

# **National Electronic Disease Surveillance System (NEDSS) OMB No. 0920-0728**

## **Agency Contact**

**John P. Abellera, MPH**

Acting Project Lead

National Electronic Disease Surveillance System

Division of Notifiable Disease Surveillance (Proposed)

Public Health Surveillance Program Office (Proposed)

Office of Surveillance, Epidemiology and Laboratory Services (Proposed)

1600 Clifton Rd, MS-E91

Atlanta, GA 30333

404-498-6684 (o)

404-234-2601 (m)

404-498-6225 (f)

E-mail: [JAbellera@cdc.gov](mailto:JAbellera@cdc.gov)

-

## **OCSO Resubmission Date:**

- **Enclosures:**
- **60 Day FRN**
- **30 Day FRN**
- **Abstract**
- **NEDSS - 2011 Supporting Statement**
- **Attachments #1 to #13**
- **Part 1 Worksheet**
- **Part 2 Worksheet**

## **A. JUSTIFICATION**

### **A.1. Circumstances of Reporting Information**

The Centers for Disease Control and Prevention (CDC) is responsible for the reporting and dissemination of nationally notifiable diseases' information and for monitoring and reporting the impact of epidemic influenza on mortality. Public Health Service Act (42 USC 241) authorizing these reports is included as **Attachment 4**.

In 1878, Congress authorized the U. S. Marine Hospital Service (later renamed the U.S. Public Health Service) to collect morbidity reports on cholera, smallpox, plague, and yellow fever from U.S. consuls overseas; this information was to be used for instituting quarantine measures to prevent the introduction and spread of these diseases into the United States. 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 United States. 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.

Reports on notifiable diseases were received from very few states and cities prior to 1900, but gradually more states submitted monthly and annual summaries. 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. In 1942, the collection, compilation, and publication of morbidity statistics, under the direction of the Division of Sanitary Reports and Statistics, PHS, was transferred to the Division of Public Health Methods, PHS.

A PHS study in 1948 led to a revision of the morbidity reporting procedures, and in 1949 morbidity reporting activities were transferred 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 a Conference of State and Territorial Epidemiologists (CSTE) for the purpose of determining the diseases that should be reported 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.

This is a request for a three-year extension for the reporting of morbidity reports from the 57 respondents (50 state, 2 cities, and 5 territorial health departments) using the NEDSS (NETSS replacement) umbrella of systems and including the National Electronic Telecommunications System for Surveillance (NETSS).

#### Privacy Impact Assessment

No individually identifiable information is being collected.

### **A.2. Purpose and Use of Information**

As of January 1, 2010, over 60 infectious diseases and conditions were designated by CSTE as nationally notifiable and were approved by the state and territorial health departments for reporting to the CDC (**Attachment 5**; and <http://www.cdc.gov/epo/dphsi/PHS/infdis.htm>).

De-identified reports from state and territorial epidemiologists are sent electronically to CDC as each case is entered and reviewed in the National Electronic Disease Surveillance System. NEDSS is comprised of a variety of NEDSS-compatible systems used by state and major local jurisdictions. Reports are no longer sent just once a

week (via NETSS) but have become an automatic part of the case entry and review process at the state level. This allows near real-time data transmission to CDC for each case entered that week rather than a once a week transmission for ALL cases (which in the past has limited the timeliness of reporting significantly). The automatic notification of cases to CDC reduces the burden of effort required in the replaced system (NETSS). NEDSS is designed to allow for dramatic improvements in the timeliness and completeness of reporting. These data are used for weekly publication in the *Morbidity and Mortality Weekly Report (MMWR)*. These data are also used by the individual program areas (e.g. CDC's hepatitis program) at CDC. 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. In instances where the report of a case (or cases) has been delayed by the physician or the city or county health department, the case/s/ are not included in the total for the current week, but are added to the cumulative total for previous weeks.

The National Center for Public Health Informatics (NCPHI) is responsible for managing the national reporting system of descriptive epidemiologic data for all notifiable infectious diseases via NEDSS (including NETSS). An annual summary presenting incidence data for these diseases is also published each year as the last issue of each volume of the *Morbidity and Mortality Weekly Report (MMWR)* entitled *Summary of Notifiable Diseases, United States*. These annual reports from CDC program areas are reported to the Office of Surveillance, Epidemiology and Laboratory Services (Proposed) for official publication in the *Summary of Notifiable Diseases*.

