

National Notifiable Diseases Surveillance System

Supporting Statement Section A

OMB Control Number 0920-0728

April 29, 2019

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)
- 2b. Public Comment
- 2c. Public Comment
3. List of Nationally Notifiable Conditions
4. List of Conditions Under Standardized Surveillance
5. Characteristics of New Nationally Notifiable Conditions
6. Characteristics of New Conditions Under Standardized Surveillance
7. List of Data Elements for Carbon Monoxide Poisoning Received from NPDS
8. Core Data
9. Laboratory Data
10. Vaccine Data
11. Vaccine Preventable Disease Data

12. Justification for the Addition of Disease-Specific Data Elements
13. Disease-Specific Data
14. Overview of Sexual Orientation and Gender Identity (SO/GI) Provisional Pilot in NNDSS
- 14a. Response to Comments on Pilot Data Collection of SO/GI variables
15. Consultants List
16. DW PIA
17. DMB PIA
18. MVPS PIA
19. NNDSS Research Determination
20. Burden Table Calculations
21. PRA Burden Statement Screenshot
22. SOGI Survey Data Collection Instrument
23. SOGI Survey Introductory Email
24. SOGI Survey Reminder Email

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 NNDSS 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 February 28, 2021. This application is the third revision to the previous 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 (or OMB # 0920-0036) ¹	Proposed Number of new NNDSS Data Elements
<i>Candida auris</i> (<i>C. auris</i>)	NNC	N	Y	N	N	0	0
Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE)	NNC	N	Y	N	Y	0	8
Carbon Monoxide (CO) Poisoning	NNC	N	Y	N	Y	0	4
Tuberculosis (TB) Disease	NNC	N	Y	N	Y	59	36
<i>S. Typhi</i> Infection	NNC	Y		Y	Y	62	4
<i>S. Paratyphi</i> Infection	NNC	N	Y	N	Y	0	60
Latent TB Infection (TB Infection)	CSS	N	Y	N	Y	0	51
Respiratory Syncytial Virus (RSV)-Associated Mortality	CSS	N	Y	N	N	0	0
Shiga Toxin-Producing <i>E. coli</i> (STEC)	NNC	Y		Y	Y	332	2
Salmonellosis	NNC	Y		Y	Y	152	1

¹ Of the 95 data elements for TB disease, 59 were previously approved under OMB # 0920-0036 and 36 were not previously approved under OMB # 0920-0036. See attachment 12, p. 2.

Shigellosis	NNC	Y		Y	Y	20	4
Campylobacteriosis	NNC	Y		Y	Y	11	2
Cryptosporidiosis	NNC	Y		Y	Y	151	1
Cyclosporiasis	NNC	Y		Y	Y	127	3
Cholera	NNC	Y		Y	Y	245	1
Vibriosis	NNC	Y		Y	Y	218	1
Lyme Disease	NNC	Y		Y	Y	25	7
<i>Haemophilus Influenzae</i> , Invasive Disease	NNC	Y		Y	Y	49	33
Meningococcal Disease	NNC	Y		Y	Y	55	37
Invasive Pneumococcal Disease (IPD)	NNC	Y		Y	Y	26	32
Psittacosis	NNC	Y		Y	Y	75	27
Legionellosis	NNC	Y		Y	Y	78	38
Tickborne Rickettsial Diseases (TBRD)	NNC	Y		Y	Y	34	35
Hepatitis	NNC	Y		Y	Y	126	5

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 disease 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 CDC². 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 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**

² 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.

Conditions and Attachment 4. List of Conditions Under Standardized Surveillance]. There are six conditions (*C. auris*, CP-CRE, CO Poisoning, TB Disease, *S. Typhi*, and *S. Paratyphi*) listed in Attachment 3 in bold and two conditions (TB Infection and RSV-Associated Mortality) listed in Attachment 4 in bold that were not included in the previous ICR.

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

C. auris

CSTE issued a position statement in 2018 that rendered *C. auris* nationally notifiable (https://cdn.ymaws.com/www.cste.org/resource/resmgr/2018_position_statements/18-ID-05.pdf).

This position statement includes the following action to be taken: “Utilize standardized criteria for case ascertainment and classification (based on Sections VI and VII and Technical Supplement of accompanying position statement) for *Candida auris* and add *Candida auris* to the Nationally Notifiable Condition List.” CDC requests permission to receive case notification data for *C. auris* as it is now nationally notifiable.

