0920-0004 (National Disease Surveillance Program - II. Disease Summaries). By consolidating 0128, and parts of 0819, 0009 and 0004 into 0728, this application supports increases in interoperability, integration and efficiency of CDC's infectious diseases surveillance systems by reducing overlap and duplication within the CDC systems, thereby reducing burden to state, territorial and local health departments that report infectious disease data to CDC. Due to the consolidation, this NNDSS application includes 11 conditions and many additional data elements for the case notifications that were not previously included in NNDSS OMB application Control No. 0920-0728. These additions are described in section A.1.1 below.

This application does not affect CDC OMB applications for a number of other nationally notifiable conditions for which CDC receives case notifications or outbreak notifications but which are not included in this application: acute pesticide-related illness and injury, cancer, elevated blood lead levels, HIV, silicosis, tuberculosis, foodborne disease outbreaks, and waterborne disease outbreaks. Other CDC programs are responsible for those surveillance systems and for those applications.

In addition, this application does not affect those aspects of OMB Control Nos. 0920-0819 (Nationally Notifiable Sexually Transmitted Disease (STD) Morbidity Surveillance), 0920-0009 (National Disease Surveillance Program - I. Case Reports) and 0920-0004 (National Disease Surveillance Program - II. Disease Summaries) for notification to CDC of conditions/not included in this application section A.1.1 or for submission of data elements not identified in this application in section A.1.1 below.

The National Notifiable Diseases Surveillance System (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) has officially designated as either “nationally notifiable” or as under “national 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 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 health 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 diseases’ 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 Center for Surveillance, Epidemiology, and Laboratory Services (CSELS), Centers within the Office of Infectious Diseases (OID) and the 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. Currently approximately 300 conditions are reportable in one or more of the states **[Attachment 2: CSTE SRCs]**. 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.

Since infectious disease agents and environmental hazards often cross geographical boundaries, public health departments have to be able to share data on certain conditions across jurisdictions and to coordinate program activities to prevent and control the conditions. Each year, CSTE, performs an assessment of conditions reported to state, territorial and local jurisdictions to determine which should be designated nationally notifiable conditions. For conditions that are nationally notifiable, case notifications are voluntarily submitted to CDC by the jurisdictions 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.

A number of different legislative and regulatory decisions have authorized federal collection of these data and given responsibility for that data collection to CDC. In 1878, Congress authorized the U.S. Marine Hospital Service (later renamed the U.S. Public Health Service) to collect morbidity reports on cholera, plague, smallpox and yellow fever from U.S. consuls overseas; this information was used for instituting quarantine measures to prevent the introduction and spread of these diseases. In 1879, a specific Congressional appropriation was made for the collection and publication of reports of these notifiable diseases. Congress expanded the authority for weekly reporting and publication in 1893 to include data from state and municipal authorities throughout the U.S. To increase the uniformity of the data, Congress enacted a law in 1902 directing the Surgeon General of the Public Health Service (PHS) to provide forms for the collection and compilation of data and for the publication of reports at the national level. In 1912, state and territorial health authorities-- in conjunction with PHS-- recommended immediate telegraphic reports of five diseases and monthly reporting by letter of 10 additional diseases, but it was not until after 1925 that all states reported regularly. A PHS study in 1948 led to a revision of the morbidity reporting procedures, and in 1949 morbidity reporting activities were transferred from the Division of Public Health Methods, PHS to the National Office of Vital Statistics. Another committee in PHS presented a revised plan to the Association of State

and Territorial Health Officers (ASTHO) at its meeting in Washington, D.C., October 1950. ASTHO authorized CSTE to determine the conditions that should be submitted by the states to PHS. Beginning in 1951, national meetings of CSTE were held every two years until 1974, then annually thereafter.

In 1961, responsibility for the collection of data on nationally notifiable diseases and deaths in 122 U.S. cities was transferred from the National Office of Vital Statistics to CDC.

