

**National Notifiable Diseases Surveillance System (NNDSS)**

**OMB Control Number 0920-0728**

**Expiration Date: 07/31/2025**

**Program Contact**

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**Submission Date:** August 2, 2022

**Circumstances of Change Request for OMB 0920-0728**

This is a non-substantive change request for OMB No. 0920-0728, expiration date 07/31/2025, for the reporting of Nationally Notifiable Diseases. Information on proposed disease-specific data elements to be added through this non-substantive change request is enumerated in the table below:

<b>Disease Name in NNDSS Collection</b>	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
Arboviral	NNC			Y	Y	159	8
Carbon Monoxide Poisoning	NNC			Y	Y	50	13
Hepatitis	NNC			Y	Y	190	8
Malaria	NNC			Y	Y	100	1
Monkeypox	NNC			N	Y	0	59

The National Notifiable Diseases Surveillance System (NNDSS) is the nation’s public health surveillance system that enables all levels of public health (local, state, territorial, federal and international) to monitor the occurrence and spread of the diseases and conditions that CDC and the Council of State and Territorial Epidemiologists (CSTE) officially designate as “nationally notifiable” or as under “standardized surveillance.” 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.

This request is for the addition of 89 new disease-specific data elements: 8 new disease-specific data elements for Arboviral, 13 new disease-specific data elements for Carbon Monoxide Poisoning, 8 new disease-specific data elements for Hepatitis, 1 new disease-specific data element for Malaria, and 59 new disease-specific data elements for Monkeypox.

<b>Arboviral</b>			
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> <li>To better align arboviral surveillance data collection with current practices for other notifiable conditions. Harmonization should decrease burden on jurisdictional public health partners in reporting notifiable conditions to CDC</li> <li>To provide more information about vaccination history among arboviral disease cases</li> </ul>		
<b>Data Element Name</b>	<b>Data Element Description</b>	<b>Value Set Code</b>	<b>CDC Priority<sup>1</sup></b>
Type of Complication	If the subject experienced severe complications due to this illness, specify the complication(s).	TBD	2
Type of Complications Indicator	Indicator for associated complication	PHVS_YesNoUnknown_CDC	2
Signs and Symptoms	Sign and symptoms associated with the illness being reported	TBD	2
Signs and Symptoms Indicator	Indicator for associated signs and symptoms	PHVS_YesNoUnknown_CDC	2
Clinical Finding	Clinical findings associated with the illness being reported	TBD	2
Clinical Finding Indicator	Indicator for associated clinical findings	PHVS_YesNoUnknown_CDC	2
Transmission Mode Detail	For rare arboviral transmission modes, indicate the determined source of infection following investigation of the case.	TBD	2
Manufacturer of Last Dose Prior to Illness Onset	Manufacturer of last vaccine dose against this disease prior to illness onset	TBD	2

<sup>1</sup> R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3

<b>Carbon Monoxide Poisoning</b>			
<b>Data Element Name</b>	<b>Data Element Description</b>	<b>Value Set Code</b>	<b>CDC Priority<sup>2</sup></b>
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> <li>To make surveillance more comprehensive and informative for public health actions including public health policy.</li> <li>Enhanced surveillance to learn about the effects of long-term exposures to low levels of CO, and monitor trends identify high risk groups.</li> <li>Additional data would help to better target outreach activities to those at increased risk for CO poisoning.</li> </ul>		
Severe Weather	Was the carbon monoxide exposure related to a severe weather event?	PHVS_YesNoUnknown_CDC	1
Severe Weather Type	Identify the severe weather event(s) occurring when the patient was exposed to carbon monoxide.	TBD	1
Intent of Exposure	Was the intent of the carbon monoxide exposure self-harm/assault (intentional) or accidental (unintentional)?	TBD	1
Carbon Monoxide Level in Air	Carbon monoxide level in air measured in parts per million (PPM) at exposure site	N/A	3
Start Date of Treatment or Therapy	Provide the date and time of when the treatment started.	N/A	2
Underlying Condition(s) Indicator	Indicator for underlying condition(s)	PHVS_YesNoUnknown_CDC	2
Signs and Symptoms Indicator	Indicator for associated sign and symptom	PHVS_YesNoUnknown_CDC	1
Specimen Collection Date/Time	Date of collection of laboratory specimen used for diagnosis of health event reported in this case report. Time of collection should be sent if available.	N/A	2
Start Date of Treatment or Therapy	Provide the date and time of when the treatment started.	N/A	2
Type of Workers Compensation Claim	Indicate if the worker's compensation claim is submitted or paid with a	TBD	2