<i>C. auris</i>	
The impetus/urgency for CDC to institute case notification and data elements for this condition	<ul style="list-style-type: none"> • To facilitate early interventions so that <i>C. auris</i> does not become widespread in health care facilities (e.g., nursing homes) like some other multi-drug resistant organisms • To monitor the effect of this emerging, highly drug-resistant, fungal pathogen that causes severe invasive infections associated with high mortality • To improve the ability to respond to this emerging threat
Existing sources of data (Federal, non-federal, private, etc.) and what those sources say about approximate national incidence and/or prevalence of the condition	<ul style="list-style-type: none"> • 1.6 per 1,000,000 [National Healthcare Safety Network (NHSN), 2018]
Incremental coverage provided by adding the condition to NNDSS (how CDC will use additional precision)	<ul style="list-style-type: none"> • NNDSS is expected to capture approximately 90% of cases not currently captured by NHSN • NHSN only captures hospitalized cases and does not capture nursing home cases or community-acquired cases. • Cases captured by NHSN are reported a month or two after they occur and include only those cases that occur in the bloodstream and are associated with central lines • 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	<ul style="list-style-type: none"> 8 jurisdictions
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)	<ul style="list-style-type: none"> 10 jurisdictions: 8 jurisdictions where reportable and 2 high prevalence jurisdictions (NY and NJ) <ul style="list-style-type: none"> No specific funding allocated
Anticipated frequency of reporting to CDC	<ul style="list-style-type: none"> Weekly for high prevalence jurisdictions (e.g., IL, NY, and NJ) Monthly or less for other jurisdictions
Based on the above information, what is the proposed priority associated with condition	States will determine the priority of adding this collection.

CP-CRE

CSTE issued a position statement in 2017 that rendered CP-CRE nationally notifiable (<http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/2017PS/2017PSFinal/17-ID-04.pdf>). This position statement includes the following action to be taken: "Utilize standardized criteria for case identification and classification (Sections VI and VII) for CP-CRE and add CP-CRE to the Nationally Notifiable Condition List." CDC requests permission to receive case notification data for CP-CRE as it is now nationally notifiable.

CP-CRE	
The impetus/urgency for CDC to institute case notification and data elements for this condition	<ul style="list-style-type: none"> To monitor the effect of this highly-resistant bacteria that are difficult to treat, associated with poor outcomes, and readily transmissible in healthcare settings No national surveillance effort of all CP-CRE cases detected in healthcare settings and the community exists To provide national information on the burden of disease, associated demographic factors, and the proportion of cases in people who have traveled internationally or received healthcare outside of the United States
Existing sources of data	<ul style="list-style-type: none"> 20% of isolates identified from 8 sites [Emerging Infections

(Federal, non-federal, private, etc.) and what those sources say about approximate national incidence and/or prevalence of the condition	<p>Program (EIP), 2016]</p> <ul style="list-style-type: none"> • 5,700 isolates identified from selected healthcare facilities [CDC’s Antibiotic Resistance Laboratory Network (ARLN), 2018]
Incremental coverage provided by adding the condition to NNDSS (how CDC will use additional precision)	<ul style="list-style-type: none"> • Exact incremental coverage is not directly quantifiable • Ad hoc case data sent to CDC is not systematic or comprehensive • Case notification data will be used in conjunction with other data sources to track prevalence and epidemiology and inform development and implementation of effective prevention strategies
Number of states that currently require reporting of these conditions and data elements	<ul style="list-style-type: none"> • 33 jurisdictions
<p>The number of states anticipated to adopt if added to NNDSS and basis of estimate</p> <p>Funding allocated specifically for a condition and/or additional elements (please list source where applicable)</p>	<ul style="list-style-type: none"> • All 33 jurisdictions <ul style="list-style-type: none"> o No specific funding allocated
Anticipated frequency of reporting to CDC	<ul style="list-style-type: none"> • Weekly or annually dependent upon incidence in jurisdiction
Based on the above information, what is the proposed priority associated with condition	<ul style="list-style-type: none"> • States will determine the priority of adding this collection.

S. Paratyphi Infection

CSTE issued a position statement in 2018 that rendered S. Paratyphi Infection nationally notifiable (https://cdn.ymaws.com/www.cste.org/resource/resmgr/2018_position_statements/18-ID-08.pdf). This position statement proposes that “a standardized case definition for S. Paratyphi Infection be developed and S. Paratyphi Infection be added to the Nationally Notifiable Condition list.” CDC requests permission to receive case notification data for S. Paratyphi as it is now nationally notifiable.

S. Typhi Infection

CSTE issued a position statement in 2018 to rename the nationally notifiable condition, Typhoid Fever, with the name “S. Typhi Infection”

(https://cdn.ymaws.com/www.cste.org/resource/resmgr/2018_position_statements/18-ID-08.pdf). This position statement proposes that: “3. Typhoid fever be renamed to S. Typhi Infection.” CDC requests permission to rename Typhoid Fever to “S. Typhi Infection” on the List of Nationally Notifiable Conditions.