Overview of case notification

The NNDSS case notification system is based on reportable disease surveillance systems described above. 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. CSTE determines which conditions are nationally notifiable.

CDC provides financial and programmatic support to public health department for their infectious reportable disease surveillance systems including developing and maintaining information technology (IT) systems for their use. For different reportable conditions, some health departments use systems supplied by CSELS, Centers within OID, or CGH, some use vendor-supplied systems and some use systems developed by the jurisdiction.

Given the way that surveillance systems for nationally notifiable diseases were developed at CDC historically, state, territorial and local health departments have transmitted and continue to transmit nationally notifiable disease data to different systems and programs at CDC including CSELS, Centers within OID, and CGH.

Case Notification to NNDSS

The transmission of data to CSELS NNDSS is supported by several interconnected frameworks for the exchange of electronic information and IT systems and platforms. The majority of case

notifications are encrypted and submitted to CSELS NNDSS electronically from already existing databases via automated electronic transfers through a secure network. On occasion, 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 *Morbidity and Mortality Weekly Report (MMWR)*. The submission and receipt of these data follow current best practices and standards available, as described in Section A.10, below.

OID and CGH receive data through several electronic surveillance systems. As state health departments develop computer capabilities, additional report formats are being developed for electronic transmission. For many conditions, OID/CGH does not receive data electronically. Most 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. The submission and receipt of these data follow current best practices and standards available, as described in Section A.10, below.

Statistical sampling

The case notification process involves no statistical sampling methods: all 50 states, New York City, the District of Columbia, and 5 U.S. territories voluntarily provide notification to CDC on all cases reported to those jurisdictions.

Description of the information submitted

The 82 nationally notifiable conditions included in this NNDSS OMB application are listed in an attachment [**Attachment 3. List of NNDs**]. Due to the coordination with other CDC programs conducting surveillance on notifiable diseases, eleven conditions not included in the 2010 NNDSS application to OMB have been added to this list: Babesiosis, California serogroup virus neuroinvasive and non-invasive disease, Central line associated bloodstream infection, Coccidioidomycosis, Infections by free living amebae, Jamestown Canyon virus neuroinvasive and non-neuroinvasive, Leptosirosis, Melioidosis, Powassan virus neuroinvasive and non-

neuroinvasive disease, St. Louis encephalitis's virus neuroinvasive and non-neuroinvasive disease, and West Nile virus neuroinvasive and non-neuroinvasive disease.

A common, core set of data elements is submitted by public health departments for all of the nationally notifiable conditions included in this OMB application [**Attachment 4. Core Data**]. The common data elements include the name of the condition; demographic data for the person with the condition (age, sex, race, ethnicity, date of birth); state, county, and ZIP code of residence; administrative data such as the jurisdiction submitting the case, information about whether the case meets the national surveillance definition, case identifier, subject identifier; epidemiologically relevant dates, such as date of disease onset, diagnosis, laboratory testing; where the disease was likely acquired; whether the case was associated with an outbreak; and markers of disease severity (such as whether the individual was hospitalized or died from the disease). Descriptions and value sets for the data elements are identified in an attachment [**Attachment 4. Core Data**].

Several data elements not included in the 2010 NNDSS OMB application have been added to the core data elements list: Immediate nationally notifiable condition; Country of birth; Country of usual residence; Binational reporting criteria; Country of exposure; State or providence of exposure; City of exposure; County of exposure; Case count; Comment; and the Name and Phone number of the person submitting the case information to CDC Descriptions and value sets for the data elements also are identified in an attachment [**Attachment 4. Core 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 notifiable conditions, as noted above, this application includes disease-specific tables for 68 diseases [**Attachment 5. Disease-Specific Data**]. The 2010 NNDSS OMB application included disease-specific data elements for only 14 of those conditions: acute viral hepatitis (A, B, C), meningococcal disease, *Haemophilus influenzae*, bacterial meningitis other, listeriosis, Lyme disease, measles, mumps, rubella, pertussis, tetanus and varicella. The disease-specific data elements submitted by participating health departments vary by disease and may include signs and symptoms of the condition, species of animal from

which a disease may have been transmitted, additional diagnostic data, treatment data, vaccination history, laboratory tests and results, and risk factors for disease acquisition (such as travel history, food consumption history, personal behaviors, transmission settings and co-morbidities). Descriptions and value sets for the data elements are identified in an attachment **[Attachment 5. Disease-Specific Data]**.

