

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

**OMB Control Number 0920-0728**

**Expiration Date: 04/30/2022**

**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 04/30/2022, 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 |
|--|--|---------------------------------|----------------------------------|--|---|---|--|
| <i>Candida auris (C. auris)</i>  | NNC  |                                 |                                  | N  |   | 0   | 18   |
| Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE) | NNC  |                                 |                                  | Y  |   | 8   | 8  |
| Malaria  | NNC  |                                 |                                  | Y  |   | 91  | 9  |

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 35 new disease-specific data elements: 18 new data element for *Candida auris* (*C. auris*), 8 new data elements for Carbapenemase-Producing Carbapenem-Resistant Enterobacteriaceae (CP-CRE) and 9 new data elements for Malaria.

| <b><i>C. auris</i></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</li> <li>To provide more information about factors that have been associated with colonization or infection and with the identification of cases (related cases and conditions, high acuity care needs, healthcare facility exposure, travel, and specimen testing).</li> <li>To monitor epidemiology</li> <li>To update guidance on infection control and prevention</li> <li>To link separate laboratory systems to case information</li> </ul> |                       |                                 |
| <b>Data Element Name</b>  | <b>Data Element Description</b>  | <b>Value Set Code</b> | <b>CDC Priority<sup>1</sup></b> |
| Previously Counted Case   | Was patient previously counted as a colonization/screening case?   | PHVS_YesNoUnknown_CDC | P                               |
| Previously Reported State Case Number                               | If patient was previously counted as a colonization/screening case or a CP-CRE case, please provide the related case ID(s)   | N/A                   | P                               |
| Tracheostomy Tube at Specimen Collection                            | Did patient have a tracheostomy tube at the time of specimen collection?   | PHVS_YesNoUnknown_CDC | P                               |
| Ventilator Use at Specimen Collection                               | Was patient on a ventilator at the time of specimen collection?  | PHVS_YesNoUnknown_CDC | P                               |
| Long-term Care Resident   | Did the patient have a stay in a long-term care facility in the 90 days before specimen collection date?   | PHVS_YesNoUnknown_CDC | P                               |

<sup>1</sup> R=Required; P=Preferred, O=Optional

|   |   |   |   |
|---|---|---|---|
| Type of Long-term Care Facility   | If patient had a stay in a long-term care facility in the 90 days before specimen collection date, indicate the type of long-term care facility.  | PHVS_LongTermCare<br>FacilityType_C.auris | P |
| Healthcare Outside Resident State   | Indicate if the patient received overnight healthcare within the United States, but outside of the patient's resident state in the year prior to the date of specimen collection.   | PHVS_YesNoUnknown_CDC                     | P |
| Travel Outside USA Prior to Illness Onset within Program Specific Timeframe | Did the patient travel internationally in the past 1 year from the date of specimen collection?   | PHVS_YesNoUnknown_CDC                     | P |
| International Destination(s) of Recent Travel                               | List the names of the country(ies) outside of the United States the patient traveled to in the year prior to the date of specimen collection, if the patient traveled outside of the United States during that time.  | PHVS_Country_ISO_3166-1                   | P |
| Healthcare Outside USA  | Indicate if the patient received overnight healthcare outside of the United States in the year prior to the date of specimen collection.  | PHVS_YesNoUnknown_CDC                     | P |
| Country(ies) of Healthcare Outside USA                                      | List the names of the country(ies) outside of the United States where the patient received overnight healthcare in the year prior to the date of specimen collection, if the patient received overnight healthcare outside of the United States during that time. | PHVS_Country_ISO_3166-1                   | P |
| Type of Location Where Specimen Collected                                   | Indicate the physical location type of the patient  | PHVS_SpecimenCollection                   | P |

