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

### OMB Control Number 0920-0728 Expiration Date: 03/31/2026

## **Program Contact**

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

This is a non-substantive change request for OMB No. 0920-0728, expiration date 03/31/2026, for the reporting of Nationally Notifiable Diseases. Information on disease-specific data elements to be modified through this non-substantive change request is enumerated in the table below:

Disease Name in NNDSS Collection	Nationally Notifiable (NNC) OR Under Standardized Surveillance (CSS)	Current Case Notification (Y/N)	Proposed Case Notification (Y/N)	Current Disease- specific Data Elements (Y/N)	Proposed Disease- specific Data Elements (Y/N)	Number of Existing Data Elements in NNDSS	Proposed Number of NNDSS Data Elements to be Modified
Free-living Amebae (FLA) Infections	CSS			Ν	Y	0	72
Viral Hemorrhagic Fevers (VHF)	NNC			Y	Y	104	18

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 90 new disease-specific data elements: 72 new disease-specific data elements for free-living amebae infections and 18 new disease-specific data elements for viral hemorrhagic fevers.

Free-living Amebae (FLA)	
The impetus/urgency for CDC to add data elements for this condition	<ul> <li>Free-living amebae (FLA) including <i>Acanthamoeba</i> spp., <i>Balamuthia mandrillaris</i>, and <i>Naegleria fowleri</i> can cause severe and often life-threatening infections in humans. They primarily infect the central nervous system, causing amebic meningoencephalitis, but <i>Balamuthia</i> and <i>Acanthamoeba</i> can infect other organ systems as well.</li> <li><i>Acanthamoeba</i>, <i>Balamuthia</i>, and <i>Naegleria fowleri</i> are commonly found in the environment, but infections are rare, occurring in approximately 30 individuals in the United States annually. FLA infections are nearly always fatal. In the United States, up to 97% of people with FLA infections have died.</li> <li>The low incidence and high mortality associated with FLA infections have resulted in a need for national surveillance efforts to assist in further understanding risk factors, epidemiology, transmission, treatment, and prevention of FLA infections.</li> <li>In the event an FLA infection is detected, national surveillance efforts are needed to confirm a case using a standardized case definition, characterize the epidemiology, and inform public health interventions for response and prevention strategies.</li> </ul>
	CDC

Data Element Name	Data Element Description	Value Set Code	Priority <sup>1</sup> (New)
Subject's Last Name	Patient Last Name	N/A	2
Subject's First Name	Patient First Name	N/A	2
Middle Initial	Patient Middle Initial	N/A	2
County of Treatment	County in which patient was treated	PHVS_County_FIPS_6-4	2
State of Treatment Hospital	State in which patient was treated	PHVS_State_FIPS_5-2	2
Recreational Water Exposure Questions Indicator	Any recreational water exposure	PHVS_YesNoUnknown_CDC	1
Recreational Water Exposure Within 14 Days Before Symptom Onset	Types of recreational water which patient was exposed	TBD	2
Recreational Water Exposure Date	Date of water exposure	N/A	2
Recreational Water Notes	Other recreational water exposure, specify	N/A	3

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

Other Recreational Water	Other recreational water	N/A	2
Exposure Date	exposure onset date		
Recreational Water Activities	Patient participation in any recreational water activities	PHVS_YesNoUnknown_CDC	2
Activity Type	Types of recreational water activities patient participated in	TBD	2
Other Recreational Water Activities Specify	Other water activity, specify	N/A	3
Nasal Irrigation Exposure	Any nasal irrigation exposure	PHVS_YesNoUnknown_CDC	1
Nasal Irrigation Water Source	Water source used by patient for nasal irrigation	TBD	1
Nasal Irrigation Exposure Indicator	Types of nasal irrigation	TBD	2
Nasal Irrigation Exposure Date	Date when patient preformed nasal irrigation	N/A	2
Other Nasal Irrigation Exposure specify	Other nasal irrigation type, specify	N/A	3
Soil Exposure	Any soil exposure	PHVS_YesNoUnknown_CDC	1
Soil Exposure Indicator	Types of soil exposure	TBD	2
Soil Exposure Date	Date when patient was exposed to soil	N/A	
Travel	Any travel within the last 2 years	PHVS_YesNoUnknown_CDC	2
International Destination of Travel	International travel destination	N/A	2
Travel State	Domestic travel destination	N/A	2
Date Of Arrival to Travel Destination	Date of Arrival to Travel Destination	N/A	2
Date of Departure from Travel Destination	Date of Departure from Travel Destination	N/A	2
Treatment Type	List of treatment/drugs used by patient in the past 2 years	TBD	1
Treatment Information	If patient using other	N/A	2
Immunocompromised Associated Condition or Treatment	treatment/drugs, specify       List of immunocompromised       conditions experienced by		1
CD4 Count	patientIf yes to HIV/AIDS, what isCD4 count (per mm3)		2
Cancer, specify	If the patient has cancer, specify the type of cancer	N/A	2
Hematologic disease	If patient has a hematologic disease, specify	N/A	2
Other autoimmune disease	If patient has other autoimmune disease, specify	N/A	2