<sup>2</sup> R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3

	finding, problem, diagnosis or other indication of exposure to carbon monoxide or carbon monoxide poisoning.		
Test Type	Please specify Carboxyhemoglobin Level or Pulse CO-oximetry Measurement test.	TBD	1
Test Result Quantitative	Please send the test results for the selected test type. The unit of test result is percent (%).	N/A	2
Specimen Collection Date/Time	Date of collection of laboratory specimen used for diagnosis of health event reported in this case report. Time of collection should be sent if available.	N/A	2

<b>Hepatitis</b>			
The impetus/urgency for CDC to add data elements for this condition	<ul style="list-style-type: none"> <li>The data elements included in this change request will contribute to enhanced surveillance efforts for those jurisdictions funded through PS21-2103 “Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments”.</li> <li>These data elements will improve standardization of data collection for CDC surveillance and improve the overall understanding of the population and factors contributing to viral hepatitis infection. The enhanced surveillance will be more comprehensive and informative for public health actions and will improve guidance on infection control and prevention.</li> </ul>		
<b>Data Element Name</b>	<b>Data Element Description</b>	<b>Value Set Code</b>	<b>CDC Priority (New)</b>
Alanine Aminotransferase (ALT) Result	What was the patient’s ALT level (IU/L)? Note: The result of the ALT test performed on the same specimen as the positive hepatitis A, B or C lab result(s) or associated with the positive hepatitis A, B or C lab result(s). CDC’s preference is for the qualitative result to be submitted when available rather than the quantitative option.	PHVS_AlanineATResult_Hepatitis	2

Vaccine Series Completed	Was the vaccine series completed?	PHVS_YesNoUnknown_CDC	2
Donor Screening	Patient was determined to have viral hepatitis during screening for blood, organ, or tissue donation. Please indicate the donation type.	PHVS_DonorScreening_Hepatitis	2
Travel Outside USA Prior to Illness Onset (within Program Specific Timeframe)	Did the patient travel or live internationally in the 15 to 50 days before symptom onset date?  Note: If the symptom onset date is unknown, then the date that the patient first tested positive for hepatitis A virus (HAV) can be used as a proxy for symptom onset date.	PHVS_YesNoUnknown_CDC	1
Specify Different Travel Exposure Window	If the travel exposure window used by the jurisdiction is different from that stated in the travel exposure questions, specify the time interval in days here. Otherwise, leave blank.	N/A (text field)	1
International Destination(s) of Recent Travel	International destination or countries the patient traveled to or lived in, in the 15 to 50 days before symptom onset Note: If the symptom onset date is unknown, then the date that the patient first tested positive for hepatitis A virus (HAV) can be used as a proxy for symptom onset date.	PHVS_Country_ISO_3166-1	1
Date of Arrival to Travel Destination	Date of arrival to travel destination	N/A (Date)	3
Date of Departure from Travel Destination	Date of departure from travel destination	N/A (Date)	3

<b>Malaria</b>			
The impetus/urgency for CDC to add data elements for this condition		<ul style="list-style-type: none"> <li>• Link reported congenital malaria cases to the mother’s reported malaria case to gain a better understanding and more complete picture of risk factors.</li> <li>• Assist in improving CDC’s epidemiologic understanding of the rare condition of congenital malaria and disease trends over time.</li> </ul>	
<b>Data Element Name</b>	<b>Data Element Description</b>	<b>Value Set Code</b>	<b>CDC Priority (New)</b>
Mother's Local Record ID	Provide the local record ID used for reporting mother's case (DE Identifier "N/A: OBR-3" in the Generic portion of the message). This will be used for linking the reported congenital case to the mother's reported case.	N/A	3

<b>Monkeypox</b>			
The impetus/urgency for CDC to add data elements for this condition		<ul style="list-style-type: none"> <li>• Since January 2022, clusters of monkeypox cases, have been reported in 71 countries that do not normally have monkeypox. As of this writing (29 July, 2022) there are over 21,148 confirmed cases globally. The number of confirmed cases in the U.S. is rapidly increasing. Since January, 4,906 confirmed cases in the U.S. have been identified. Most of U.S. cases do not have direct travel-associated exposure risks (i.e., travel to monkeypox endemic countries). Transmission during close contact and intimate contact is thought to be a major transmission route.</li> <li>• NNDSS reporting will enhance the speed, accuracy, and comparability of data capture for monkeypox case notifications during this outbreak, particularly as new states are onboarded.</li> <li>• Data collected will inform public health interventions to interrupt disease transmission and identify risk factors for infection.</li> </ul>	
<b>Data Element Name</b>	<b>Data Element Description</b>	<b>Value Set Code</b>	<b>CDC Priority (New)</b>
Tribal Residence	If you reside in a Tribal Area, please specify	TBD	2
Tribal Name	If the selected race is	PHVS_TribeName_NND	3

