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

 **OMB Control Number 0920-0728**

**Expiration Date: 03/31/2024**

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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 03/31/2024, 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:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Disease Name** **in NNDSS Collection** | Nationally Notifiable (NNC) OR Under Standardized Surveillance (CSS) | Current Case Notification (Y/N) | Proposed Case Notification (Y/N) | Current Disease-specific Data Elements (Y/N) | Proposed Disease-specific Data Elements (Y/N) | Number of Existing Data Elements in NNDSS  | Proposed Number of new NNDSS Data Elements |
| Babesiosis | NNC |  |  | Y |  | 73 | 1 |
| Hepatitis | NNC |  |  | Y |  | 179 | 5 |
| Multisystem Inflammatory Syndrome (MIS) associated with Coronavirus Disease 2019 (COVID-19) | CSS |  |  | Y |  | 44 | 10 |

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 17 new data elements: 1 new core data element for all conditions, and 16 new disease-specific data elements. The 16 new disease-specific data elements include: 1 new disease-specific data elements for Babesiosis, 5 new disease-specific data elements for Hepatitis and 10 new disease-specific data elements for Multisystem Inflammatory Syndrome (MIS) associated with Coronavirus Disease 2019 (COVID-19).

|  |  |
| --- | --- |
| **Core: 1 Data Element** |  |
| The impetus/urgency for CDC to add data element for all conditions | * To make surveillance more comprehensive and informative for public health actions
* To monitor epidemiology
* To update guidance on infection control and prevention
 |
| **Data Element Name** | **Data Element Description** | **Value Set Code** | **CDC Priority[[1]](#endnote-1)**  |
| Birth Sex | What was patient’s sex at birth? | N/A | 1 |

|  |  |
| --- | --- |
| **Babesiosis: 1 Data Element** |  |
| The impetus/urgency for CDC to add data elements for this condition | * The data element included in this request will allow jurisdictions to submit the local record ID of a mother’s case within a congenital case.
* Link reported congenital babesiosis cases to the mother’s reported babesiosis case to gain a better understanding and more complete picture of risk factors.
* Assist in improving CDC’s epidemiologic understanding of the rare condition of congenital babesiosis and disease trends over time.
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| **Data Element Name** | **Data Element Description** | **Value Set Code** | **CDC Priority [[2]](#footnote-1) (New)** |
| 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 |

|  |  |
| --- | --- |
| **Hepatitis: 5 Data Elements** |  |
| The impetus/urgency for CDC to add data elements for this condition | * 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”.
* Improve the overall understanding of the population and factors contributing to viral hepatitis infection.
* Enhanced surveillance will be more comprehensive and informative for public health actions and will improve guidance on infection control and prevention.
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| --- | --- | --- | --- |
| **Data Element Name** | **Data Element Description** | **Value Set Code** | **CDC Priority [[3]](#footnote-2) (New)** |
| Transplant Date | Date(s) of organ transplant(s). | NA | 2 |
| Subject of Lab Test Performed | Indication to specify whether the Lab Test Performed was for the mother or infant. | PHVS\_MotherInfantIndicator\_NND | 1 |
| Previously Infected Individual  | Did the subject meet the case definition for a previous case investigation of this disease or condition? | Yes No Unknown (YNU) | 2 |
| Previous State Case Number | If the subject previously met the case definition for the disease or illness, what was the previously submitted sending system-assigned local ID (case ID) of the case investigation with which the subject is associated? | N/A | 2 |
| Other Reported Case(s) | Select all of the newly reported case(s) of the hepatitides confirmed within the current reporting year other than the primary condition reported for this case notification. | PHVS\_NotifiableConditions\_Hepatitis | 2 |

|  |  |
| --- | --- |
| **Multisystem Inflammatory Syndrome (MIS) associated with Coronavirus Disease 2019 (COVID-19): 10 Data Elements** |  |
| The impetus/urgency for CDC to add data elements for this condition | * To allow the CDC COVID-19 response to conduct enhanced domestic surveillance of multisystem inflammatory syndrome in children (MIS-C), a condition which was first identified in April 2020 and was reported out of the UK. This rare but severe condition is temporally related to previous SARS-CoV-2 infection. Due to the urgency in collecting information on these cases to learn more about this condition, a national surveillance system was rapidly developed and deployed under the COVID-19 public health emergency declaration.
* This new syndrome does not have a diagnostic test and relies on the CDC MIS-C case definition for diagnosis. Due to the reliance on the case definition, the data elements listed enable CDC to assess whether reported cases align with our case definition. Without these elements, it would not be possible to identify incident cases of MIS-C.
* Obesity has been associated with adverse outcomes associated with COVID-19; therefore, collecting data elements related to this comorbidity enables investigation of potential links between obesity and MIS-C.
* To assist with determination of timeline from acute SARS-CoV-2 infection to MIS-C to better determine the course of illness.
* Data elements reflect potential risk factors for MIS-C. It is important to identify which children with SARS-CoV-2 infection are at risk for MIS-C and which children with MIS-C have specific risk factors leading to severe illness.
* Data elements covering clinical complications, outcomes, and treatments will optimize diagnostic and treatment practices for MIS-C.
* Data elements regarding COVID-19 vaccination are critical to understanding the relationship, if any, between development of MIS-C and receipt of COVID-19 vaccination.
* Data elements will allow for better characterization of MIS-C, potentially leading to an update of the case definition.
* All health departments have set up their reporting databases to align with the case report form for streamlined reporting and standardization of reporting.
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|  |  |  |  |
| --- | --- | --- | --- |
| **Data Element Name** | **Data Element Description** | **Value Set Code** | **CDC Priority [[4]](#footnote-3) (New)** |
| MIS Inclusion | Did the patient meet all inclusion criteria associated with MIS illness case definition | PHVS\_YesNoUnknown\_CDC | 1 |
| MIS Inclusion Criteria | Inclusion criteria associated with the illness being reported | MIS Inclusion (MIS) | 1 |
| MIS Inclusion Criteria indicator | Indicator for associated inclusion criteria | PHVS\_YesNoUnknown\_CDC | 1 |
| Patient outcome date | Date of hospital discharge or death | N/A | 1 |
| Medical history | Does the patient have a history of the following illnesses prior to developing MIS-C symptoms? | Patient history (MIS) | 1 |
| Medical history indicator | Indicator for associated medical history diagnosis | Patient history (MIS) | 1 |
| Date of medical history | Date of past medical history diagnosis |  N/A | 1 |
| Imaging Study | Listing of imaging studies the subject received for this illness | Imaging Studies | 1 |
| Imaging Study indicator | Provide a response for normal or abnormal results for each imaging study received | Normal, Abnormal, Not Done | 1 |
| Left ventricular ejection fraction (LVEF) level | Specify left ventricular ejection fraction (LVEF) | 1:≥55%, 2: 50-54% 3: <50% | 1 |

