National Notifiable Diseases Surveillance System

Supporting Statement Section A

OMB Control Number 0920-0728

December 28, 2020

Program Contact
Umed A. Ajani

Associate Director for Science, 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)
3. List of Nationally Notifiable Conditions
4. List of Conditions Under Standardized Surveillance
5. Core Data
6. Laboratory Data
7. Justification for the Addition of Vaccine Data Elements
8. Vaccine Data
9. Vaccine Preventable Disease Data
10. Justification for the Addition of Disease-Specific Data Elements
11. Disease-Specific Data
12. Consultants List
13. DW PIA

14. DMB PIA
15. MVPS PIA
16. NNDSS Research Determination
17. Burden Table Calculations
18. PRA Burden Statement Screenshot

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. Recently the NNDSS platform was modernized and expanded as a low-cost, common portal for collecting information on other conditions.**
- **Among the thousands of diseases that affect the health of the population, CDC and the Council of State and Territorial Epidemiologists (CSTE) have prioritized the approximately 120 Nationally Notifiable Conditions as those most important for public health monitoring and response.**
- **NNDSS is a case-based surveillance system meaning that the unit of reporting is a case – a person with a specific condition. The associated data might include clinical information, vaccine history, laboratory tests, patient characteristics, demographics, and epidemiologic variables such as exposures and risk factors.**
- **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. State and local health departments share data that they have already collected and stored in their own surveillance systems.**
- **The respondent population consists of 60 jurisdictions: public health departments in every U.S. state, New York City, Washington DC, 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and 3 freely associated states (Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).**
- **CDC publishes numbers of cases and incidence rates of nationally notifiable conditions based on NNDDS data on CDC WONDER and in other scientific journals.**

A1. Circumstances Making the Collection of Information Necessary

CDC requests a three-year approval for the revision of the National Notifiable Diseases Surveillance System (NNDSS) Information Collection Request (ICR), OMB Control No. 0920-0728, expiration date April 30, 2023. This application is the fifth revision to the application for 0920-0728 (approved by OMB on January 15, 2014) which consolidated four other CDC applications for nationally notifiable diseases case notification: Control Nos. 0920-0128, (Congenital Syphilis Surveillance), parts of 0920-0819 (Nationally Notifiable Sexually Transmitted Disease (STD) Morbidity Surveillance), parts of 0920-0009 (National Disease Surveillance Program - I. Case Reports) and parts of 0920-0004 (National Disease Surveillance Program - II. Disease Summaries). Consolidation of the information collection requests across multiple

diseases has reduced the administrative costs of the OMB PRA application process and has resulted in increased standardization across the disease components of the application.

Key changes in this revision are enumerated in the table below:

Disease Name in NNDSS Collection	Nationally Notifiable (NNC) OR Under Standardized Surveillance (CSS)	Current Case Notification (Y/N)	Proposed Case Notification (Y/N)	Current Disease-specific Data Elements (Y/N)	Proposed Disease-specific Data Elements (Y/N)	Number of Existing Data Elements in NNDSS	Proposed Number of new NNDSS Data Elements
Anthrax	NNC	Y		Y	Y	108	25
Brucellosis	NNC	Y		Y	Y	216	9
Campylobacteriosis	NNC	Y		Y	Y	13	1
Cholera	NNC	Y		Y	Y	246	2
Cryptosporidiosis	NNC	Y		Y	Y	152	2
Hansen's Disease	NNC	Y		Y	Y	72	5
Leptospirosis	NNC	Y		Y	Y	94	5
Melioidosis	CSS	Y		Y	Y	55	103
Multisystem Inflammatory Syndrome (MIS) associated with Coronavirus Disease 2019 (COVID-19)	CSS	N	Y	N	Y	0	44
2019 Novel Coronavirus Disease (COVID-19)	NNC	Y		Y	Y	63	3
S. Paratyphi Infection	NNC	Y		Y	Y	60	2