<p>S. Paratyphi</p> <p>The impetus/urgency for CDC to institute case notification and data elements for this condition</p>	<ul style="list-style-type: none"> • To monitor the effect of these serious and potentially life-threatening diseases that can be transmitted within populations • Receiving case notifications for S. Paratyphi with other Salmonella infections • Data used to detect outbreaks and monitor national trends • Cases trigger immediate public health actions • Case notifications are necessary to inform response and prevent further transmission
<p>Existing sources of data (Federal, non-federal, private, etc.) and what those sources say about approximate national incidence and/or prevalence of the condition</p>	<ul style="list-style-type: none"> • CDC received 71 reports of paratyphoid fever [NNDSS, 2015]
<p>Incremental coverage provided by adding the condition to NNDSS (how CDC will use additional precision)</p>	<ul style="list-style-type: none"> • NNDSS is the only source of case data
<p>Number of states that currently require reporting of these conditions and data elements</p>	<ul style="list-style-type: none"> • 50 jurisdictions require reporting
<p>The number of states anticipated to adopt if added to NNDSS and basis of estimate</p> <p>Funding allocated specifically for a condition and/or additional elements (please list source)</p>	<ul style="list-style-type: none"> • All 50 jurisdictions <ul style="list-style-type: none"> o No specific funding allocated

where applicable)	
Anticipated frequency of reporting to CDC	<ul style="list-style-type: none"> • Less than 10 annually
Based on the above information, what is the proposed priority associated with condition	<ul style="list-style-type: none"> • States will determine the priority of adding this collection.

CO Poisoning

CO Poisoning became nationally notifiable in 2013

(<http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PS/13-EH-01.pdf>). Currently, CDC is not notified of CO Poisoning cases through NNDSS. The 2013 CSTE position statement on CO Poisoning recommended that jurisdiction health departments use the American Association of Poison Control Centers' (AAPCC) National Poison Data System (NPDS) as the mechanism to notify CDC of CO Poisoning cases. Fifty-five Poison Centers (PCs) that serve the 50 states, American Samoa, District of Columbia, Federated States of Micronesia, Guam, Puerto Rico, and the US Virgin Islands automatically upload cases to NPDS in near real-time

(https://aapcc.s3.amazonaws.com/pdfs/annual_reports/2014_AAPCC_NPDS_Annual_Report.pdf). CDC purchases NPDS data from AAPCC so the Paperwork Reduction Act (PRA) does not apply. AAPCC provides CDC with online access to NPDS per a data use agreement and provides CDC with a limited number of data elements [**Attachment 7. List of Data Elements for Carbon Monoxide Poisoning Received from NPDS**].

Healthcare providers and other individuals (e.g., parents) call PCs to report CO Poisoning cases and these cases get reported through NPDS. Despite this effort, the cases reported do not reflect the entire universe of reportable CO Poisoning cases in the US. In jurisdictions where CO Poisoning is reportable, PCs will report to a jurisdiction health department. Jurisdiction health departments also receive CO Poisoning case reports from other sources such as laboratories and medical examiners. These sources may not report a case of CO Poisoning to a PC and therefore, these cases would not be captured in NPDS. Furthermore, the cases in NPDS do not have all of the required data elements CDC needs to conduct CO Poisoning surveillance.

CSTE issued a position statement in 2018 that recommended that states notify CDC directly of CO Poisoning cases. (https://cdn.ymaws.com/www.cste.org/resource/resmgr/2018_position_statements/18-EH-01.pdf). This position statement says that “CSTE recommends that all States and Territories enact laws (statute or rule/regulation as appropriate) to make this disease or condition reportable in their jurisdiction. Jurisdictions (e.g. States and Territories) conducting surveillance (according to these methods) should submit case notifications to CDC.”

CO Poisoning	
The impetus/urgency for CDC to institute case notification and data elements for this condition	<ul style="list-style-type: none"> • No current national surveillance system for intentional cases • Incomplete national surveillance for nonintentional cases • One of the leading causes of injuries in the aftermath of extreme weather events (e.g., tornadoes, hurricanes, winter storms); case notifications would be valuable to capture before and during these events
Existing sources of data (Federal, non-federal, private, etc.) and what those sources say about approximate national incidence and/or prevalence of the condition	<ul style="list-style-type: none"> • Annual age-adjusted rate of CO poisoning in the United States is 1.46 deaths/million for unintentional, non-fire related CO poisoning [National Center for Health Statistics' National Vital Statistics System, 1999 - 2012] • 23.2 per 1 million population from 2000 - 2009 [unintentional only, National Poison Data System (NPDS)] • 4.1 cases/million people admitted to hospitals for unintentional, non-fire related CO poisoning [Nationwide Inpatient and Emergency Department Sample of the Hospitalization Cost and Utilization Project, 2003 - 2013] • 1,018 unintentional (fire, non-fire, unknown) inpatient cases from 28 states and 6,774 emergency department visits (fire, non-fire, unknown) from 17 states [Environmental Public Health Tracking Network (EPHTN), 2007] • Over 230,000 ED visits (772 visits/million) and over 22,000 hospitalizations (75 stays/million) were related to confirmed, probable, and expected cases of unintentional, non-fire-related CO poisoning [Nationwide Inpatient and Emergency Department Sample of the Hospitalization Cost and Utilization Project, 2007] <ul style="list-style-type: none"> o 2,302 hospitalizations (8 stays/million) were confirmed cases of unintentional non-fire CO poisoning [Nationwide Inpatient and Emergency Department Sample of the Hospitalization Cost and Utilization Project, 2007]
Incremental coverage provided by adding the condition to NNDSS (how	<ul style="list-style-type: none"> • Estimates of incremental coverage of CO poisoning by data source: <ul style="list-style-type: none"> o Mortality data: Adding NNDSS will yield nearly