Four personal identifiers are submitted to NNDSS. For all conditions (as indicated in the core data table), the name of the person submitting the case report to CDC and the date of birth (month, day, and year) of the person with the condition are submitted. The Malaria program accepts reporting of the name of the individual diagnosed with malaria in order to link with other information and to avoid duplication of records. Some OID and CGH programs collect medical identification numbers, e.g., hospital identification number. In addition, a unique Case ID for the specific disease or condition for a given patient and a Subject ID for that patient are submitted to NNDSS. Some combinations of submitted data elements, including date of birth, date of death (month/day/year), sex, ethnic group, race, state, county, and ZIP code could potentially be used to identify individuals.

However, there are security measures and policies in place that protect the data and minimize the possibility of identifying individuals using NNDSS data (**Section A.10, below**).

A.2. Purpose and Use of Information Collection

As described in section A.1., NNDSS enables all levels of public health (local, state, territorial, federal and international) to monitor the occurrence and spread of more 82 nationally diseases and conditions and to plan and evaluate public health activities to prevent and control those diseases/conditions.

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 Program 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. Information is also shared with jurisdictions. In addition, information is collected that allows OID and CGH 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)*. The number of cases of nationally notifiable diseases reported to state health departments by local city or county health departments during the preceding "reporting week" is included in the morbidity report. CDC also publishes an annual summary presenting finalized official incidence data for these diseases in the *Morbidity and Mortality Weekly Report (MMWR)* series entitled *Summary of Notifiable Diseases, United States*. The annual report is used to update annual tables published by the World Health Organization, the Pan American Health Organization, the U.S. Bureau of the Census, and the National Center for Health Statistics. 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 disease data to publish surveillance summaries and other reports in *MMWR* and in scientific, public health and medical journals.

Data are also shared with outside users 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/>). Shared data are summary statistics of aggregate data produced after personal identifiers have been removed (Section A.15, below).

In addition, restricted access data sets may be shared with members of the public after the requestor and the notifiable diseases Data Steward complete a Data Use Agreement (Section A.15, below).

A.3. Use of Improved Information Technology

As noted above, submission of data by state, territorial and local health departments is supported by several interconnected frameworks for the exchange of electronic information and electronic information technology systems and platforms. However, data are submitted in a number of different ways and to a number of different systems or programs in CSELS, OID and CGH.

Since OMB last approved the NNDSS surveillance system in January 2011(NEDSS), OMB Control No. 0920-0728, CDC has requested and obtained two independent external peer reviews of NNDSS following CDC guidance on external review of scientific programs. The CDC guidance references OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies http://www.whitehouse.gov/omb/fedreg/final_information_quality_guidelines.html/. Through a cooperative agreement with CDC, the Public Health Informatics Institute selected and funded an independent external peer review panel that conducted review of NNDSS systems, frameworks and processes for infectious diseases within CDC. In addition, through a cooperative agreement with CDC, CSTE selected and funded independent external peer review panel to review state and local systems, frameworks and processes for reportable conditions and for submission of information on notifiable infectious diseases to CDC. These reviews provided a number of recommendations to CDC to improve the use of information technology and related frameworks and systems, summarized in Section A.8.B, below.