Burden

The burden to add 17 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 2 hours is incurred for respondents to add 17 data elements to their surveillance system and modify their electronic case notification message to accommodate those 17 additional data elements. This one-time burden of 2 hours is noted in the following table:

One-Time Burden to Add 17 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 17 Data Elements** |  |
| States | 50 | 1 | 2 |  |
| Territories | 5 | 1 | 2 |  |
| Freely Associated States | 3 | 1 | 2 |  |
| Cities | 2 | 1 | 2 |  |
|  |  |  |  |  |

The total annualized one-time burden is 39 hours (33 hours for states, 3 hours for territories, 2 hours for freely associated states and 1 hour for cities) as noted in the table below.

Annualized One-Time Burden to Add 17 Data Elements to NNDSS

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Respondents** | **Number of Respondents** | **Number of Responses per Respondent** | **Average Burden Per Response (in hours): Annualized One-time Addition of 17 Data Elements** | **Total Annualized One-Time Burden (in hours)** |
| States | 50 | 1 | 40/60 | 33 |
| Territories | 5 | 1 | 40/60 | 3 |
| Freely Associated States | 3 | 1 | 40/60 | 2 |
| Cities | 2 | 1 | 40/60 | 1 |
| Total |  |  |  | 39 |

39 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 |
| States | One-time Addition of Diseases and Data Elements  | 50 | 1 | 40/60 | 800 |
| 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 | 40/60 | 80 |
| 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 | 40/60 | 48 |
| 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 | 40/60 | 32 |
| **Total** |  |  |  |  | **19,194** |

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 | $46.23 | $40,081 |
| States | Weekly (Non-automated) | 10 | 52 | 2 | 1,040 | $37.64 | $39,146 |
| States | Weekly (NMI Implementation) | 50 | 52 | 4 | 10,400 | $46.23 | $480,792 |
| States | Annual | 50 | 1 | 75 | 3,750 | $37.64 | $141,150 |
| States | One-time Addition of Diseases and Data Elements  | 50 | 1 | 40/60 | 800 | $46.23 | $36,984 |
| Territories | Weekly (Automated) | 5 | 52 | 20/60 | 87 | $46.23 | $4,022 |
| Territories | Weekly, Quarterly (Non-automated) | 5 | 56 | 20/60 | 93 | $37.64 | $3,501 |
| Territories | Weekly (NMI Implementation) | 5 | 52 | 4 | 1,040 | $46.23 | $48,079 |
| Territories | Annual | 5 | 1 | 5 | 25 | $37.64 | $941 |
| Territories | One-time Addition of Diseases and Data Elements  | 5 | 1 | 40/60 | 80 | $46.23 | $3,694 |
| Freely Associated States | Weekly (Automated) | 3 | 52 | 20/60 | 52 | $46.23 | $2,404 |
| Freely Associated States | Weekly, Quarterly (Non-automated) | 3 | 56 | 20/60 | 56 | $37.64 | $2,108 |
| Freely Associated States | Annual | 3 | 1 | 5 | 15 | $37.64 | $565 |
| Freely Associated States | One-time Addition of Diseases and Data Elements | 3 | 1 | 40/60 | 48 | $46.23 | $2,219 |
| Cities | Weekly (Automated) | 2 | 52 | 20/60 | 35 | $46.23 | $1,618 |
| Cities | Weekly (Non-automated) | 2 | 52 | 2 | 208 | $37.64 | $7,829 |
| Cities | Weekly (NMI Implementation) | 2 | 52 | 4 | 416 | $46.23 | $19,232 |
| Cities | Annual | 2 | 1 | 75 | 150 | $37.64 | $5,646 |
| Cities | One-time Addition of Diseases and Data Elements  | 2 | 1 | 40/60 | 32 | $46.23 | $1,479 |
| **Total** |  |  |  |  |  |  | **$841,490** |

1. R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3, TBD=To be determined [↑](#endnote-ref-1)
2. R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3 [↑](#footnote-ref-1)
3. R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3 [↑](#footnote-ref-2)
4. R=Required; 1=Priority 1, 2=Priority 2, 3=Priority 3 [↑](#footnote-ref-3)