<p>CDC will use additional precision)</p>	<p>100% coverage as deaths are only a small fraction of cases</p> <ul style="list-style-type: none"> o A community-based system is needed to identify the non-fatal poisonings in a timely fashion o Hospital discharge and emergency department data: Adding NNDSS will significantly increase coverage but hard to estimate o National Poison Data System: Adding NNDSS will yield incremental coverage of 54% o Laboratory data: Adding NNDSS will increase coverage, particularly for critical data elements not collected by national poison control centers; most case notifications are expected to be from in-patient or emergency department visits <ul style="list-style-type: none"> • Expect to receive intentional CO poisoning cases through NNDSS • Data will be used to: target outreach activities to vulnerable groups (particularly during disasters) at increased risk for CO poisoning; understand the health consequences of CO poisoning across the United States; learn about the effects of long-term exposures to low levels of CO; monitor trends; identify high risk groups; determine the impact of public health policy aimed at preventing CO poisoning
<p>Number of states that currently require reporting of these conditions and data elements</p>	<ul style="list-style-type: none"> • 15 jurisdictions
<p>The number of states anticipated to adopt if added to NNDSS and basis of estimate</p> <p>Funding allocated specifically for a condition and/or additional elements (please list source where applicable)</p>	<ul style="list-style-type: none"> • All 15 jurisdictions <ul style="list-style-type: none"> o Enhancing Innovation and Capabilities of the Environmental Public Health Tracking Network Cooperative Agreement
<p>Anticipated frequency of reporting to CDC</p>	<ul style="list-style-type: none"> • Monthly
<p>Based on the above information, what is the proposed priority associated with condition</p>	<ul style="list-style-type: none"> • States will determine the priority of adding this collection.

TB Disease

TB Disease became nationally notifiable in 2009

(<https://c.ymcdn.com/sites/www.cste.org/resource/resmgr/PS/09-ID-65.pdf>). The CDC TB Program has maintained OMB approval to receive case notification data through the National TB Surveillance System under a separate ICR (OMB No. 0920-0026, Report of Verified Case of Tuberculosis (RVCT), https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201610-0920-012) which expires on 12/31/2019. Since DHIS will manage receipt of case notification data for TB Disease through the NNDSS infrastructure and the National Tuberculosis Surveillance System (NTSS) will be retired, CDC requests permission to add TB Disease to this ICR and receive case notification data for TB Disease through NNDSS. After permission is granted, 0920-0026 will be discontinued.

TB Disease	
The impetus/urgency for CDC to institute case notification and data elements for this condition	<ul style="list-style-type: none"> • Data used to monitor national trends of TB by demographic and risk conditions • Respond to TB outbreaks or changes in morbidity patterns • Facilitate evaluation of federal, state, and local TB prevention and control effort
Existing sources of data (Federal, non-federal, private, etc.) and what those sources say about approximate national incidence and/or prevalence of the condition	<ul style="list-style-type: none"> • In 2017, a total of 9,105 TB cases reported in the United States. Nationally, the incidence rate was 2.8 cases per 100,000 persons [National Tuberculosis Surveillance System (NTSS)]
Incremental coverage provided by adding the condition to NNDSS (how CDC will use additional precision)	<ul style="list-style-type: none"> • No additional coverage expected by consolidating the TB OMB package and the NNDSS OMB package. After merging 0920-0026 with 0920-0728, 0920-0026 will be discontinued
Number of states that currently require reporting of these conditions and data elements	<ul style="list-style-type: none"> • 60 jurisdictions
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	<ul style="list-style-type: none"> • N/A

(please list source where applicable)	
Anticipated frequency of reporting to CDC	<ul style="list-style-type: none"> Weekly
Based on the above information, what is the proposed priority associated with condition	<ul style="list-style-type: none"> States will determine the priority of adding this collection

TB Infection

CSTE issued a position statement in 2017 that rendered TB Infection under standardized surveillance (<http://c.ymcdn.com/sites/www.cste.org/resource/resmgr/2017PS/2017PSFinal/17-ID-09.pdf>). This position statement says to “utilize standardized criteria for case identification and classification (Sections VI and VII) for TB Infection but do not add TB Infection to the Nationally Notifiable Condition List. If requested by CDC, jurisdictions (e.g. States and Territories) conducting surveillance according to these methods may submit case information to CDC.” CDC requests permission to receive case notification data for TB Infection as it is now under standardized surveillance.