In response to these independent reviews, CSELS in collaboration with OID and CGH has initiated a number of improvements for NNDSS. Those improvements will include increasing communication and coordination within the agency and with public health departments. Enhancements include transitioning from non-electronic to automated electronic submission of information to CDC. Changes will include more consistently using common national standards for electronic health records and messaging, including vocabulary and code sets, content structure, transport, security and service (providing the right information to the right people). This will increase interoperability among public health departments and with CDC and increase interoperability between systems in public health and with electronic systems in medical care. In

addition, data elements, definitions and value sets for notifiable conditions will be reviewed and harmonized. The enhancements will, over time, reduce duplication of data submission to CDC and the number of locations to which data on NNDs are sent and standardize the methods by which the data is submitted to CDC. The improvements will increase efficiency of the data management and transmission process and the timeliness, completeness and accuracy of data, making the data more useful for disease prevention and control activities.

Both the increased communication and coordination with state, territorial and local health departments and the implementation of new electronic systems and technologies by the departments in collaboration with CDC may initially increase the burden to the departments as they devote time and other resources to making these changes. However, the burden may be substantially reduced as the new technologies are implemented and labor intensive manual processes are replaced by more efficient, standardized automated electronic systems.

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. In addition, consolidation the NNDSS-related OMB application 0128, and parts of 0819, 0009 and 0004 into 0728 facilitates the developments in information systems noted above in A.3 above. So, as the CSELS NNDSS electronic systems are developed to allow state and local health departments to submit more nationally notifiable disease data to CDC through CSELS NNDSS, 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. 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 08/09//2013, vol, 78, No. 154, pp. 48680-48681 [**Attachment 11. 60 d FRN**].

One comment received [**Attachment 11a. Public Comment**]. CDC’s standard response was sent.

A.8.B. CDC has consulted with external stakeholders in various ways. As stated in section A. 1, consultations with state epidemiologists and health officers are conducted routinely through CSTE and the Association of State and Territorial Health Officers. CDC has collaborated with CSTE since CSTE’s inception in 1951, and it is through the CSTE annual conference that the cooperation of all states is formally maintained. Although formal CSTE meetings are usually held only once a year, CSTE-CDC surveillance working groups exist to regularly address issues throughout the year that require federal-state collaboration. Telephone and e-mail communication between CDC and CSTE groups and individual members of those organizations continue on a regular basis throughout the year.

As noted in section A.3, above, through cooperative agreements, two independent external peer review panels conducted reviews of NNDSS. The first panel focused on systems, frameworks and processes for infectious diseases within CDC and consulted with CDS staff. The second independent peer review panel reviewed 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 are listed in the attachment [**Attachment 12. Consultants List**].

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

There are no payments or gifts provided to respondents.

A.10. Assurance of Confidentiality Provided to Respondents

The Privacy Act is applicable. No assurance of confidentiality has been obtained. The relevant Privacy Act System of Records Notice is 0920-0136 “Epidemiologic Studies and Surveillance of Disease Problems.”

As stated in section A.1 above, private personally identifiable information is collected. In addition, some combinations of submitted data elements could potentially be used to identify individuals.

The security of private information during electronic transmission to CSELS 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 processed within the Data Warehouse and/or the Public Health Platform at CDC. 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 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. On occasion, 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. CSELS provides NNDSS data to CDC programs for their analysis by posting it to the CDC's Consolidated Statistical Platform. The platforms are subject to CDC's Certification and Accreditation process, in which these controls are examined and validated by the CDC's Office of the Chief Information Security Officer.

All hard copy materials submitted to CDC are stored in locked cabinets in restricted access areas in buildings that require card key access.

Within OID and CGH, all records with personal identifiable information are held in locked cabinets in secure buildings accessed only by secure card key. Different methods for data collection and processing apply for different notifiable conditions and are described in more detail below.