|                             |  |                              |   |
|-----------------------------|--|------------------------------|---|
|                             | when the specimen was collected  | SettingType_C.auris          |   |
| County of Facility          | County of facility where specimen was collected  | PHVS_County_FIPS_6-4         | P |
| State of Facility           | State of facility where specimen was collected   | PHVS_State_FIPS_5-2          | P |
| Infection with Another MDRO | Does the patient have infection or colonization with another MDRO?   | PHVS_YesNoUnknown_CDC        | P |
| Co-infection Type           | If patient has infection or colonization with another MDRO, indicate the MDRO.   | PHVS_TypeCoInfection_C.auris | P |
| State Lab specimen ID       | State lab specimen ID  | N/A                          | P |
| WGS ID Number               | NCBI SRA Accession number (SRX#)<br><br>We would describe this as:<br>The accession number generated by NCBI's Sequence Read Archive when sequence data are uploaded to NCBI. This provides both the sequence data and metadata on how the sample was sequenced. | N/A                          | P |

| <b>CP-CRE</b>   |  |                         |                     |
|---|--|-------------------------|---------------------|
| <b>Data Element Name</b>  | <b>Data Element Description</b>  | <b>Value Set Code</b>   | <b>CDC Priority</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</li> <li>To provide more information about risk factors (healthcare facility exposure, travel, and specimen testing) that have been associated with colonization or infection</li> <li>To monitor and expand current epidemiology on an emerging pathogen</li> <li>To update guidance on infection control and prevention</li> <li>To link separate laboratory systems to case information</li> </ul> |                         |                     |
| Travel Outside USA Prior to Illness Onset within Program Specific Timeframe | Did the patient travel internationally in the past 1 year from the date of specimen collection?  | PHVS_YesNoUnknown_CDC   | P                   |
| International Destination(s) of Recent Travel                               | This data element is used to capture the names of the country(ies) outside of the United States the patient traveled to in the year prior to the date of specimen collection, if the patient has traveled outside of the United States during that time.   | PHVS_Country_ISO_3166-1 | P                   |
| Healthcare Outside USA  | This data element is used to capture if the patient received healthcare outside of the United States in the year prior to the date of specimen collection.   | PHVS_YesNoUnknown_CDC   | P                   |
| Country(ies) of Healthcare Outside USA                                      | This data element is used to capture the names of the country(ies) outside of the United States where the patient received healthcare in the year prior to the date of specimen collection, if the patient traveled outside of the United States during that time.   | PHVS_Country_ISO_3166-1 | P                   |

|                                       |  |                       |   |
|---------------------------------------|--|-----------------------|---|
|                                       |  |                       |   |
| Gene Identifier                       | Gene identifier  | PHVS_GeneName_CP-CRE  | P |
| Previously Counted Case               | Was patient previously counted as a colonization/screening case?   | PHVS_YesNoUnknown_CDC | P |
| Previously Reported State Case Number | If patient was previously counted as colonization/screening case please provide related case ID(s)   | N/A                   | P |
| WGS ID Number                         | NCBI SRA Accession number (SRX#)<br><br>We would describe this as:<br>The accession number generated by NCBI's Sequence Read Archive when sequence data are uploaded to NCBI. This provides both the sequence data and metadata on how the sample was sequenced. | N/A                   | P |

| <b>Malaria</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</li> <li>To assess treatment timeliness and appropriateness of care</li> <li>To better monitor for adverse events related to antimalarial medications</li> </ul>    |  |                     |
| <b>Data Element Name</b>  | <b>Data Element Description</b>  | <b>Value Set Code</b>                                    | <b>CDC Priority</b> |
| Admitted as Inpatient   | Was subject admitted to the hospital for greater than 24 hours as an inpatient?  | PHVS_YesNoUnknown_CDC                                    | P                   |
| Date Treatment or Therapy Started                                   | Date the treatment was initiated   | N/A  | P                   |
| Date Treatment or Therapy Stopped                                   | Date treatment stopped   | N/A  | P                   |
| Treatment Duration  | Number of days the patient was prescribed antimalarial treatment   | N/A  | P                   |
| Medication Administered Relative to Treatment                       | Indicate if the patient took the medication 2 weeks before treatment or within the 4 weeks after starting treatment.   | PHVS_MedicationAdministered<br>RelativeTreatment_Malaria | P                   |
| Medication Administered   | Please list all prescription and over the counter medicines the patient had taken during the 2 weeks before and during the 4 weeks after starting treatment for malaria. If information for both pre- and post-treatment are available, please complete below questions for each time frame. | N/A  | P                   |
| Medication Start Date   | Medication Start Date  | N/A  | P                   |
| Medication Stop Date  | Medication Stop Date   | N/A  | P                   |
| Medication Duration   | Number of days that patient took the medication referenced   | N/A  | P                   |