TB Infection	
The impetus/urgency for CDC to institute case notification and data elements for this condition	<ul style="list-style-type: none"> To monitor the effectiveness of public health interventions To generate standardized, annual prevalence estimates based on reporting of cases of TB infection to track progress in testing/treating of persons with TB infection To use data to efficiently detect and respond to changes in morbidity patterns, monitor trends in TB infection in high-risk populations, and facilitate evaluation of federal, state, and local TB prevention and control efforts
Existing sources of data (Federal, non-federal, private, etc.) and what those sources say about approximate national incidence and/or prevalence of the condition	<ul style="list-style-type: none"> 3–5% of the U.S. population, approximately 13 million people, have TB infection [NHANES Testing/ National Tuberculosis Surveillance System (NTSS)]
Incremental coverage provided by adding the condition to NNDSS (how CDC will use additional precision)	<ul style="list-style-type: none"> Exact incremental coverage is not directly quantifiable Program anticipates an increasing percentage of all TB infection cases to be reported as TB infection reporting is mandated in other jurisdictions, in addition to the 20 already reporting
Number of states that	<ul style="list-style-type: none"> 20 jurisdictions

currently require reporting of these conditions and data 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)	<ul style="list-style-type: none"> All 20 jurisdictions participating in pre-existing cooperative agreements, specifically: <ul style="list-style-type: none"> CDC's Tuberculosis Elimination and Laboratory Cooperative Agreement (CDC-RFA-PS15-1501) funds salaried positions for data reporting Accelerating the Prevention and Control of HIV/AIDS, Viral Hepatitis, STDs and TB in the U.S. Affiliated Pacific Islands Cooperative Agreement (CDC-RFA-PS13-1301) funds positions
Anticipated frequency of reporting to CDC	<ul style="list-style-type: none"> Weekly
Based on the above information, what is the proposed priority associated with condition	States will determine the priority of adding this collection

RSV-Associated Mortality

CSTE issued a position statement in 2018 that rendered RSV-Associated Mortality under standardized surveillance (https://cdn.ymaws.com/www.cste.org/resource/resmgr/2018_position_statements/18-ID-01.pdf). This position statement says that "if requested by CDC, jurisdictions (e.g., States and Territories) conducting surveillance according to these methods may voluntarily submit case information to CDC." CDC request permission to receive case notification data for RSV-Associated Mortality as it is now under standardized surveillance.

RSV-Mortality	
The impetus/urgency for CDC to institute case notification and data elements for this condition	<ul style="list-style-type: none"> To establish pre-vaccine baseline mortality associated with RSV, which is vital for assessing the effectiveness of vaccines when they are introduced in the United States
Existing sources of data (Federal, non-federal, private, etc.) and what those sources say about approximate national	<ul style="list-style-type: none"> 1001 death certificates with a code for an RSV-associated cause of death for either the underlying or a contributing cause of death [National Center for Health Statistics (NCHS) multiple-cause-of-death vital statistics data for all ages in the US from 2005 to 2016]

incidence and/or prevalence of the condition	
Incremental coverage provided by adding the condition to NNDSS (how CDC will use additional precision)	<ul style="list-style-type: none"> • Not possible to anticipate the incremental coverage • Case-based notification includes critical information not included in death certificates, specifically data regarding laboratory-confirmation of RSV
Number of states that currently require reporting of these conditions and data elements	<ul style="list-style-type: none"> • 6 jurisdictions
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)	<ul style="list-style-type: none"> • 15 jurisdictions <ul style="list-style-type: none"> o No specific funding allocated
Anticipated frequency of reporting to CDC	<ul style="list-style-type: none"> • Quarterly or less frequent, as it aligns with suggested reporting frequency guidance for RSV (provided by CDC to jurisdictions)
Based on the above information, what is the proposed priority associated with condition	States will determine the priority of adding this collection

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 8. 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 6. 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 9. 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 10. 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 vaccine data elements were included in the previously approved ICR. Names, descriptions and value set codes for the data elements are identified in **Attachment 11. 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. 451 new data elements that were not included in the previously reviewed ICR were added for 22 conditions: CP-CRE, CO Poisoning, TB Disease, TB Infection, STEC, Salmonellosis, Shigellosis, Campylobacteriosis, Cryptosporidiosis, Cyclosporiasis, Cholera, Vibriosis, *S. Typhi* Infection, *S. Paratyphi* Infection, Lyme Disease, Invasive *Haemophilus influenzae* Disease, Meningococcal Disease, Invasive Pneumococcal Disease, Psittacosis, Legionellosis, TBRD, and Hepatitis. Names, descriptions, value set codes, and justification for the addition of these new data elements are in **Attachment 12. 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 13. 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 jurisdiction 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.

SO/GI Data Elements for STD

CDC submitted a change request to add SO/GI data elements and was granted provisional approval in May 2017 for two years.

OMB previously approved a 2 year trial of adding SO/GI data elements to the collection of STDs. One of the terms of clearance was that CDC submit another change request for continued use of the data elements with empirical analysis of the pilot data. CDC will not have enough data for an empirical analysis before the expiration of the 2-year approval so CDC requests an extension of 3 additional years to make sure that there is enough time to receive a sufficient amount of pilot data for empirical analysis.