	American Indian or Alaska Native, what is the tribal affiliation?		
Gender Identity	Do you currently describe yourself as male, female, or transgender?	PHVS_GenderIdentity_USCDI	1
Sexual Orientation	Patient identified sexual orientation (i.e., an individual's physical and/or emotional attraction to another individual of the same gender, opposite gender, or both genders).	PHVS_SexualOrientation_USCDI	2
Birth Sex	What sex were you assigned at birth, on your original birth certificate?	PHVS_Sex_MFU	1
Reason Vaccine Administered	Reason individual received a vaccine against this condition	TBD	2
Sexual Contact	Did you engage in any sex and/or close intimate contact before your first symptom appeared?	PHVS_YesNoUnknown_CDC	2
Sex with Male Partners	Sex with male partners?	PHVS_YesNoUnknown_CDC	2
Number of Male Sexual Partners	Number of male partners or description if no number is provided	N/A	2
Numerical Range of Male Partners	If individual is unable to specify, provide a range of options for the number of male partners	TBD	2
Sex with Female Partners	Sex with female partners?	PHVS_YesNoUnknown_CDC	2
Number of Female Sexual Partners	Number of female partners or description if no number is provided	N/A	2
Numerical Range of Female Partners	If individual is unable to specify, provide a range of options for the number of female partners	TBD	2
Sex with Transgender Female Partners	Sex with transgender female partners?	PHVS_YesNoUnknown_CDC	2
Number of Transgender Female Partners	Number of transgender female partners or description if no number is provided	N/A	2
Numerical Range of	If individual is unable to	TBD	2

Female Transgender Partners	specify, provide a range of options for the number of transgender female partners		
Sex with Transgender Male Partners	Sex with transgender male partners?	PHVS_YesNoUnknown_CDC	2
Number of Transgender Male Partners	Number of transgender male partners or description if no number is provided	N/A	2
Numerical Range of Transgender Male Partners	If individual is unable to specify, provide a range of options for the number of transgender male partners	TBD	2
Sex with Other Gender Identity Partners	Sex with other gender identity partners?	PHVS_YesNoUnknown_CDC	2
Number of Other Gender Identity Partners	Number of other gender identity partners or description if no number is provided	N/A	2
Numerical Range of Other Identity Gender Partners	If individual is unable to specify, provide a range of options for the number of other gender identity partners	TBD	2
Epi Linked	Specify if this case is epidemiologically linked to another confirmed or probable case	PHVS_YesNoUnknown_CDC	1
CDC Event Case ID	This ID is used to track information about the case-patient in CDC data systems and must be provided on all forms or specimens related to this individual	N/A	3
Linked Case Number	Provide State assigned Case ID	N/A	3
Contact Type	Type of contact	TBD	1
Specify Other Contact Type	Other contact type	N/A	1
Did The Case Travel Domestically Prior To Illness Onset?	Did you spend time (within the US) outside your home state or territory during the [time period] before your first symptom appeared (also called symptom onset)?	PHVS_YesNoUnknown_CDC	3

Travel State	State traveled to	PHVS_State_FIPS_5-2	3
Date Of Departure From Travel Destination	Date of departure (MM/DD/YYYY)	N/A	3
Date Of Arrival To Travel Destination	Date of return (MM/DD/YYYY)	N/A	3
Sexual Contact During Domestic Travel	Did you have intimate or sexual contact with new partners on domestic trip?	PHVS_YesNoUnknown_CDC	3
Domestic Travel Comment	Any additional comments on travel within the US that may be important	N/A	3
Travel Outside USA Prior To Illness Onset Within Program Specific Timeframe	Did you spend time in a country outside the US during the [time period] before your first symptom appeared (also called symptom onset)?	PHVS_YesNoUnknown_CDC	3
International Destination(s) of Recent Travel	Country traveled to	PHVS_Country_ISO_3166-1	3
Sexual Contact During International Travel	Did you have any intimate or sexual contact with new partners on international trip?	PHVS_YesNoUnknown_CDC	3
International Travel Comment	Any additional comments on travel outside the US that may be important?	N/A	3
Case Patient a Healthcare Worker	Is this individual a health care worker who was exposed at work?	PHVS_YesNoUnknown_CDC	1
Location of Exposure	Please provide the suspect location of exposure	TBD	1
Exposure Comment	Please provide any additional details on the location of exposure (e.g., health care setting, large gathering, private party)	N/A	1
Number of Household Contacts	Please provide the number of identified contacts this case may have exposed (either named or anonymous)	N/A	2
Signs and Symptoms	Signs and symptoms associated with the illness being reported	TBD	3
Signs and Symptoms	Indicator for associated	PHVS_YesNoUnknown_CDC	3