S. Typhi Infection	NNC	Y	N	Y	Y	66	2
Salmonellosis	NNC	Y	N	Y	Y	153	1
Shiga toxin-producing *Escherichia Coli* (STEC)	NNC	Y	N	Y	Y	334	1
Shigellosis	NNC	Y	N	Y	Y	24	1
Vibriosis	NNC	Y	N	Y	Y	219	2

Background and Respondent Population

The NNDSS is the nation's public health surveillance system that enables all levels of public health (local, state, territorial, federal and international) to monitor the occurrence and spread of the diseases and conditions that CDC and the Council of State and Territorial Epidemiologists (CSTE) officially designate as "nationally notifiable" or as under "standardized surveillance." CSTE is an organization of member states and territories representing public health epidemiologists. CDC and CSTE determine which diseases and data elements should be monitored as part of national surveillance. New diseases and data elements under consideration for inclusion in NNDSS are described in CSTE position statements (authored by CDC and CSTE members) that are voted on by all participating local and state health departments at the CSTE annual meeting. The NNDSS program creates the infrastructure for the surveillance system and facilitates the submission and aggregation of case notification data voluntarily submitted to CDC from 60 jurisdictions: public health departments in every U.S. state, New York City, Washington DC, 5 U.S. territories (American Samoa, the Commonwealth of Northern Mariana Islands, Guam, Puerto Rico, and the U.S. Virgin Islands), and 3 freely associated states (Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau).

The NNDSS also facilitates relevant data management, analysis, interpretation and dissemination of the information. The data are used to monitor the occurrence of notifiable conditions and to plan and conduct prevention and control programs at the state, territorial, local and national levels.

CDC is responsible for the reporting and dissemination of nationally notifiable conditions' information, as authorized by the Public Health Service Act (42 USC 241) of January 4, 2012 **[Attachment 1. Authorizing Legislation]**.

A.2. Purpose and Use of the Information Collection

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

Conditions are included in the NNDSS when CDC and CSTE agree that the condition is of sufficient public health significance to warrant the states and territories submitting case-based surveillance data to CDC to allow monitoring on a national level. Among the thousands of diseases that affect the population, only about 120 have been prioritized for inclusion in NNDSS. This collaborative relationship between CDC and the states began in 1903, when the US Surgeon General Walter Wyman presided over the first annual conference of state and territorial health officers and led a discussion about disease surveillance. By 1912, states developed a list of diseases that they deemed notifiable (5 immediately by telegraph and 10 monthly by letter) to the Surgeon General. Responsibility for developing consensus among the states on which health conditions the states would submit to CDC was given to the State Epidemiologists by CDC in the 1950s. State Epidemiologists convened for this reason in 1951 with the encouragement of Alexander Langmuir, Chief of the Bureau of Epidemiology at CDC[1]. CSTE was created and is funded by CDC to provide guidance on which conditions should be nationally notifiable or under standardized surveillance.

Each year, CSTE, supported by CDC, determines which reportable conditions should be designated nationally notifiable or under standardized surveillance. When states decide whether to make a

[1] Koo, D., & Wetterhall S. (1996). History and Current Status of the National Notifiable Diseases Surveillance System. Journal of Public Health Management and Practice, 2(4), 4-10.

condition reportable and when the CSTE membership and CDC decide whether to make a condition nationally notifiable, they consider the following issues: severity, incidence, communicability, preventability, impact on the community or society and need for public health action. CSTE position statements must be sponsored by a CSTE Active Member, specifically, a person engaged in the practice of epidemiology for a government public health authority at the local, tribal, state, and territorial level. The position statements are discussed and then reviewed at the CSTE national office. Next, a technical review by a select group of subject matter experts is done. The national office then shares the position statement with appropriate CSTE Executive Board members. The national office then circulates the draft position statement among voting members and the position statement is voted on at the Annual CSTE Conference. The final approved position statement is then published on the CSTE website. When CSTE approves a position statement placing a condition under standardized surveillance, this establishes standardized case definitions and surveillance methods for use by jurisdictions conducting surveillance for this condition and recommends that jurisdictions conducting surveillance share the case data with CDC if it is requested by the relevant CDC program. When CSTE takes the additional step of making a condition nationally notifiable, this expresses the consensus of the CSTE membership that all states and territories should enact laws or regulations to make this condition reportable in their jurisdictions and should voluntarily submit the data to CDC so that information can be shared across jurisdictional boundaries and so that surveillance and prevention and control activities can be coordinated at regional and national levels. CSTE, in conjunction with CDC, makes annual recommendations for additions and deletions to the list of conditions under standardized surveillance and nationally notifiable diseases.