Although only two jurisdictions had begun submitting SO/GI data elements by the summer of 2018 (approximately 7 months after the reporting system was changed to allow jurisdictions to report these data elements), as of March 8, 2019, twelve jurisdictions are transmitting these data elements.

Efforts to encourage additional reporting states to implement SO/GI data reporting are ongoing. Guidance for message mapping guide (MMG) and National Electronic Telecommunications System for Surveillance (NETSS) implementation has been available for over a year and with data closeout completed, additional jurisdiction will begin implementing MMGs. The on-boarding process is multi-step and intensive validation is required by CDC; only a small number of jurisdictions can be accommodated at a time for the three-month on-boarding process. Additionally, data for 2018 will not be finalized until summer of 2019; we anticipate that additional jurisdictions may provide these data during the 2018 data close-out process and for the 2019 reporting year. Furthermore, four pilot jurisdictions are in the process of on-boarding the STD MMG, with additional jurisdictions in queue in cohorts of 4-5 each; we anticipate that jurisdictions sending data via the MMGs will include these data elements. Although we don't know the exact number of jurisdiction that will begin reporting these data elements in the next year, we have seen a steady uptake over the past 14 months and anticipate that the number of jurisdictions able to transmit these data elements will continue to increase.

Although the twelve jurisdictions currently reporting SO/GI data elements include a mix of high and low morbidity jurisdictions, there was limited coverage across HHS regions, with three HHS regions not yet included and four HHS regions represented by only a single state each. These preliminary data from the twelve jurisdictions indicate that a significant proportion of all reported cases are estimated to be occurring among people identifying as "Transgendered" and/or as "Gay/Lesbian/Bisexual or Other;" however, the proportion varied among these jurisdictions suggesting that there is likely significant variation across the country. Therefore, we do not know how many locations need to adopt the data element to provide enough cases to evaluate the quality of the data being collected/submitted. The extent of the diversity in burden of STIs among sexual minorities is unknown. However, we anticipate additional jurisdictions will begin sending data elements in the next few years and we will be better situated to examine the number of locations needed if our pilot period is extended. Additionally, once the 2018 case data are finalized (in summer of 2019), we will conduct preliminary analyses using the indicated direction of transgender (male-to-female or female-to-male) for cases reported with sex

indicated as male or female to better understand how transgendered patients are coded with respect to the current NNDSS sex data element.

CDC requests an additional provisional approval period of 3 years to continue piloting these data elements and evaluating them. Additionally, analyses of these pilot data will include comparison of the proposed STD-specific data element for transgender to values reported in the sex data element to allow CDC to directly ascertain what proportion of cases with “unknown” sex is accounted for by transgendered individuals. Further analysis using the indicated direction of transgender (male-to-female or female-to-male) for cases reported with sex indicated as male or female will allow for better understanding of how transgendered patients have historically been coded with respect to the ‘current sex’ data element.

CDC also requests permission to administer a short assessment survey [**Attachment 22, SOGI Survey Data Collection Instrument**] to jurisdictions reporting SO/GI data in the fall of 2019; results of this survey will provide additional insight regarding burden, cost and data quality issues associated with reporting for both the sexual orientation and transgender data elements to inform continued data collection. CDC is only requesting that jurisdictions who already collect these data elements for local surveillance efforts provide them to CDC. Therefore, because these data elements are optional, we estimate the burden to be minimal. At this time, we have no evidence that reporting of these additional data elements in these twelve jurisdictions increased burden above what was estimated in our initial change request. This suggests reporting of these data elements to be cost effective; however, we would like to hear from additional jurisdictions who begin sending the data elements in 2019 to ensure that there are not costs incurred above what was previously estimated.

Brief telephone surveys will be conducted with 12 jurisdictions reporting SO/GI data elements as of March 2019 (Alaska, Arizona, Arkansas, Hawaii, Indiana, Louisiana, Maryland, Mississippi, New Mexico, Ohio, Oklahoma and Wyoming). Surveys will be administered August through September 2019; data capture at CDC will be paper-based, with subsequent entry into an Excel workbook. Respondents will be recruited through an introductory e-mail [**Attachment 23, SOGI Survey Introductory Email**] sent by July 30, 2019. This introductory e-mail will be sent to either the jurisdiction’s STD Surveillance Coordinator or the STD Epidemiologist (based on CDC-maintained lists) with instructions to identify the staff member most familiar with the jurisdiction’s data management system for handling and reporting STDs to CDC.

Response to the introductory e-mail, which will include the specific questions to be asked, and subsequent scheduling of a formal phone survey will constitute consent to participate in this brief evaluation survey. A reminder e-mail [**Attachment 24, SOGI Survey Reminder Email**] will be sent one week prior to the scheduled call to confirm participation and verify the appropriate contact information. Data will be captured on paper copies of the survey by CDC staff conducting the survey and entered into an Excel spreadsheet. Frequencies will be calculated for each categorical response option; total burden, average burden per jurisdiction and range between jurisdictions will also be calculated. Total number of reported cases, from the respondents NNDSS reporting will also be obtained to determine if there is any correlation between reported morbidity and reported burden. An anonymized summary report will be prepared for dissemination to stakeholders and for planning future implementation efforts.

