National Notifiable Diseases Surveillance System

Supporting Statement Section A

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National Notifiable Diseases Surveillance System - Request for Revision

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A. Justification

- **The National Notifiable Diseases Surveillance System (NNDSS) is the nation's public health surveillance system used to monitor the occurrence and spread of nationally notifiable conditions. NNDSS provides the official source of statistics in the United States for nationally notifiable conditions and CDC is the sole repository for these national, population-based data. 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 (the 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 July 31, 2025. This application is the seventh 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
Brucellosis	NNC	Y		Y	Y	225	4
Candida auris	NNC	Y		Y	Y	18	2
Carbapenemase-Producing Organisms (CPO)	NNC	N	Y	N	Y	0	21
Carbon Monoxide Poisoning	NNC	Y		Y	Y	63	1
Hepatitis	NNC	Y		Y	Y	198	1
Leptospirosis	NNC	Y		Y	Y	99	7
Melioidosis	NNC	Y		Y	Y	158	21
Strongyloidiasis	CSS	N	Y	N	N	0	0
Viral Hemorrhagic Fevers	NNC	Y		N	Y	0	104

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 is a case-based surveillance system meaning that the unit of reporting is a case – a person with a specific condition. 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 program 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) as of March 22, 2022 **[Attachment 1. Authorizing Legislation]**.

A.2. <u>Purpose and Use of the Information Collection</u>

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 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

[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 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 are two conditions, Carbapenemase-Producing Organisms (CPO), listed in Attachment 4 in bold and Strongyloidiasis, listed in Attachment 3 in bold that were not included in the previous ICR.

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

Carbapenemase-Producing Organisms

CSTE issued a position statement in 2022 that rendered CPO nationally notifiable (https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/ps2022/22-ID-04_CPO.pdf).

This position statement includes the following statement: “Jurisdictions (e.g., States and Territories) conducting surveillance under this case definition can voluntarily submit de-identified case information to CDC, if requested and in a mutually agreed upon format.” CDC requests permission to receive case notification data for CPO as it is now nationally notifiable.

Carbapenemase-Producing Organisms (CPO)	
The impetus/urgency for CDC to institute case notification and data elements for this condition	• To make surveillance more comprehensive and informative for public health actions • To provide more information about risk factors (related cases and conditions, high acute care needs, healthcare facility exposure, travel, and specimen testing) that have been associated with colonization or infection • To monitor epidemiology • To update guidance on infection control and prevention • To update guidance and priorities for laboratory

	detection
Existing sources of data (Federal, non-federal, private, etc.) and what those sources say about approximate national incidence and/or prevalence of the condition	• CPOs include CP-CRE, CP-CRPA, and CP-CRAB. • CP-CRE: According to the AR Threats report (2019), approximately 13,000 cases of CRE occur each year in the United States. This is approximately 2.7% of all Enterobacteriaceae tested in NHSN. Among this 2.7%, about 35% are found to be a CPO (because they are CP-CRE). • CP-CRPA: According to the AR Threats report (2019), approximately 33,000 cases of CRPA occur each year in the United States. This is approximately 13% of all Pseudomonas aeruginosa tested in NHSN. Among this 13%, only 2% are found to be a CPO (because they are CP-CRPA). • CP-CRAB: According to the AR Threats report (2019), approximately 85,000 cases of CRAB occur each year in the United States. This is approximately 40% of all Acinetobacter tested in NHSN. Among this 40%, only 2% are found to be a CPO (because they are CP-CRAB).
Incremental coverage provided by adding the condition to NNDSS (how CDC will use additional precision)	• Currently, case data may be sent to CDC on an ad hoc basis for special projects or an identified outbreak or ongoing outbreak investigation. It is not systematic or comprehensive. We do not have a systematic way to receive notification of CPO detection and epidemiologic data for all cases detected national. • Data elements requested through NNDSS (specifically the demographic factors, hospitalization and travel history) are not collected in any other surveillance system and no other surveillance system tracks these (carbapenemase-producing) organisms. The AR Lab Network focuses on detection of CPOs but is not national surveillance. Rather, it is a laboratory-only system that tests and reports on a convenience sample of carbapenem-resistant specimens.
Number of states that currently require reporting of these conditions and data elements	• State (or jurisdiction like Washington D.C. and Puerto Rico) reporting by varies type of CPO identified): CRE is currently reportable in 44, CRPA is currently reportable in 19, and CRAB is currently reportable in 19.
Number of states anticipated to adopt if added to NNDSS and basis of estimate	• At least 44, based on where carbapenem-resistant organisms are already reportable. Additional