Description of Conditions for which Case Notifications are Received

The nationally notifiable conditions and conditions under standardized surveillance that are received by CDC through NNDSS are listed in two attachments **[Attachment 3. List of Nationally Notifiable Conditions and Attachment 4. List of Conditions Under Standardized Surveillance].** There is one condition, MIS associated with COVID-19, listed in Attachment 4 in bold that was not included in the previous ICR.

Detailed characteristics about the condition including the reasons why the condition is being added to NNDSS are described below:

MIS associated with COVID-19

NNDSS currently receives case notifications for MIS associated with COVID-19 under the Public Health Emergency (PHE) PRA Waiver for COVID-19 activities performed during the Emergency Response. Although there is no CSTE position statement for MIS designating it as an NNC or a CSS, it is a rare complication of COVID-19 that is of interest to public health. CDC requests permission to receive case notification data for MIS associated with COVID-19 under standardized surveillance.

MIS associated with COVID-19	
The impetus/urgency for CDC to institute case notification and data elements for this condition	• Multisystem inflammatory syndrome in children (MIS-C) was a new but severe condition reported out of the UK in April 2020 with temporal association to SARS-CoV-2. • Due to the urgency in collecting these cases in the United States to learn more about this condition of public health significance, a national surveillance system was developed. • Enables assessment of true burden of MIS-C. • Will provide potential to learn more about emerging reports of a similar syndrome in adults (MIS-A). • Will be critical for monitoring MIS as an adverse event and potential vaccine effectiveness outcome once a SARS-CoV-2 vaccine has been developed.
Existing sources of data (Federal, non-federal, private, etc.) and what those sources say about approximate national incidence and/or prevalence of the condition	• At this time incidence for MIS-C is not known in the United States. Per publication by Dufort, et al, the incidence of MIS-C in New York at the time of publication found that laboratory-confirmed SARS-CoV-2 infection was 322 per 100,000 in <21 years of age, and the incidence of MIS-C was 2 per 100,000 persons <21 years of age.
Incremental coverage provided by adding the condition to NNDSS (how CDC will use additional precision)	• MIS was added to NNDSS in response to the urgent need for reporting during the pandemic. Therefore, we are requesting continuation of this reporting and not adding a new condition or activity. No states reported originally and since reporting began in mid-May, 42 states, New York City, and Washington, DC, have reported at least one case of MIS-C to CDC (through NNDSS or submission of a national case report form, https://www.cdc.gov/mis-c/cases/index.html). • This request is to extend the work to capture cases of MIS that will otherwise go unreported at a national level. Case notifications will allow CDC to track epidemiology and update evidence-based guidance.
Number of states that currently require reporting of these conditions and data elements	• All jurisdictions participating in NNDSS include provision for reporting of MIS from healthcare providers to public health, either explicitly or as part of a broad category of "other events of public health concern."
The number of states anticipated to adopt if added	• As noted above, MIS was added to NNDSS earlier in the pandemic and is in place, so we are not requesting a new

to NNDSS and basis of estimate Funding allocated specifically for a condition and/or additional elements (please list source where applicable)	condition or activity at this time. Up to 42 states, New York City, and Washington, DC, have reported at least one case of MIS-C to CDC (through NNDSS or submission of a national case report form), and we would expect this will increase with funding. • Funding has been provided to all jurisdictions through the Epidemiology and Laboratory Capacity (ELC) cooperative agreement to report national surveillance activities.
Anticipated frequency of reporting to CDC	MIS-C cases are requested to be reported from jurisdictions to CDC weekly.
Based on the above information, what is the proposed priority associated with condition	• There is high priority to ensure continued reporting of this severe condition in children. • There is still much to learn about this new syndrome and case reporting will allow improved knowledge to assist with refinement of case definition and clinical diagnosis and treatment of MIS.