The timeliness of the provisional weekly reports provides information, which CDC and state or local epidemiologists use to detect and more effectively interrupt outbreaks. Also, reporting provides the timely information needed to measure and demonstrate the impact of changed immunization laws or new therapies. Reports of an increased number of cases of diseases, which are no longer endemic in the United States, facilitate recognition of a disease's resurgence. The finalized annual data also provide information on reported disease incidence that is necessary for the evaluation of epidemiologic trends and the development of disease prevention policies. CDC is the sole repository for these national, population-based data. The data are widely used by schools of medicine and public health, communications media, and pharmaceutical or other companies producing health-related products, as well as local, state, and federal health agencies and other agencies or persons concerned with the trends of reportable conditions in the United States.

#### Privacy Impact Assessment

No individually identifiable information is being collected.

#### **A.3. Use of Improved Information Technology**

CDC has worked with CSTE to improve the efficiency of the reporting procedures; all changes in reporting procedures are made in collaboration with CSTE.

In April 1984, the Epidemiology Program Office (EPO) in cooperation with CSTE and epidemiologists in six states began a pilot project, the Epidemiologic Surveillance Project (ESP), designed to demonstrate the efficiency and effectiveness of computer transmission of surveillance data between CDC and the state health departments. Each state health department used its existing computerized disease surveillance system to transmit specific data concerning each case of a notifiable disease, and CDC technicians developed computer software to automate the transfer of data from the state to CDC.

In June 1985, CSTE passed a resolution supporting ESP as a workable system for electronic transmission of notifiable disease case reports from the states/territories to CDC, and as the program was extended beyond the original group of states; EPO began to provide software, training and technical support to state health department staff overseeing the transition from hard-copy to automated transmission of surveillance data. By 1989, all 50 states were using this computerized disease surveillance system, which was then renamed the National Electronic Telecommunications System for Surveillance (NETSS) to reflect its national scope.

Since 1999, CDC staff has worked with CSTE, state and local public health system staff, and other CDC disease prevention and control program staff to identify information and information technology standards to support integrated disease surveillance. That effort is now focused on development of the National Electronic Disease Surveillance System (NEDSS). NEDSS has begun to electronically integrate and link together a wide variety of surveillance activities and will facilitate more accurate and timely reporting of disease information to CDC and state and local health departments. Consistent with recommendations supported by our state and local surveillance partners and described in the 1995 report, Integrating Public Health Information and Surveillance Systems (<http://www.cdc.gov/nedss/Archive/katz.pdf>), NEDSS includes data standards, an internet based communications infrastructure built on industry standards, and policy-level agreements on data access, sharing, burden reduction, and protection of confidentiality by specifying only de-identified data. To support NEDSS, CDC has supported the development of an information system, the NEDSS Base System (NBS), that uses NEDSS technical and information standards (<http://www.cdc.gov/nedss/BaseSystem/NEDSSBaseSysDescription.pdf>). The decision to concurrently support both state-developed NEDSS based surveillance systems and develop a CDC-built version of this software was made at the request of a number of states. This was primarily driven by their inability to support the design, development, distribution, and support of software that met the requirements for NEDSS standards-based systems.

In 2006, CDC collaborated with CSTE in a resolution to adopt **HL7 v 2.5** as the national standard for exchanging public health electronic messages. Subsequent to this, the Healthcare Information Technology Standards Panel (HITSP) of the American Health Information Community (AHIC) also adopted this message standard.

The use of NEDSS standards enhances data accuracy by establishing coding and data vocabulary requirements that eliminate the ambiguity seen in NETSS regarding interpretation of data submitted from different local and state jurisdictions to CDC.

The NETSS (legacy) information system application will be phased-out state-by-state over the next several years (state implementation process for NEDSS began in the fourth quarter of 2002). NETSS' functionality will be replaced by the NEDSS functionality, either through the NEDSS Base System in states who choose to use it, or through their own information systems developed to conform to NEDSS architectural standards. At the time that a state transitions from NETSS to NEDSS, the common descriptive epidemiologic data collected for the National Notifiable Disease Surveillance System (NNDSS) will be modified for the following reasons: to accommodate revised OMB guidance on collection of race and ethnicity data; to include confirmatory lab information when available; and to support the collection of socioeconomic information.