funding allocated specifically for a condition and/or additional elements (please list source where applicable)	reporting requirements and NNDSS adoption uptake is anticipated with time. • No specific funding allocated for reporting through NNDSS, but all states did receive ARP funding to conduct testing of CRE, CRPA, and CRAB.
Anticipated frequency of reporting to CDC	• Monthly
Based on the above information, what is the proposed priority associated with condition	• No proposed priority associated with this condition • Approved as nationally notifiable condition • Included among Serious and Urgent Threats in CDC's 2019 AR Threats Report

Strongyloidiasis

CSTE issued a position statement in 2022 that rendered Strongyloidiasis under standardized surveillance (https://cdn.ymaws.com/www.cste.org/resource/resmgr/ps/ps2022/22-ID-09_Strongyloidiasis.pdf). This position statement includes the following statement: "Jurisdictions (e.g., States and Territories) conducting surveillance under this case definition can voluntarily submit de-identified case information to CDC, if requested and in a mutually agreed upon format." CDC requests permission to receive case notification data for Strongyloidiasis as it is now under standardized surveillance.

Strongyloidiasis	
The impetus/urgency for CDC to institute case notification and data elements for this condition	• Track transplant-associated infections and address any related implications • Track and respond to potential outbreaks of locally acquired strongyloidiasis • Assess the burden and geographical distribution of strongyloidiasis as an environmentally mediated pathogen
Existing sources of data (Federal, non-federal, private, etc.) and what those sources say about approximate national incidence and/or prevalence of the condition	• There are no national or state level passive or active surveillance data available • A few small studies in limited geographic areas have reported seroprevalence of US-acquired infections ranging from 5-16.5% • Estimates of prevalence in Immigrant communities nationwide ranging from 0-46%, with a study in Sudanese refugees in 2004 finding 46% of those tested were seropositive
Incremental coverage provided by adding the condition to NNDSS (how CDC will use additional precision)	Case notifications will allow CDC to track occurrence of cases and assist with identifying locally acquired cases with no current formal case reporting process
Number of states that currently require reporting of these conditions and data	0

elements	
The number of states anticipated to adopt if added to NNDSS and basis of estimate Funding allocated specifically for a condition and/or additional elements (please list source where applicable)	• 0-2 o No specific funding allocated
Anticipated frequency of reporting to CDC	As needed
Based on the above information, what is the proposed priority associated with condition	No proposed priority associated with this condition

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 timelier.

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. All of these vaccine 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 7. 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 8. 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. 161 new data elements that were not included in the previously reviewed ICR were added for 8 conditions: Brucellosis, *Candida auris*, CPO, Carbon Monoxide Poisoning, Hepatitis, Leptospirosis, Melioidosis, and Viral Hemorrhagic Fevers. Names, descriptions, value set codes, and justification for the addition of these new data elements are in **Attachment 9. Justification for the Addition of Disease-Specific Data Elements**. Names, descriptions and value set codes for all of the data elements are in an attachment **[Attachment 10. 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

CDC's Data Modernization Initiative (DMI) is the first unified, comprehensive effort to modernize core data and surveillance capabilities across the federal and state public health landscape (https://www.cdc.gov/surveillance/index.html). CDC is modernizing NNDSS to allow public health agencies to send data about notifiable diseases to CDC more quickly and easily and to enhance the ability to provide comprehensive, timely, and high-quality data for public health decision making. CDC continues 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.

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. Four territories (the Commonwealth of the Northern Mariana Islands, Guam, the U.S. Virgin Islands, and Puerto Rico) and one Freely Associated State (the Republic of the Marshall Islands) implemented the National Electronic Disease Surveillance System (NEDSS) Base System (NBS) as their electronic integrated surveillance system that they will use to send automated 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 (https://www.cdc.gov/nbs/index.html).