Description of Data Elements Received

For each nationally notifiable condition or condition under standardized surveillance that a state, territorial, or local jurisdiction chooses to report to CDC, a common, core set of data elements is requested for each case. The core data elements include the name of the condition, demographic data for the person with the condition, epidemiologic data, and administrative data. All of these core data elements were included in the previously approved ICR. Names, descriptions and value set codes for the data elements are identified in an attachment **[Attachment 5. Core Data].** Twelve of these core data elements are required for a valid case notification message. The rest of the core data elements are optional since the jurisdiction may not collect these data elements or the jurisdiction may not have the information for a particular case. If any one of the twelve data elements is not present in the message, the message cannot be processed by CDC and an error message will be generated. These 12 data elements are highlighted in yellow on Attachment 5. Core Data. The creation of a core set of data for each disease case report was an important accomplishment of NNDSS. It not only standardized case data coming into CDC but it promoted standardization across states as well. Other CDC surveillance programs are now incorporating the core data elements into their systems so that data at CDC will be interoperable and more shareable. And, during a public health emergency, it makes data collection and exchange more timely.

For each nationally notifiable condition or condition under standardized surveillance that a state, territorial, or local jurisdiction chooses to report to CDC, a common set of optional laboratory data elements is requested for each case. All of these laboratory data elements were included in the previously approved ICR. Names, descriptions and value set codes for the data elements are identified in an attachment **[Attachment 6. Laboratory Data]**.

For each nationally notifiable condition or condition under standardized surveillance that a state, territorial, or local jurisdiction chooses to report to CDC, a common set of optional vaccine data elements is requested. 10 new vaccine data elements that were not included in the previously reviewed ICR were added. Names, descriptions, value set codes, and justification for the addition of these new data elements are in **Attachment 7. Justification for the Addition of Vaccine Data Elements**. Names, descriptions and value set codes for the data elements are identified in an attachment **[Attachment 8. Vaccine Data]**.

For each vaccine preventable disease (VPD) that is nationally notifiable or under standardized surveillance that a state territorial, or local jurisdiction chooses to report to CDC, a common set of optional data elements are requested. All of these VPD data elements were included in the previously approved ICR. Names, descriptions and value set codes for the data elements are identified in **Attachment 9. Vaccine Preventable Disease Data**.

Among the conditions established as nationally notifiable or under standardized surveillance, participating public health departments voluntarily submit requested data elements which are specific to each condition. These data elements are optional and are submitted in addition to the core set of data elements. With the coordination with the CDC programs conducting surveillance on nationally notifiable conditions, as noted above, this application includes disease-specific tables for 56 diseases. 208 new data elements that were not included in the previously reviewed ICR were added for 16 conditions: Anthrax, Brucellosis, Campylobacteriosis, Cholera, Cryptosporidiosis, Hansen's Disease, Leptospirosis, Melioidosis, MIS associated with COVID-19, COVID-19, *S.* Paratyphi Infection, *S.* Typhi Infection, Salmonellosis, STEC, Shigellosis, and Vibriosis. Names, descriptions, value set codes, and justification for the addition of these new data elements are in **Attachment 10. Justification for the Addition of Disease-Specific Data Elements**. Names, descriptions and value set codes for all of the data

elements are in an attachment **[Attachment 11. Disease-Specific Data]** with the new data elements identified in bold.

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

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

A.3. Use of Improved Information Technology and Burden Reduction

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

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

Territories also participate in NMI. All 60 NNDSS jurisdictions (including territories and freely associated states) receive funding through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) cooperative agreement (https://www.cdc.gov/ncezid/dpei/epidemiology-laboratory-capacity.html) and some of that funding is used to implement electronic integrated surveillance systems. Several of the territories are at some stage of implementing the National Electronic Disease Surveillance System (NEDSS) Base System (NBS) as their electronic integrated surveillance system that they will use to send automated HL7 case notifications to CDC. NBS is a CDC-developed integrated information system that helps local, state, and territorial public health departments manage reportable disease data and send notifiable disease data to CDC.