The "NETSS Format (Individual) Case Records Specifications" (**Attachment 6**) document (including extended record fields; Columns 61 – 1060, CDC PROGRAM DATA, Event-Specific data area.) is also included as part of the submission packet. The extended record fields vary in size and content depending on the event being reported. By necessity, the transition from NNDSS reporting using NETSS to NNDSS reporting via use of the NEDSS technical architecture and standards (**Examples: Attachments: 7A. Copy of MASTER Legacy to NEDSS Spreadsheet.xls and 7B. NBS-NND\_Mapping\_Guide (2).xls**) will occur state-by-state and, often, by public health prevention program within a state.

Reporting of nationally notifiable disease incidence data to NNDSS to support weekly and annual morbidity reporting in the *MMWR* is voluntary. CDC and CSTE have recommended the modification of the descriptive data currently reported to NNDSS (NETSS format) to better describe the epidemiologic characteristics of disease incidence in an effort to focus the public health system's prevention and control efforts (NETSS record format transitioning to NEDSS data standards). However, reporting of these data elements (and use of the NEDSS technical architecture and standards) continues to be voluntary. We anticipate that states will transition from NETSS to NEDSS as the NETSS system is phased out over the next several years.

**Attachment 1**, (<http://www.cdc.gov/phinf/resources/guides.html>) "The Implementation Guides for PHIN Applications and Services, includes the listings of the individual HL7 Case Notification Guides currently

available for public health data exchange from the states to the CDC. Also see **Attachment 2, the "MESSAGE MAPPING GUIDE (MMG) Process Overview"**. **Attachment 8, "Copy of Generic Case Notification Message Mapping Guide v.1.xl"**, represents a Message Guide that **"can"** be used by the states for reporting when a specific disease/condition guide has not been posted. The Message Mapping Guides (MMG) defines the message content and format for each specific data element contained in that message.

#### **A.4. Efforts to Identify Duplication and Use of Similar Information**

Information maintained in NNDSS serves as a centralized, integrated source of common (or core) descriptive epidemiologic data on notifiable infectious disease incidence and distribution in the United States, and it is not available from any other source. NNDSS data are linked at the local and State level during routine surveillance information management to additional disease-specific surveillance data collected by other programs that are primarily responsible for the prevention and control of the notifiable diseases reported to NNDSS. Weekly provisional NNDSS data are finalized to support the *MMWR* annual *Summary of Notifiable Diseases*. All 50 states, two cities, and Puerto Rico are now participating in NETSS and NNDSS and have eliminated the use of hard-copy annual report forms since 1990. The transition to NEDSS will further decrease the duplication of reporting through its use of a single secure portal for transmission of electronic public health notifications which are then imported and merged into a single integrated database – avoiding duplicate reporting from state health departments.

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

This collection 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 collection process.

The older weekly reporting of national morbidity data via NETSS does not allow timely assessment of disease burden on a national scale for many conditions, particularly emerging disease threats. Changes in disease distribution by age, sex, race/ethnicity, and geographic locations can be continuously monitored, and, if necessary, appropriate investigation or intervention may be rapidly undertaken. In addition, by having surveillance data available in a consolidated database, state health departments are better able to monitor both intrastate and interstate disease trends.

The annual report is also 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.

There are no 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", reporting of national morbidity data is essential to the rapid identification of disease epidemics and more timely and complete understanding of disease trends.

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

##### **A.8.A.**

The agency's notice of proposed data reporting as part of the weekly and annual morbidity and mortality reports was printed in the Federal Register on July 27, 2010, **Volume 75 , Number 143 , Page 43984 (Attachment 9)**. No public comments were received in response to this notice.

### **A.8.B.**

As mentioned previously in A.I, consultations with the state epidemiologists and the state health officers are conducted routinely through their respective professional organizations, CSTE and the Association of State and Territorial Health Officers (ASTHO). 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 maintained. Although formal CSTE meetings are usually held only once a year, communication between CDC and CSTE groups and individual members of those organizations continue on a regular basis. Issues related to conditions of national public health importance were discussed at the 1994 National Surveillance Conference jointly sponsored by CSTE and CDC. The names and telephone numbers of CSTE members are listed in **Attachment 10**. No major surveillance reporting problems exist that could not be resolved through consultation with CSTE and ASTHO.