Users of STDNet (in Division of Sexually Transmitted Disease Prevention (DSTDP) only) must

read the STD Surveillance Data Use and Release Policy and sign and return the STDNet Data Use Agreement before access is granted by the data steward. STD morbidity data sets used by CDC epidemiologists and investigators in DSTDP are stored on CDC network servers in multi-user share file folders. Where applicable, these forms are maintained as a system of records under the Privacy Act system notice 09-20-0136, “Epidemiologic Studies and Surveillance of Disease Problems,” last published in its entirety in the Federal Register, Vol. 57, No. 252, December 31, 1992, pp. 62812-62814, and updated December 29, 1993 and December 28, 1994. All records are safeguarded appropriately. Access is limited to personnel whose official job duties require them to utilize the records. Paper forms are kept in locked file cabinets in a locked room. Computer files are password protected. State health departments reporting patient names electronically encrypt identifiers before sending them to CDC. These systems are password protected electronic databases and accessible by authorized users only. Permissions to multi-user share folders are granted to users by the data steward

ArboNet (the National West Nile Surveillance System) provides an electronic-based surveillance and reporting system for West Nile and other arbovirus activity in humans, birds, mosquitoes and other mammals in order to facilitate the exchange of information and data between federal, state and local authorities. ArboNet captures information on cases of arbovirus infection from states in five categories: human, mosquito, avian, veterinary, and sentinel animals. ArboNet does not collect PII.

The Botulism System in the Enteric Diseases Epidemiology Branch (EDEB) comprises three databases. The database known as “Master Line List 1899_2010.mdb” is used for case surveillance, collects no PII, and is in a secured folder on the EDEB National Surveillance share drive. The other three databases collect forms related to the tracking of antitoxin release and patient monitoring under an IRB (Institutional Review Board)-approved IND (Investigational New Drug) protocol. The database known as “Botulism.mdb” is used for forms 1 and 2 under the IND; this database contains PII and is in a secured folder on the EDEB National Surveillance share drive. Two tables within Botulism.mdb are stored on a SQL server (BOT_EOCLINELIST) and accessed through the Microsoft Access frontend. The database known as “HBAT2.mdb” is used for patient clinical symptom tracking and antitoxin

accountability; this database contains PII, is linked to Botulism.mdb by a single variable and is in a secured folder on the EDEB National Surveillance share drive. PII is shared with Division of Global Migration and Quarantine (DGMQ), Regulatory Affairs (OD, NCEZID), and Drug Services (Division of Scientific Resources) for patient follow up to ensure all required IRB forms are completed, and with officials from Drug Services (Division of Scientific Resources) to ensure delivery of antitoxin to the correct person. No one can access the PII on the EDEB share drive without permission from the BOT administrator. Users need AD credentials to access the share drive. Pass through identification is required between the Access database and the SQL server. BOT administrator grants access to the SQL database.

The CDC maintains a voluntary surveillance system to collect data on culture-confirmed *Vibrio* infections in all 50 states. Investigators collect demographic, clinical, and epidemiologic data on case-patients. Data have been used to identify environmental risk factors, retail food outlets where high-risk exposures occur, and target groups that may benefit from consumer education. The system does collect PII. Only current staff has access to the system. The system is behind the firewall and the servers are managed by ITSO.

The Laboratory Based Enteric Disease Surveillance (LEDS) system is used to conduct national surveillance on specific foodborne pathogens. This information is collected from state health laboratories and epidemiology offices. Detailed isolate information is collected along with minimal demographic information such as state, county, sex and age. Once or twice a year, case studies are conducted and the interview questions are transmitted and added to the database. No PII data is collected for case studies. The data is stored in a SQL table and only designated program personnel have access to it. The data is used to report national trends, outbreak detection and to guide and promote CDC's programs in reducing foodborne illness. Some of the pathogens are on the nationally notifiable list, but personal information submission is deemed voluntary.

Shared Data within CDC

Electronic data sets provided by CSELS NNDSS, OID and CGH to CDC epidemiologists are stored on CDC network servers in multi-user share file folders. Access is granted to users

through the CDC Information Technology Service Organization. Login permissions or authorization rights to multi-user share folders are granted to users by the data steward.

Additional measures to secure private information are described in section A.2.1, above. Private information will not be disclosed unless otherwise compelled by law.

IRB

This activity does not require Institutional Review Board (IRB) documentation as this activity is public health practice (surveillance and program evaluation), not research [**Attachment 13. NNDSS Research Determination; Attachment 14. OID Research Determinations**].