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

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

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

more nationally notifiable disease data to CDC, both the duplication of reporting to CDC by state and local public health departments and the burden to state and local public health departments may be reduced.

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

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

A.6. Consequences of Collecting the Information Less Frequently

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

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

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

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

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

A.8.A.

A 60-day Federal Register Notice was published in the *Federal Register* on October 23, 2020, Vol. 85, No. 206, pp. 67544-67545 **[Attachment 2a. 60-Day FRN]**. No comments were received.

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 12. 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 the Data Warehouse (DW), Data Message Brokering (DMB) and the Message Validation, Processing, and Provisioning System (MVPS). HL7 case notifications that use older MMGs are processed by DMB, and HL7 messages that use newer MMGs are processed by MVPS. NETSS case notifications are processed in the DW which ultimately stores all electronic case notifications. The Privacy Act is applicable as personally identifiable information (PII) is collected and information can be retrieved by PII. However, data are not retrieved by PII. Jurisdictions remove most PII before data are submitted to CDC, but some data elements (e.g., date of birth, date of diagnosis, county of residence) could potentially be combined with other information to identify individuals. See Privacy Impact Assessments (PIAs) for the DW, DMB, and MVPS **[Attachments 13 through 15]**. Private information will not be disclosed unless otherwise compelled by law. No assurance of confidentiality has been obtained.

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

standards for messaging systems which provide security mechanisms for jurisdictions to use when submitting data. Case notifications are encrypted and submitted to NNDSS electronically from already existing databases via automated electronic transfers through a secure network. Electronic data are transmitted to and securely processed at CDC. When automated transmission is not possible, case counts are emailed or uploaded to a secure network or entered into a secure website. Information that is emailed or uploaded is in the form of an aggregate weekly or annual case counts. Once in DHIS, all case notification data are treated in a secure manner consistent with the technical, administrative, and operational controls required by the Federal Information Security Management Act of 2002 (FISMA). These DHIS systems are also in compliance with more recent standards to protect information: the NIST Recommended Security Controls for Federal Information Systems and Organizations, Special Publication 800-53, Revised May 1, 2010.

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

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), not research **[Attachment 16. NNDSS Research Determination]**.

Sensitive Questions

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

A.12. Estimates of Annualized Burden Hours and Costs

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

The burden estimates in Table A12A below include the estimates of burden hours for the key changes in this revision including:

1) the one-time increase in burden hours that states, territories, freely associated states, and cities will incur to send case notification data for MIS associated with COVID-19; 2) the one-time increase in burden hours that states, territories, freely associated states, and cities will incur to process and send a total of 208 new data elements for 16 conditions: Anthrax, Brucellosis, Campylobacteriosis, Cholera, Cryptosporidiosis, Hansen's Disease, Leptospirosis, Melioidosis, MIS associated with COVID-19, COVID-19, S. Paratyphi Infection, S. Typhi Infection, STEC, Shigellosis, and Vibriosis; and 3) The one-time burden to add 10 vaccine data elements for all conditions.

The burden estimates are shown for four types of respondents: states, territories, freely associated states, and cities. **Attachment 17. Burden Table Calculations** describes the burden table calculations in detail.

States

States incur burden by: 1) sending weekly automated case notification data to CDC, 2) sending weekly non-automated case notification data to CDC, 3) modernizing their surveillance systems as part of NMI implementation, 4) reconciling and sending annual case notification data to CDC, and 5) modifying their surveillance systems and automated case notification messages to accommodate new data elements and diseases. All 50 states send weekly automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours. 10 states send weekly non-automated case notification data to CDC for at least one disease or condition and their average burden is 2 hours. All 50 states perform weekly activities to modernize their surveillance systems as part of NMI implementation and their average burden is 4 hours. All 50 states reconcile and send annual case notification data to CDC and their average burden is 75 hours. All 50 states modify their surveillance systems and automated case notification messages to accommodate new data elements. As shown on the Total Diseases + Data Elements tab on **Attachment 17. Burden Table Calculations,** the one-time average burden per response is 51 hours and the one-time total burden is 2,550 hours. As shown on Table A12A below, the annualized one-time average burden per response is 12 hours and the annualized one-time total burden is 600 hours.