Indicator	sign and symptom		
Skin Lesion(s) (disorder)	Did you have a rash during the course of your illness?	PHVS_YesNoUnknown_CDC	3
Rash Onset Date	If yes, what was the date of rash onset (i.e., the date the rash first appeared)?	N/A	3
Body Region(s) of Rash	If yes, where on your body is the rash? (choose all that apply)	TBD	3
Ocular Manifestations	Any evidence of ocular involvement (ocular lesions, keratitis, conjunctivitis, eyelid lesions)?	TBD	3
Co-infection	Has this individual been diagnosed with any acute infections other than [condition] during this current illness/or within [time period]?	PHVS_YesNoUnknown_CDC	3
Co-infection Type	Specify other co-infections	TBD	3
HIV Status	What is the individual's HIV status?	PHVS_HIVStatus_STD	1
HIV Viral Load Undetectable	If HIV positive, was the individual's viral load undetectable when it was last checked?	PHVS_YesNoUnknown_CDC	2
Patient Immunocompromised	Does the individual have any known immunocompromising conditions (excluding HIV) or take immunosuppressive medications?	PHVS_YesNoUnknown_CDC	1
Immunocompromised Condition or Treatment	Describe the associated immunocompromising condition or treatment	TBD	1
Reason for Hospitalization	Reason for the hospitalization? (choose all that apply)	TBD	2
Receiving HIV Pre-exposure Prophylaxis	Is the individual currently receiving HIV pre-exposure prophylaxis?	PHVS_YesNoUnknown_CDC	2
Currently Breastfeeding	Are you currently breastfeeding?	PHVS_YesNoUnknown_CDC	2
Household pets	Do any pets live in your household?	PHVS_YesNoUnknown_CDC	2
Type of animal(s)	Which type of animal(s) in	TBD	2

	household? (select all that apply)		
Other pet(s)	Please specify other pet(s)	N/A	2

Burden

The burden to add 89 data elements to NNDSS is applicable to all 50 states, 5 territories, 3 freely associated states, and 2 cities. Although not all territories and freely associated states use electronic, automated transmission for their case notifications, it is expected that they will adopt electronic, automated transmission in the next three years. This burden includes the one-time burden incurred by the respondents to add the data elements to their surveillance system and modify their case notification message. A one-time average burden of 9 hours is incurred for respondents to add 89 data elements to their surveillance system and modify their electronic case notification message to accommodate those 89 additional data elements. This one-time burden of 9 hours is noted in the following table

One-Time Burden to Add 89 Data Elements to NNDSS:

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours): One-time Addition of 89 Data Elements	
States	50	1	9	
Territories	5	1	9	
Freely Associated States	3	1	9	
Cities	2	1	9	
Total				

The total annualized one-time burden is 180 hours (150 hours for states, 15 hours for territories, 9 hours for freely associated states and 6 hours for cities) as noted in the table below.

Annualized One-Time Burden to Add 89 Data Elements to NNDSS

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours): Annualized	Total Annualized One-Time Burden (in hours)

			<b>One-time Addition of 89 Data Elements</b>	
States	50	1	3	150
Territories	5	1	3	15
Freely Associated States	3	1	3	9
Cities	2	1	3	6
<b>Total</b>				<b>180</b>

180 hours were added to the existing burden hours in Table A.12A and Table A.12B below.

A.12A. 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
<b>States</b>	<b>One-time Addition of Diseases and Data Elements</b>	<b>50</b>	<b>1</b>	<b>4</b>	<b>200</b>
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
<b>Territories</b>	<b>One-time Addition of Diseases and Data Elements</b>	<b>5</b>	<b>1</b>	<b>4</b>	<b>20</b>
Freely Associated States	Weekly (Automated)	3	52	20/60	52
Freely Associated States	Weekly, Quarterly (Non-automated)	3	56	20/60	56
Freely Associated	Annual	3	1	5	15

States					
Freely Associated States	One-time Addition of Diseases and Data Elements	3	1	4	12
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	4	8
<b>Total</b>					<b>18,474</b>

A.12B. 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 (NMI 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	4	200	\$49.14	\$9,828
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 (NMI 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	4	20	\$49.14	\$982.80
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	4	12	\$49.14	\$589.68
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 (NMI 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	4	8	\$49.14	\$393.12
<b>Total</b>							<b>\$868,106</b>