10.1 Privacy Impact Assessment

Privacy Impact Assessments have been completed and approved for the electronic systems used by CSELS NNDSS: the Data Warehouse, Public Health Surveillance Platform, and Consolidated Statistical Platform used by CSELS. (<http://www.hhs.gov/pia/cdc-pia-summary-fy12q4.pdf>) and **Attachment [Attachment 8. PIAs Warehouse Platform]**.

Privacy Impact Assessments have been completed and approved for some of the OID and CGH systems and methods of collecting and processing data including ArboNet (the National West Nile Surveillance System), Laboratory Based Enteric Disease Surveillance system, the Cholera and Other Vibrio Illness Surveillance Systems and the Botulism Database.

<http://www.hhs.gov/pia/cdc-pia-summary-fy12q4.pdf>) and **Attachments [Attachment 9. PIAs Botulism, Enteric; Attachment 10. PIAs Nile, Vibrio]**.

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 WONDER (<http://wonder.cdc.gov/>) Privacy is protected in a number of ways: WONDER only provides summary statistics of aggregate data to these users. Data for WONDER are produced by CDC programs, which have already stripped the data of all personal identifying information 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 WONDER web application, in compliance with each data set's specific data use policy. CDC WONDER is also subject to and has met CDC's Certification and Accreditation process, in which these controls are examined and validated by the CDC's Office of the Chief Information Security Officer.

As noted in A.2 above, restricted access data sets may be shared with members of the public after the requestor and the notifiable diseases Data Steward complete a Data Use Agreement. To protect confidentiality of private information, CDC follows the CDC policy on releasing and sharing data [Attachment 6. Data Sharing Policy] and data release guidelines and procedures for re-release of state-provided data [Attachment 7. Data Sharing Guide]. These guidelines and procedures are consistent with the Federal Committee on Statistical Methodology. Statistical Policy Working Paper 22 (Second version, 2005). Report on Statistical Disclosure Limitation Methodology. Office of Information and Regulatory Affairs, Office of Management and Budget and the National Center for Health Statistics, CDC, Policy on Micro-data Dissemination, July, 2002. Procedures include removal of individually-identifying information (name, ZIP code and birthdate), aggregation of data (temporally, spatially, by age or race, etc.) and suppression of data, e.g. if the total number of cases in a cell is small or the denominator in a rate is small.

A.11. Justification for Sensitive Questions

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. 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

During the 1984 EPO and CSTE Pilot (As referenced in the previously approved OMB docket, 2006 ICB report) and periodically thereafter, a sample (fewer than 10) of potential respondents have been queried in order to obtain information on which to base hour burden estimates. The

samples include high volume reporting, low volume reporting and medium volume reporting jurisdictions. The averages are used to estimate the national burden.

Using legacy systems, health department personnel spend more time each week doing manual data entry than with current applications. Because a significant and increasing portion and of the records entered into current systems are received electronically, the burden of work to process these reports within health departments has decreased. Electronically received records were not an option for legacy systems. With current systems, health department personnel spend about ½ hour per week reviewing data logs to ensure that the automated data uploads to CDC have run properly. This replaces legacy manual data entry for those records that are electronically received. Therefore, the increase in the number of states using current systems will decrease the estimated weekly burden and annual burden of dedicated work hours of quality assurance review.

In addition, the annual summary report is easier to generate from the automatic report functions in current systems. The states, territories, and cities do not need to gather the information by hand or collate multiple data sources to calculate the annual reports (as they did under legacy systems) since current systems will rapidly generate that information.

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 burden on the states and cities is estimated to be 10 hours per response, while the burden on the territories is estimated to be 5 hours per response. Using \$23.11 as an average hourly wage rate (based on the sampling above), it is estimated that the average national annual burden for weekly and annual reporting is 28,340 hours at a national cost of \$654,937.40.