Territories

Territories incur burden by: 1) sending weekly automated case notification data to CDC, 2) sending weekly and quarterly non-automated case notification data to CDC, 3) modernizing their surveillance systems as part of NMI implementation, 4) reconciling and sending annual case notification data to CDC and 5) modifying their surveillance systems and automated case notification messages to accommodate new data elements and diseases. All 5 territories send weekly automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours. All 5 territories send weekly and quarterly non-automated case notification data to CDC for at least one disease or condition and their average burden per response is 20/60 hours. All 5 territories perform weekly activities to modernize their surveillance systems as part of NMI implementation and their average burden is 4 hours. All 5 territories reconcile and send annual case notification data to CDC and their average burden is 5 hours. All 5 territories modify their surveillance system and automated case notification message to accommodate new data elements and diseases. As shown on the Total Diseases + Data Elements tab on Attachment 16. Burden Table Calculations, the one-time average burden per response is 51 hours and the one-time total burden is 255 hours. As shown on Table A12A below, the annualized one-time average burden per response is 12 hours and the annualized one-time total burden is 60 hours.

Freely Associated States

Freely associated states incur burden by: 1) sending weekly automated case notification data to CDC, 2) sending weekly and quarterly non-automated case notification data to CDC, 3) reconciling and sending annual case notification data to CDC and 4) modifying their surveillance systems and automated case notification messages to accommodate new data elements and diseases. All 3 freely associated states send weekly automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours. All 3 freely associated states send weekly and quarterly non-automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours. All 3 freely associated states reconcile and send annual case notification data to CDC and their average burden is 5 hours. All 3 freely associated states modify their surveillance systems and automated case notification message to accommodate new data elements and diseases. As shown on the Total Diseases + Data Elements tab on Attachment 16. Burden Table Calculations, the one-time average burden per response is 51 hours and the one-time total burden is 153 hours. As shown on Table A12A below, the annualized one-time average burden per response is 12 hours and the annualized one-time total burden is 36 hours.

Cities

Cities incur burden by: 1) sending weekly automated case notification data to CDC, 2) sending weekly non-automated case notification data to CDC, 3) modernizing their surveillance systems as part of NMI implementation, 4) reconciling and sending annual case notification data to CDC, and 5) modifying their surveillance systems and automated case notification messages to accommodate new data elements and diseases. Both of the 2 cities send weekly automated case notification data to CDC for at least one disease or condition and their average burden is 20/60 hours. Both of the 2 cities send weekly non-automated case notification data to CDC for at least one disease or condition and their average burden per response is 2 hours. Both of the 2 cities perform weekly activities to modernize their surveillance systems as part of NMI implementation and their average burden is 4 hours. Both of the 2 cities reconcile and send annual case notification data to CDC and their average burden is 75 hours. Both of the 2 cities modify their surveillance systems and automated case notification messages to accommodate new data elements and diseases. As shown on the Total Diseases + Data Elements tab on Attachment 16. Burden Table Calculations, the one-time average burden per response is 51 hours and

the one-time total burden is 102 hours. As shown on Table A12A below, the annualized one-time average burden per response is 12 hours and the annualized one-time total burden is 24 hours.

According to the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2019 National Occupational Employment and Wage Estimates, the estimated mean hourly wage for Computer Systems Analysts is $46.23 (https://www.bls.gov/oes/current/oes_nat.htm#15-0000) and the estimated mean hourly wage for Epidemiologists is $37.64 (http://www.bls.gov/oes/current/oes_nat.htm#19-0000) The estimated hourly wage for a Computer Systems Analyst is used for weekly automated submissions and weekly NMI implementation activities and the estimated hourly wage for an Epidemiologist is used for weekly non-automated submissions and annual data reconciliation. These wage estimates were used because these two occupations represent the category of occupations held by the respondents that perform these activities. Using $46.23 as an average hourly wage rate for Computer Systems Analysts and using $37.64 as an average hourly wage rate for Epidemiologists, it is estimated that the average national annual burden for weekly and annual reporting is 18,954 hours at a national cost of $830,400.