The only other public contacts concerning the publication of the weekly summary involve the dissemination strategy for this publication. There are currently four options for receiving copies of this publication. Paper copies are available through the U.S. Government Printing Office (GPO) or the Massachusetts Medical Society (MMS) Publications. Volumes 33-44 of the *MMWR* are available on microfilm from University Microfilms, International. Volumes 1-51 are available electronically through the World-wide Web at web site <http://www.cdc.gov/mmwr>. Persons querying *MMWR* data tables via the World-wide Web (<http://wonder.cdc.gov/mmwr/mmwmorb.asp>) are also able to post questions and comments directly to the Surveillance Systems Branch, EPO via an e-mail link ([soib@cdc.gov](mailto:soib@cdc.gov)).

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

No payment or gift, other than remuneration of grantees, is provided to respondents.

### **A.10. Assurance of Confidentiality Provided to Respondents**

The OMB application has been reviewed and it has been determined that the Privacy Act is not applicable. Personal identifiers such as name and address are not transmitted through NEDSS to CDC. Respondents are state and local governments and the unique Case ID assigned by the State for Case Reports is not a number (like a SSN) that in and of itself can lead to identification of an individual. Data release guidelines developed in collaboration with CSTE is attached (**Attachment 11A**). This policy on dissemination of data ensures data are adequately safeguarded. Data release guidelines are established at the request of CSTE so that submitting states are assured that their case data are only released in aggregate format in tables and reports previously approved by them (i.e. *MMWR* Tables).

This ICR does not require Internal Review Board (IRB) documentation as there are no human subjects (**Attachment 11B**, "IRB Memo").

### **Privacy Impact Assessment**

No individually identifiable information is being collected.

### **A.11. Justification for Sensitive Questions**

There are no questions of a sensitive nature.

### **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.

Under NETSS, health department personnel spend more time each week doing manual data entry than with NEDSS applications. Because a significant and increasing portion of the records entered into NEDSS 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 NETSS. With NEDSS, 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 NETSS manual data entry for those records that are electronically received. Therefore, the increase in the number of states using NEDSS will decrease the estimated weekly burden and annual burden of dedicated work hours of quality assurance review. It is estimated that the average national annual burden for weekly reporting is 8,502 hours at a national cost of \$107,975.

In addition, the annual summary report is easier to generate from the automatic report functions in NBS. 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 NETSS) since the NEDSS system will rapidly generate that information. The annual report information is more reliable and can be used for many more purposes than reporting to CDC. The state, territory and city health departments can also generate summary reports for their internal assessment, assurance, and policy decision-making purposes. It is estimated that the average national burden for annual reporting is 892 hours at a national cost of \$11,328.

Furthermore, state, territory and city health departments that migrate from NETSS to NEDSS 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 NEDSS has 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.

### Morbidity and Mortality Reporting

Morbidity reporting is briefly described in A.3.

### Annual Summary of Notifiable Diseases

During the four (4) months following the close of the calendar year, most health departments review the accumulated case report data for the previous year, deleting misdiagnosed cases or allocating reported cases to the correct disease etiologies, collecting missing items of information necessary for completion of the final report, and cross-checking with the file of surveillance case reports to determine whether each reported case of a disease under surveillance has been epidemiologically investigated. CDC retrieves needed information from the NEDSS data base and sends each state a state-specific annual report of each disease by month, county, age group, and race (i.e., the data variables used for tables published in the *Summary of Notifiable Diseases*). State data are verified by state surveillance staff comparing reports from the CDC NEDSS database with reports produced from the state database.

Errors are corrected by transmission of deletions/updates to the CDC NEDSS database. Based on information from several states using the NETSS system, we estimate that it takes each NEDSS state 16 hours to verify the preliminary and final annual morbidity reports (**Attachment 12**, which includes sample letters sent to state reporters for verification of data and to the state epidemiologist to confirm the state's final annual data.). The territorial health departments report annual data using forms (**Attachment 13**, from American Samoa) that are sent (mailed, fax, etc) to CDC.

The data stored in the NEDSS data base and the annual summary forms received from the territorial health departments are consolidated and published annually as the last issue of each volume of the *Morbidity and Mortality Weekly Report* entitled *Summary of Notifiable Diseases, United States*. This *MMWR* issue is widely used by schools of medicine and public health, communications media, and pharmaceutical or other companies

producing health-related products, as well as by local, state, and federal health agencies and other agencies or persons concerned with communicable disease epidemiology in the United States.