Furthermore, state, territory and city health departments that migrate to current systems realize other benefits other than reducing the reporting requirements. The time saved from manual data entry enables personnel to be redirected to other high priority activities. Also, in some health departments where current systems have been implemented, an electronic interface with existing

health information management systems in physician, hospital and laboratory offices has greatly increased the number of records entered into the health department’s surveillance information system.

A.12A. Estimates of Annualized Burden Hours

Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
Weekly and Annual Submissions				
States	50	52	10	26000
Territories	5	52	5	300
Cities	2	52	10	1040
Total				28,340

A.12B. Estimates of Annualized Cost Burden

Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Hourly Wage Rate	Respondent Cost
Weekly and Annual Submissions					
States	50	52	10	23.11	\$600,860
Territories	5	52	5	23.11	\$30,043
Cities	2	52	10	23.11	\$24,034.40
Total					\$654,937.40

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 14	FY 15	FY 16
Personnel - Software development, support, and management (intramural)	\$8,605,792	\$7,605,792	\$7,605,792
Cooperative Agreements with States for NNDSS case notification and management (extramural)	\$10,474,636	\$10,474,636	\$10,474,636
Total	\$19,080,428	\$18,080,428	\$18,080,428

The estimated annualized cost to the government of the NNDSS systems (both CDC developed and federal support to the states) is s \$18,413,761 (average of three year).

A.15. Explanation for Program Changes or Adjustments

As noted in section A.1, this NNDSS application was developed in coordination with four other CDC applications to OMB for nationally notifiable diseases case notification, i.e. Control Nos. 0920-0128, (Congenital Syphilis Surveillance), 0920-0819 (Nationally Notifiable Sexually Transmitted Disease (STD) Morbidity Surveillance), 0920-0009 (National Disease Surveillance Program - I. Case Reports) and 0920-0004 (National Disease Surveillance Program - II. Disease Summaries). As described in section A.1.1, because this OMB application includes case notifications that were not part of the 2010 NNDSS/NEDSS application, replaces one other OMB application, and replaces parts of four other OMB applications, burden estimates have been adjusted to incorporate burden estimates from the other four applications. The estimates are adjusted for the increased number of conditions reported to NNDSS, the expansion of core data elements, and the inclusion of more data elements described in the disease-specific tables. These changes have increased the burden estimates in this application in comparison with the burden estimates in the 2010 NNDSS/NEDSS OMB application (OMB Control No. 0920-0728). As CDC works with state, territorial and local health departments to develop and implement new information technologies to submit these data through NNDSS, burden may increase as the public health departments commit resources to implementing the new technologies. However,

over the next 3 years, as the new automated electronic systems are implemented, burden may be decreased.

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

CDC tabulates and publishes provisional counts of notifiable diseases each week.

The data are published in the *Morbidity and Mortality Weekly Report (MMWR)* and are available electronically through the World-wide Web at <http://wonder.cdc.gov/mmwr/mmwr morb.asp>.

The *MMWR* weekly tables of nationally notifiable diseases are also available electronically on the *MMWR* web site (http://www.cdc.gov/mmwr/mmwr_wk/wk_cv ol.html) within the “Notifiable Disease and Mortality Tables” section of each week’s publication.

In August, finalized case counts by jurisdiction of nationally notifiable diseases 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: http://www.cdc.gov/mmwr/mmwr_nd/index.html. A limited number of hard copies of the Annual Summary are available and are distributed based on the CDC mailing list and the list provided by the Superintendent of Documents. 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 requests approval to not display the expiration date for OMB approval of an information collection form since most data are not submitted on a form. Most data are submitted to CDC electronically from already existing databases via automated electronic transfers. There is no

electronic location for an OMB expiration date. Although some data are submitted by telephone, fax, e-mail and mail, those methods of data submission are only used to collect information that cannot be submitted electronically. NNDSS does not mandate use of any specific form. NNDSS is working with the jurisdictions to increase the use of automated electronic data submission.

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

No exceptions are requested.