A12A. Estimates of Annualized Burden Hours

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden (in hours)
States	Weekly (Automated)	50	52	20/60	867
States	Weekly (Non-automated)	10	52	2	1,040
States	Weekly (NMI Implementation)	50	52	4	10,400
States	Annual	50	1	75	3,750
States	One-time Addition of Diseases and Data Elements	50	1	12	600
Territories	Weekly (Automated)	5	52	20/60	87
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93

Territories	Weekly (NMI Implementation)	5	52	4	1,040
Territories	Annual	5	1	5	25
Territories	One-time Addition of Diseases and Data Elements	5	1	12	60
Freely Associated States	Weekly (Automated)	3	52	20/60	52
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56
Freely Associated States	Annual	3	1	5	15
Freely Associated States	One-time Addition of Diseases and Data Elements	3	1	12	36
Cities	Weekly (Automated)	2	52	20/60	35
Cities	Weekly (Non-automated)	2	52	2	208
Cities	Weekly (NMI Implementation)	2	52	4	416
Cities	Annual	2	1	75	150
Cities	One-time Addition of Diseases and Data Elements	2	1	12	24
Total					**18,954**

A12B. Estimates of Annualized Cost Burden

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Respondent Cost
States	Weekly (Automated)	50	52	20/60	867	$46.23	$40,081
States	Weekly (Non-automated)	10	52	2	1,040	$37.64	$39,146
States	Weekly (NMI	50	52	4	10,400	$46.23	$480,792

	Implementation)						
States	Annual	50	1	75	3,750	$37.64	$141,150
States	One-time Addition of Diseases and Data Elements	50	1	12	600	$46.23	$27,738
Territories	Weekly (Automated)	5	52	20/60	87	$46.23	$4,022
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93	$37.64	$3,501
Territories	Weekly (NMI Implementation)	5	52	4	1,040	$46.23	$48,079
Territories	Annual	5	1	5	25	$37.64	$941
Territories	One-time Addition of Diseases and Data Elements	5	1	12	60	$46.23	$2774
Freely Associated States	Weekly (Automated)	3	52	20/60	52	$46.23	$2,404
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56	$37.64	$2,108
Freely Associated States	Annual	3	1	5	15	$37.64	$565
Freely Associated States	One-time Addition of Diseases and Data Elements	3	1	12	36	$46.23	$1664
Cities	Weekly (Automated)	2	52	20/60	35	$46.23	$1,618
Cities	Weekly (Non-automated)	2	52	2	208	$37.64	$7,829
Cities	Weekly (NMI Implementation)	2	52	4	416	$46.23	$19,232
Cities	Annual	2	1	75	150	$37.64	$5,646
Cities	One-time Addition of Diseases and Data Elements	2	1	12	24	$46.23	$1110
Total							**$830,400**

A.13. <u>Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers</u>

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 19	FY 20	FY 21
Personnel - Software development, support, and management (intramural)	$5,484,199	$6,327,018	7,357,766
Contracts – Program and web support	$9,943,144	$10,077,518	8,791,958
Cooperative Agreements with States for NNDSS case notification and management (extramural)	$9,388,955	$9,014,027	5,553,034
Total	$24,816,298	$25,418,563	$21,702,758

The estimated annualized cost to the government for NNDSS is $23,979,206 (average of three years).

A.15. Explanation for Program Changes or Adjustments

Changes to NNDSS in this revision include receipt of case notification data for MIS associated with COVID-19 for standardized surveillance, receipt of vaccine data elements, and receipt of disease-specific data elements for Anthrax, Brucellosis, Campylobacteriosis, Cholera, Cryptosporidiosis, Hansen's Disease, Leptospirosis, Melioidosis, MIS associated with COVID-19, COVID-19, *S.* Paratyphi Infection, *S.* Typhi Infection, Salmonellosis, STEC, Shigellosis, and Vibriosis.