Burden

Burden to add 35 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 4 hours is incurred for respondents to add 35 data elements to their surveillance system and modify their electronic case notification message to accommodate those 35 additional data elements. This one-time burden of 4 hours is noted in the following table:

One-Time Burden to Add 35 Data Elements to NNDSS

| <b>Type of Respondents</b> | <b>Number of Respondents</b> | <b>Number of Responses per Respondent</b> | <b>Average Burden Per Response (in hours): One-time Addition of 35 Data Elements</b> |  |
|----------------------------|------------------------------|---|--|--|
| States                     | 50                           | 1   | 4  |  |
| Territories                | 5                            | 1   | 4  |  |
| Freely Associated States   | 3                            | 1   | 4  |  |
| Cities                     | 2                            | 1   | 4  |  |
| Total                      |                              |   |  |  |

The total annualized one-time burden is 60 hours (50 hours for states, 5 hours for territories, 3 hours for freely associated states and 2 hours for cities) as noted in the table below.

Annualized One-Time Burden to Add 35 Data Elements to NNDSS

| <b>Type of Respondents</b> | <b>Number of Respondents</b> | <b>Number of Responses per Respondent</b> | <b>Average Burden Per Response (in hours): Annualized One-time Addition of 35 Data Elements</b> | <b>Total Annualized One-Time Burden (in hours)</b> |
|----------------------------|------------------------------|---|---|--|
| States                     | 50                           | 1   | 1   | 50   |
| Territories                | 5                            | 1   | 1   | 5  |

|                          |   |   |   |    |
|--------------------------|---|---|---|----|
| Freely Associated States | 3 | 1 | 1 | 3  |
| Cities                   | 2 | 1 | 1 | 2  |
| Total                    |   |   |   | 60 |

60 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                                  | 21                                     | 1,050                   |
| 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                                  | 10                                     | 50                      |
| 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                                  | 7                                      | 21                      |

|               |  |          |          |           |               |
|---------------|--|----------|----------|-----------|---------------|
| 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           |
| <b>Cities</b> | <b>One-time Addition of Diseases and Data Elements</b> | <b>2</b> | <b>1</b> | <b>21</b> | <b>42</b>     |
| <b>Total</b>  |  |          |          |           | <b>19,398</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                | \$44.59          | \$38,660        |
| States                   | Weekly (Non-automated)                                 | 10                    | 52                                 | 2                                      | 1,040              | \$36.65          | \$38,116        |
| States                   | Weekly (NMI Implementation)                            | 50                    | 52                                 | 4                                      | 10,400             | \$44.59          | \$463,736       |
| States                   | Annual   | 50                    | 1                                  | 75                                     | 3,750              | \$36.65          | \$137,438       |
| <b>States</b>            | <b>One-time Addition of Diseases and Data Elements</b> | <b>50</b>             | <b>1</b>                           | <b>21</b>                              | <b>1,050</b>       | <b>\$44.59</b>   | <b>\$46,820</b> |
| 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           |
| <b>Territories</b>       | <b>One-time Addition of Diseases and Data Elements</b> | <b>5</b>              | <b>1</b>                           | <b>10</b>                              | <b>50</b>          | <b>\$44.59</b>   | <b>\$2,230</b>  |
| 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  | 7     | 21  | \$44.59 | \$936            |
| 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  | 21    | 42  | \$44.59 | \$1,873          |
| <b>Total</b>             |   |   |    |       |     |         | <b>\$822,575</b> |