Once case notification data are received by NNDSS, CDC data analysts conduct quality control assessments, including evaluating the information submitted against an established case definition. Analysts standardize the data and then share the data with CDC subject matter experts who have responsibility for prevention and control of those diseases. Data are used by CDC subject matter experts to monitor the occurrence of the conditions, identify populations or geographic areas at high risk, plan prevention and control programs and policies, allocate resources appropriately, and evaluate the effectiveness of programs and policies. In addition, information is collected that allows CDC to trace cases and their contacts and their travel histories, or other linkages necessary to describe and manage outbreaks or conduct public health follow-up to minimize the spread of disease.

NNDSS provides the official source of statistics in the United States for nationally notifiable conditions and CDC is the sole repository for these national, population-based data. CDC also uses the notifiable condition data to publish surveillance summaries and other reports in scientific, public health and medical journals.

Data are also shared with jurisdictions and with the public. For certain nationally notifiable conditions, CDC releases national data to the public through CDC's web-based query system known as WONDER (<http://wonder.cdc.gov/>) and through Data.CDC.gov (<https://data.cdc.gov>). Shared data are summary statistics of aggregate data produced after personal identifiers have been removed (Section A.16, below). Surveillance programs in the Office of Infectious Diseases (OID) and the Center for Global Health (CGH) receive nationally notifiable condition data for infectious diseases from DHIS and use, release

and/or share their programs' data according to guidance established by CDC, their Centers and programs.

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. While there are other federal and non-federal data sources and systems for some of the new nationally notifiable conditions and new conditions under standardized surveillance, these data sources and systems do not provide a complete national case-based surveillance picture. These data sources and systems include the National Healthcare Safety Network (NHSN) for *C. auris*, the National Poison Data System (NPDS) for CO poisoning, the National Health and Nutrition Examination Survey (NHANES) for TB disease and TB infection, and the New Vaccine Surveillance Network (NVSN) and the Emerging Infection Program (EIP) Surveillance Project for RSV-Associated Mortality.

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 June 13, 2018, Vol. 83, No. 114, pp. 27601-27602 [**Attachment 2a. 60-Day FRN**]. Two non-substantive comments [**Attachment 2b. Public Comment and Attachment 2c. Public Comment**] were received and the standard CDC response was sent.

A.8.B.

Through cooperative agreements, two independent external peer review panels conducted reviews of NNDSS. The report from the first panel was issued in December 2011 and focused on the results of an

assessment of systems, frameworks and processes for infectious diseases within CDC. The report from the second panel was issued in April 2013 and focused on the results of a review of state and local systems, frameworks and processes for reportable conditions and for submission of information on notifiable infectious diseases to CDC. External consultants to the second independent external peer review panel, conducted by CSTE, are listed in the attachment [**Attachment 15. 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. In addition, some combinations of submitted data elements could potentially be used to identify individuals. See Privacy Impact Assessments (PIAs) for the DW, DMB, and MVPS [**Attachments 16 through 18**]. 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 19. 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 third 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, and cities, will incur to send case notification data for *C. auris*, CP-CRE, CO Poisoning, TB Disease, TB Infection, *S. Paratyphi*, and RSV-Associated Mortality; 2) the one-time increase in burden hours that states and cities will incur to process and send a total of 451 new data elements for 22 conditions: CP-CRE, CO Poisoning, TB Disease, TB Infection, STEC, Salmonellosis, Shigellosis, Campylobacteriosis, Cryptosporidiosis, Cyclosporiasis, Cholera, Vibriosis, *S. Typhi* Infection, *S. Paratyphi* Infection, Lyme Disease, Invasive *Haemophilus influenzae* Disease, Meningococcal Disease, Invasive Pneumococcal Disease, Psittacosis, Legionellosis, TBRD, and Hepatitis; and 3) the administration of the SO/GI survey.

The burden estimates are shown for four types of respondents: states, territories, freely associated states, and cities. **Attachment 20. 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 20. Burden Table Calculations**, the one-time average burden per response is 59 hours and the one-time total burden is 2950 hours. As shown on Table A12A below, the annualized one-time average burden per response is 20 hours and the annualized one-time total burden is 1000 hours. It is anticipated that 12 states will be sending SO/GI data elements; these 12 states will be administered the SO/GI survey. The one-time average burden per response is 15/60 hours and the one-time total burden is 2 hours. As shown on Table A12A below, the annualized one-time average burden per response is 5/60 hours and the annualized one-time total burden is 1 hour.