Opportunities exist to decrease the burden for public health departments that send case notification data to CDC. Implementing DMI will reduce the burden since public health departments will have more flexibility in how they send case notification messages to CDC. In addition, CDC developed a dashboard

that displays case notification data sent by jurisdictions. The dashboard includes 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 can 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 likely decrease the burden from the annual data reconciliation effort. As more flexible reporting mechanisms are implemented, the overall burden will be reduced. The effort required to implement the standardized data content needed for electronic case notification is represented in the burden table as "DMI 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 improved through DMI 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 November 16, 2022, Vol. 87, No. 220, pp. 68699-68701 **[Attachment 2a. 60-Day FRN]**. No comments were received.

A.8.B.

There were two recent external assessments involving NNDSS that were completed in 2021 that are related to NNDSS. CDC contracted with the MITRE Corporation, a Federally Funded Research and Development Center, to perform a qualitative analysis and technology landscape analysis to examine the presentation of content and format specifications for NNDSS data transmitted by the public health jurisdictions to CDC. The assessment was based on publicly available information and input from public health jurisdictions and provided recommendations on workforce skills, technical processes, and technology for both CDC stewards of NNDSS and jurisdictional implementation partners. In addition, as part of DMI, CDC engaged the Public Health Informatics Institute (PHII) to identify the capabilities and technical requirements of future surveillance systems that will meet those specifications. PHII identified five key partner groups (public health jurisdictions, public health associations, public health informatics partners, technology partners, and the CDC) that routinely interact with current surveillance systems and could inform what is needed to enhance their flexibility, scalability, and interoperability with

healthcare and public health. Results are detailed in the attached DMI report **[Attachment 11. Case-based Surveillance Capabilities and Technology Recommendations]**.

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

The Privacy Act applies. The applicable SORN is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. NNDSS data are stored in the Message Validation, Processing, and Provisioning System (MVPS). Personally identifiable information (PII) is collected, and information can be retrieved by PII. However, information is 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 the Privacy Impact Assessment (PIA) for MVPS **[Attachment 12]**. 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 few 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 13. 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 seventh 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 CPO and Strongyloidiasis; and 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 161 new data elements for 8 conditions: Brucellosis, *Candida auris*, CPO, Carbon Monoxide Poisoning, Hepatitis, Leptospirosis, Melioidosis, and Viral Hemorrhagic Fevers.

The burden estimates are shown for four types of respondents: states, territories, freely associated states, and cities. **Attachment 14. 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 DMI 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 DMI 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 14. Burden Table Calculations,** the one-time average burden per response is 17 hours and the one-time total burden is 850 hours. As shown on Table A12A below, the annualized one-time average burden per response is 6 hours and the annualized one-time total burden is 300 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 DMI 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 DMI 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 14. Burden Table Calculations, the one-time average burden per response is 17 hours and the one-time total burden is 85 hours. As shown on Table A12A below, the annualized one-time average burden per response is 6 hours and the annualized one-time total burden is 30 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) modernizing their surveillance systems as part of DMI 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 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 14. Burden Table Calculations, the one-time average burden per response is 17 hours and

the one-time total burden is 51 hours. As shown on Table A12A below, the annualized one-time average burden per response is 6 hours and the annualized one-time total burden is 18 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 DMI 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 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 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 2 cities perform weekly activities to modernize their surveillance systems as part of DMI implementation and their average burden is 4 hours. Both two cities reconcile and send annual case notification data to CDC and their average burden is 75 hours. Both 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 14. Burden Table Calculations, the one-time average burden per response is 17 hours and the one-time total burden is 34 hours. As shown on Table A12A below, the annualized one-time average burden per response is 6 hours and the annualized one-time total burden is 12 hours.