The overall burden hours increased since the last revision because there were more one-time burdens associated with disease-specific and vaccine data elements in this revision (208 disease-specific and 10 vaccine data elements) as compared to the last revision (107 disease-specific data elements). Going forward, there will be a one-time increase in the burden estimates each time new data elements or new conditions are added. The one-time increase in the burden estimates for adding new data elements will continue to be reflected as a separate line in the burden table in an ICR revision or a non-substantive change request.

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

CDC tabulates and publishes provisional counts of nationally notifiable conditions each week. In the past, these data were published in the *MMWR* and were available through CDC WONDER and data.cdc.gov. Beginning in 2018, the weekly tables of nationally notifiable diseases have not been published in the *MMWR* but are available through CDC WONDER and data.cdc.gov. The *MMWR Summary of Notifiable Diseases*, *United States*, *2015*, was the last summary of finalized notifiable disease data that was published by *MMWR*. Going forward and beginning with 2016 data, finalized notifiable disease data are published on CDC WONDER and disease-specific data are published by individual CDC programs. This transition to using CDC WONDER and CDC.data.gov as the primary forums for presentation of weekly tables allows CDC to finalize and publish annual data more quickly. In addition, CDC programs routinely publish reports on specific notifiable conditions in the *MMWR* and in other scientific, medical and public health journals.

CDC continue to implement an anticipated schedule of non-substantive change requests and revisions for NNDSS. Notifiable disease data collection is continuous, data are collected on approximately 120 conditions, and the epidemiology of these conditions is continuously evolving. As such, this information collection will continue to evolve to provide the knowledge needed for effective disease tracking and control. Many disease-specific messages need to be modernized as programs continue to convert disease notifications to Health Level 7 (HL7) messages, and each requires a substantial investment of time. This proposed schedule allows the production of a few updated messages with new data elements three times per year through routine non-substantive change requests as well as other substantive changes once per year through a revision (a revision may also include the addition of new data elements that were not added through a non-substantive change request but the need to add new data elements will not trigger the initiation of a revision). In addition to the proposed schedule for updated messages, requests for new data elements are occasionally received from programs to reflect changes in the epidemiology of the condition or the laboratory tests available for detection and diagnosis. These requests will usually be grouped into non-substantive change requests or added to the annual revision. However, when urgent situations arise, such as the need to make a new condition notifiable in response to an emergent outbreak, there may be additional revisions or non-substantive change requests outside of the proposed schedule.

CDC will continue to notify OMB of all non-substantive change requests and revisions in advance. CDC will notify OMB of routine non-substantive change requests through memorandums and CDC will notify OMB of urgent non-substantive change requests and revisions through telephone briefings.

If CSTE generates and approves a position statement deeming MIS associated with COVID-19 an NNC, CDC will initiate a non-substantive change request to that effect.

An anticipated schedule for submission of non-substantive change requests and revisions is presented in the table below:

Submission Type	Purpose	Approximate Frequency	Approximate Timeline
Non-substantive change request	• New data elements	• 3 times per year	• January / February • April / May • July / August
Revision	• New diseases or conditions • New data elements that were not added through a non-substantive change request* • Changes in the respondent population (e.g., addition of freely associated states) • Changes in the scope (e.g., addition of case-based surveillance of conditions that are not nationally notifiable or under standardized surveillance)	• Annually	• September / October

*A revision may include the addition of new data elements that were not added through a non-substantive change request but the need to add new data elements will not trigger the initiation of a revision

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

Since approximately 90% of case notifications are submitted to CDC electronically from already existing databases via automated electronic transfers, CDC requests approval to place the PRA burden statement and OMB expiration date on the NNDSS Data Collection and Reporting webpage. Respondents can navigate to the list of required data elements from this central location. A screenshot of the webpage is shown in **Attachment 18. PRA Burden Statement Screenshot.**

A.18. <u>Exceptions to Certification for Paperwork Reduction Act Submissions</u>

There are no exceptions to the certification.