Transplant Type	If patient had organ transplant, which organ	N/A	1
ENT/Respiratory Indicator	List of ENT/Respiratory TBD conditions experienced by patient		1
Other ENT	Specify other ENT conditionN/Aexperienced by patient		2
Other Respiratory	Specify other respiratory condition experienced by patient	N/A	2
Underlying Conditions(s)	List of other health conditions experienced by patient	TBD	2
Other condition	Specify other condition experience by patient	N/A	2
Second Hospitalization	Other hospitalizations in the past 90 days	PHVS_YesNoUnknown_CDC	2
History of Present Illness	Description of patient's clinical course prior to hospitalization	N/A	1
Patient Outcome	Did patient survive	PHVS_YesNoUnknown_CDC	1
Neurologic deficits	If survived, residual neurologic deficits	PHVS_YesNoUnknown_CDC	1
Neurologic Manifestations	Describe neurologic deficits	N/A	2
Cause of Death	Cause of death	TBD	1
Other cause of death	Specify other cause of death	N/A	2
Organs transplant donor	If died, were organs transplanted	PHVS_YesNoUnknown_CDC	1
Specify organs transplanted	Specify which organs were transplanted	N/A	2
Clinical Outcome	Description of patient's clinical course	N/A	1
Sign and Symptoms	List of general and neurological signs and symptoms experienced by patient	TBD	1
Signs and Symptoms Indicator	Indicator for associated sign and symptom	PHVS_YesNoUnknown_CDC	1
Other Signs and Symptoms, Specify	Specify other general sign or symptoms	N/A	2
Onset date of neurological symptom	Onset date of first neurological sign/symptom	N/A	1
Other neurological sign/symptom	Specify other neurological sign/symptom	N/A	2
Skin lesions	Skin lesions present on patient	PHVS_YesNoUnknown_CDC	1

Character of Lesions	Type of lesion (ulcers, plaques,	TBD	2
	erythematous nodules)		
Lesion location	Location of lesions	N/A	2
Total number of Lesions	Number of lesions	N/A	2
CSF Panel Testing Date	Date of CSF testing	N/A	1
CSF Panel Test Result	CSF Panel Test Result	TBD	1
Diagnostic imaging	Use of diagnostic imaging	PHVS_YesNoUnknown_CDC	1
Diagnostic imaging type indicator	Type of imaging preformed	TBD	2
Diagnostic imaging findings indicator	Findings of diagnostic imaging	TBD	2
Diagnostic imaging findings specify indicator	Other findings of diagnostic imaging, specify	N/A	3
Number of brain lesions	How many brain lesions	TBD	2
Ring-enhancing brain lesions	Were brain lesions ring- enhancing	PHVS_YesNoUnknown_CDC	2
Location of brain lesions	If yes to brain lesions, location of brain lesions	N/A	2
Surgical resection	Did surgical resection occur	PHVS_YesNoUnknown_CDC	1
Medications	Types of medication used to treat patient	TBD	1
Medication start date	When did medication start	N/A	2
Medication end date	When did medication end	N/A	2
Route of Administration	How was medication administered to patient	TBD	2

Viral hemorrhagic fevers (VHF)	
The impetus/urgency for CDC to add data elements for this condition	<ul> <li>Viral hemorrhagic fevers (VHFs) are a group of diseases that affect the organ systems of the body, damaging the overall cardiovascular system, and may result in bleeding, or hemorrhaging.</li> <li>The number of viruses known to cause disease in humans around the globe is ever-increasing, and the way VHF viruses</li> </ul>
	<ul> <li>spread is likely to shift due to globalization, international travel, and climate change.</li> <li>Due to these dynamics of viral spread, the risk of introducing a VHF into the United States is increasing. Therefore, the need for national notifiable disease surveillance to assist in understanding the transmission and epidemiology of VHFs in</li> </ul>