According to the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2021 National Occupational Employment and Wage Estimates, the estimated mean hourly wage for Computer Systems Analysts is $49.14 (https://www.bls.gov/oes/current/oes_nat.htm#15-0000) and the estimated mean hourly wage for Epidemiologists is $41.70 (http://www.bls.gov/oes/current/oes_nat.htm#19-0000). The estimated hourly wage for a Computer Systems Analyst is used to calculate the cost for weekly automated submissions, weekly DMI implementation activities, and one-time addition of diseases and data elements. The estimated hourly wage for an Epidemiologist is used to calculate the cost 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 $49.14 as an average hourly wage rate for Computer Systems Analysts and using $41.70

as an average hourly wage rate for Epidemiologists, it is estimated that the average national annual burden is 18,594 hours at a national cost of $874,002.

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 (DMI Implementation)	50	52	4	10,400
States	Annual	50	1	75	3,750
States	One-time Addition of Diseases and Data Elements	50	1	6	300
Territories	Weekly (Automated)	5	52	20/60	87
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93
Territories	Weekly (DMI Implementation)	5	52	4	1,040
Territories	Annual	5	1	5	25
Territories	One-time Addition of Diseases and Data Elements	5	1	6	30
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	6	18

Cities	Weekly (Automated)	2	52	20/60	35
Cities	Weekly (Non-automated)	2	52	2	208
Cities	Weekly (DMI Implementation)	2	52	4	416
Cities	Annual	2	1	75	150
Cities	One-time Addition of Diseases and Data Elements	2	1	6	12
Total					**18,594**

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	$49.14	$42,604
States	Weekly (Non-automated)	10	52	2	1,040	$41.70	$43,368
States	Weekly (DMI Implementation)	50	52	4	10,400	$49.14	$511,056
States	Annual	50	1	75	3,750	$41.70	$156,375
States	One-time Addition of Diseases and Data Elements	50	1	6	300	$49.14	$14,742
Territories	Weekly (Automated)	5	52	20/60	87	$49.14	$4,275
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93	$41.70	$3,878
Territories	Weekly (DMI Implementation)	5	52	4	1,040	$49.14	$51,106
Territories	Annual	5	1	5	25	$41.70	$1,043
Territories	One-time Addition of Diseases and Data Elements	5	1	6	30	$49.14	$1,474
Freely Associated States	Weekly (Automated)	3	52	20/60	52	$49.14	$2,555

Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56	$41.70	$2,335
Freely Associated States	Annual	3	1	5	15	$41.70	$626
Freely Associated States	One-time Addition of Diseases and Data Elements	3	1	6	18	$49.14	$885
Cities	Weekly (Automated)	2	52	20/60	35	$49.14	$1,720
Cities	Weekly (Non-automated)	2	52	2	208	$41.70	$8,674
Cities	Weekly (DMI Implementation)	2	52	4	416	$49.14	$20,442
Cities	Annual	2	1	75	150	$41.70	$6,255
Cities	One-time Addition of Diseases and Data Elements	2	1	6	12	$49.14	$590
Total							$874,002

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 22	FY 23	FY 24
Personnel - Software development, support, and management (intramural)	$7,068,674	$7,280,734	$7,280,734
Contracts – Program and web support	$23,651,154	$24,668,936	$24,668,936
Cooperative Agreements with States for NNDSS case notification and management (extramural)	$6,517,000	$6,517,000	$6,517,000
Total	$37,236,828	$38,466,670	$38,466,670

The estimated annualized cost to the government for NNDSS is $38,056,723 (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 CPO since it is now nationally notifiable, receipt of case notification data for Strongyloidiasis since it is under standardized surveillance, and receipt of disease-specific data elements for Brucellosis, *Candida auris*, CPO, Carbon Monoxide Poisoning, Hepatitis, Leptospirosis, Melioidosis, and Viral Hemorrhagic Fevers.

The overall burden hours increased since the last revision because there were more one-time burdens associated with disease-specific data elements in this revision (161 disease-specific data elements) as compared to the last revision (24 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 updated, 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	• Annually	• September / October

	surveillance of conditions that are not nationally notifiable or under standardized surveillance)		

*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. <u>Reason(s) Display of OMB Expiration Date is Inappropriate</u>

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 15. PRA Burden Statement Screenshot.**

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

There are no exceptions to the certification.