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 20. Burden Table Calculations**, the one-time average burden per response is 25 hours and the one-time total burden is 125 hours. As shown on Table A12A below, the annualized one-time average burden per response is 9 hours and the annualized one-time total burden is 45 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 20. Burden Table Calculations**, the one-time average burden per response is 16 hours and the one-time total burden is 6 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 20. Burden Table Calculations**, **the one-time average burden per response is 59 hours and the one-time total burden is 118 hours.** As shown on Table A12A below, the annualized one-time average burden per response is 20 hours and the annualized one-time total burden is 40 hours.

According to the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2017 National Occupational Employment and Wage Estimates, the estimated mean hourly wage for Computer Systems Analysts is \$44.59 (https://www.bls.gov/oes/current/oes_nat.htm#15-0000) and the estimated mean hourly wage for Epidemiologists is \$36.65 (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, annual data reconciliation, and the one-time SO/GI survey. These wage estimates were used because these two occupations represent the category of occupations held by the respondents that perform these activities. Using \$44.59 as an average hourly wage rate for Computer Systems Analysts and using \$36.65 as an average hourly wage rate for Epidemiologists, it is estimated that the average national annual burden for weekly and annual reporting is 19,337 hours at a national cost of \$819,863

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	20	1,000
States	One-time SO/GI Survey	12	1	5/60	1
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	9	45

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 (NMI Implementation)	2	52	4	416
Cities	Annual	2	1	75	150
Cities	One-time Addition of Diseases and Data Elements	2	1	20	40
Total					19,338

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	\$44.59	\$38,660
States	Weekly (Non-automated)	10	52	2	1,040	\$36.65	\$38,116
States	Weekly (NMI	50	52	4	10,400	\$44.59	\$463,736

	Implementation)						
States	Annual	50	1	75	3,750	\$36.65	\$137,438
States	One-time Addition of Diseases and Data Elements	50	1	20	1,000	\$44.59	\$44,590
States	One-time SO/GI Survey	12	1	5/60	1	\$36.65	\$37
Territories	Weekly (Automated)	5	52	20/60	87	\$44.59	\$3,879
Territories	Weekly, Quarterly (Non-automated)	5	56	20/60	93	\$36.65	\$3,408
Territories	Weekly (NMI Implementation)	5	52	4	1,040	\$44.59	\$46,374
Territories	Annual	5	1	5	25	\$36.65	\$916
Territories	One-time Addition of Diseases and Data Elements	5	1	9	45	\$44.59	\$2,007
Freely Associated States	Weekly (Automated)	3	52	20/60	52	\$44.59	\$2,319
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56	\$36.65	\$2,052
Freely Associated States	Annual	3	1	5	15	\$36.65	\$550
Freely Associated States	One-time Addition of Diseases and Data Elements	3	1	6	18	\$44.59	\$803
Cities	Weekly (Automated)	2	52	20/60	35	\$44.59	\$1,561
Cities	Weekly (Non-automated)	2	52	2	208	\$36.65	\$7,623
Cities	Weekly (NMI Implementation)	2	52	4	416	\$44.59	\$18,549
Cities	Annual	2	1	75	150	\$36.65	\$5,498
Cities	One-time Addition of Diseases and Data Elements	2	1	20	40	\$44.59	\$1,784
Total							\$819,900

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 17	FY 18	FY 19
Personnel - Software development, support, and management (intramural)	\$6,156,238	\$6,156,238	\$6,156,238
Contracts - Program and web support	\$13,830,353	\$13,830,353	\$13,830,353
Cooperative Agreements with States for NNDSS case notification and management (extramural)	\$9,373,323	\$9,373,323	\$9,373,323
Total	\$29,359,914	\$29,359,914	\$29,359,914

The estimated annualized cost to the government for NNDSS is \$29,359,914 (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 *C. auris* which is now nationally notifiable; receipt of case notification data and disease-specific data elements for CP-CRE which is now nationally notifiable; receipt of case notification data and disease-specific data elements for *S. Paratyphi* Infection which is now nationally notifiable; renaming Typhoid Fever to “*S. Typhi* Infection” on the List of Nationally Notifiable Conditions; receipt of case notification data and disease-specific data elements for CO Poisoning; receipt of case notification data and disease-specific data elements for TB Disease; receipt of case notification data and disease-specific data elements for TB Infection which is now under standardized surveillance; receipt of case notification data for RSV-Associated Mortality which is now under standardized surveillance; receipt of disease-specific data elements for STEC, Salmonellosis, Shigellosis, Campylobacteriosis, Cryptosporidiosis, Cyclosporiasis, Cholera, Vibriosis, *S. Typhi* Infection, *S. Paratyphi* Infection, Lyme Disease, Invasive *Haemophilus influenzae* Disease, Meningococcal Disease, Invasive Pneumococcal Disease, Psittacosis, Legionellosis, TBRD, and Hepatitis; the extension of the pilot period by three years for receiving SO/GI data elements for STD; and the administration of a short assessment survey to jurisdictions reporting SO/GI data elements.

The total burden hours increased since the last revision because of the addition of diseases and 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.

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 21. PRA Burden Statement Screenshot**.

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

There are no exceptions to the certification.