		nationwide disease s consistent case ident potential burden of i medically attended community transmis clusters of illness an	critical. case is detected in the United State surveillance is necessary to provid tification and classification, measu llness, characterize the epidemiole VHFs in the United States, detect ssion, and inform public health res d efficacy of population-based no eventions during the outbreak.	e ire the ogy of ponse to
Data Element Name	Da	ta Element Description	Value Set Code	CDC Priority <sup>2</sup> (New)
Travel	Did the United	patient travel outside the States in the 3 weeks becoming ill?	PHVS_YesNoUnknown_CDC	1
Contact with Case	sympto confirm	e patient had contact with a matic VHF case (suspect or ned), or VHF survivor in eeks before becoming ill?	PHVS_YesNoUnknown_CDC	1
Contact with Case Start Date	Contac	t with VHF case start date	N/A	1
Contact with Case End Date	Contact with VHF end date		N/A	1
Provide Care for ill patient	Did the patient care for someone who was sick or died in the 3 weeks before becoming ill?		PHVS_YesNoUnknown_CDC	1
Provide Care for ill patient Start Date		r sick person start date	N/A	1
Provide Care for ill patient End Date	Care fo	r sick person end date	N/A	1
Attend Funeral	outside	patient attend a funeral of the United States in the s before becoming ill?	PHVS_YesNoUnknown_CDC	1
Consumed Meat	harvest outside	patient consume any meat ed from wild animals of the United States in the s before becoming ill?	PHVS_YesNoUnknown_CDC	1
Reported Pathogen		VHF pathogen reported	TBD	1
Reported Pathogen Other	Other \	/HF pathogen reported	TBD	1
Tick Mosquito Contact	or mose	patient experience any tick quito bites while outside of ted States?	PHVS_YesNoUnknown_CDC	1
Specify Tick Mosquito	Specify	tick and/or mosquito	TBD	1

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

Туре	contact		
Tick Mosquito	Tick/Mosquito location country	TBD	2
Location Country			
Tick Mosquito	Tick/Mosquito location district	TBD	3
Location District			
Last Date of Tick	Last date of tick bite (or tick	N/A	2
Contact	removal)		
Last Date of Mosquito	Last date of mosquito bite	N/A	2
Contact			
Positive Results	Positive results for which	TBD	1
Pathogen	pathogen		

## <u>Burden</u>

The burden to add 90 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 90 data elements to their surveillance system and modify their case notification additional data elements. This one-time burden of 9 hours is noted in the following table:

## One-Time Burden to Add 90 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 <mark>90</mark> Data Elements	
States	50	1	9	
Territories	5	1	9	
Freely Associated	3	1	9	
States				
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.

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours): Annualized One-time Addition of <mark>90</mark> Data Elements	Total Annualized One-Time Burden (in hours)
States	50	1	3	150
Territories	5	1	3	15
Freely Associated States	3	1	3	9
Cities	2	1	3	6
Total				180

Annualized One-Time Burden to Add 90 Data Elements to NNDSS

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
<mark>States</mark>	One-time Addition of Diseases and Data Elements	<mark>50</mark>	1	<mark>9</mark>	<mark>450</mark>
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>	One-time Addition of Diseases and Data Elements	<mark>5</mark>	1	<mark>9</mark>	<mark>45</mark>
Freely	Weekly	3	52	20/60	52

Associated States	(Automated)				
Freely Associated States	Weekly, Quarterly (Non- automated)	3	56	20/60	56
Freely Associated States	Annual	3	1	5	15
<mark>Freely</mark> Associated States	One-time Addition of Diseases and Data Elements	3	1	<mark>9</mark>	<mark>27</mark>
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
<mark>Cities</mark>	One-time Addition of Diseases and Data Elements	2	1	<mark>9</mark>	<mark>18</mark>
<mark>Total</mark>					<mark>18,774</mark>

# 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
<mark>States</mark>	One-time Addition of Diseases and Data Elements	<mark>50</mark>	1	9	<mark>450</mark>	<mark>\$49.14</mark>	<mark>\$22,113</mark>
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
<b>Territories</b>	One-time Addition of Diseases and Data Elements	5	1	9	<mark>45</mark>	<mark>\$49.14</mark>	<mark>\$2,211</mark>
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	<mark>3</mark>	1	<mark>9</mark>	<mark>27</mark>	<mark>\$49.14</mark>	<mark>\$1,327</mark>
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
<mark>Cities</mark>	One-time Addition of Diseases and Data Elements	2	1	9	<mark>18</mark>	<mark>\$49.14</mark>	<mark>\$885</mark>
<mark>Total</mark>							<mark>\$882,848</mark>