A12-A. Estimates of Annualized Burden Hours

<b>Respondents</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden Per Response (in hours)</b>	<b>Total Burden (in hours)</b>
<b>Weekly Reporting</b>				
States	50	52	3	7,800
Territories	5	52	1.5	390
Cities	2	52	3	312
<b>Annual Reporting</b>				
States	50	1	16	800
Territories	5	1	10	50
Cities	2	1	16	32
<b>Total</b>				<b>9,384</b>

A-12B. Estimates of Annualized Cost Burden

<b>Respondents</b>	<b>Number of Respondents</b>	<b>Number of Responses per Respondent</b>	<b>Average Burden Per Response (in hours)</b>	<b>Hourly Wage Rate</b>	<b>Respondent Cost</b>
<b>Weekly Reporting</b>					
States	50	52	3	\$12.70	\$99,060
Territories	5	52	1.5	\$12.70	\$4,953
Cities	2	52	3	\$12.70	\$3,962
<b>Annual Reporting</b>					
States	50	1	16	\$12.70	\$10,160
Territories	5	1	10	\$12.70	\$762
Cities	2	1	16	\$12.70	\$406
<b>Total</b>					<b>\$119,303</b>

**A.13. Estimate of Other Total Annual Cost Burden to Respondents or Recordkeepers**

There are no other annual costs to respondents or recordkeepers.

**A.14. Annualized Cost to the Federal Government**

Item	NEDSS Estimated Cost to Federal Government
------	--

	FY 11	FY 12	FY 13
Personnel - Software development, support, and NEDSS management (intramural)	\$6,229,605	\$6,416,493	\$6,608,988
Cooperative Agreements with States for NEDSS data collection and management (extramural)	\$10,450,000	\$10,450,000	\$10,450,000
Total	\$16,679,605	\$16,866,493	\$17,058,988

The estimated annualized cost to the government of the NEDSS systems (both CDC developed and federal support to the states) is \$16,868,362 (average of three year).

**A.15. Explanation for Program Changes or Adjustments**

This is an extension request.

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

Weekly reports

The weekly *MMWR* report of notifiable diseases covers the week preceding the report's publication. The beginning and ending dates of the reporting week are those established by CSTE, and correspond with the usual workweek. The reporting period is constant from week to week. The report should be received electronically in Atlanta as soon as possible after the close of the reporting week, and no later than noon on the following Tuesday.

When a Federal holiday falls on Monday, the statistical tables are issued as if no holiday has occurred. Reports from the state health departments should therefore be received in Atlanta no later than Tuesday noon. If the holiday falls on Tuesday, reports should be received in Atlanta no later than Monday 4:00 P.M.

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

Annual Summary

In February, annual summary forms and tables are sent by mail to Territorial Epidemiologists for reporting final notifiable disease totals for the previous year. This is required for verification and correction of data prior to publication.

From the period March through July, NEDSS\NETSS data are verified and an annual summary database is created by merging NEDSS\NETSS data with data from annual report forms and data reported by CDC programs.

In August, final annual data tables are published in the *Morbidity and Mortality Weekly Report*.

During the period from October to November, camera-ready copies are completed and distributed to the Publications Management Branch for printing. Annual summaries 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.

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

As previously approved; the CDC requests approval to not display the expiration date for OMB approval of the information collection instrument (**Attachment 11**). The content and format of the data collection forms have not changed from the previous application. The territories would prefer to avoid the destruction of unused forms.

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

No exceptions are requested.

**B. Collections of Information Employing Statistical Methods**

Because of the nature of this national population-based passive surveillance activity, this data reporting process does not involve statistical methods.

**List of Attachments**

- 1. Implementation Guides for PHIN Applications and Services**
- 2. Message Mapping Guide (MMG) Process Overview**
- 3. US Map of NEDSS Sites**
- 4. Public Health Service Act (42 USC 241)**
- 5. Nationally Notifiable Infectious Disease List (2010)**
- 6. NETSS Format (Individual) Case Records Specifications**
- 7A. Copy of MASTER Legacy to NEDSS Spreadsheet.xls**
- 7B. NBS-NND\_Mapping\_Guide (2).xls**
- 8. Copy of Generic\_Case\_Notification\_Message\_Mapping\_Guide\_v.1.xls**
- 9. Federal Register Notice**
- 10. Council of State and Territorial Epidemiologists (CSTE) membership list**
- 11A. Data Release Guidelines of the Council of State and Territorial Epidemiologists for the National Public Health Surveillance System**
- 11B. IRB Memo**
- 12. Sample Letters sent to State Reporters**
- 13. Forms for Collecting Data -Territorial Health (American Samoa, 2008)**