**Non-substantive Change Request**

**OMB Control Number** **0920-0978**

**Emerging Infections Programs (EIP)**

**Expiration Date:09/30/2027**

**Date Submitted: 04/23/2025**

**Summary of request:** CDC/NCEZID is requesting a change request to revise questions to align with EO 14168 *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government.*

**Description of Changes Requested:** This request updates sex to be in accordance with EO 14168 for the following 13 approved EIP ICR/Forms. (The remainder of approved EIP forms are all in compliance with EO14168.):

* FN.200.9 Hemolytic Uremic Syndrome (HUS) Surveillance
* HAIC.400.1 HAIC MuGSI Case Report Form - 2024
* HAIC.400.1 HAIC MuGSI Case Report Form - 2025
* HAIC.400.4 Invasive Methicillin-Resistant *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2022
* HAIC.400.4 Invasive Methicillin-Sensitive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2022
* HAIC.400.4 Invasive Methicillin-Resistant *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2023
* HAIC.400.4 Invasive Methicillin-Sensitive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2023
* HAIC.400.4 Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2024
* HAIC.400.4 Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2025
* HAIC.400.7 HAIC - CDI Case Report and Treatment Form  – 2024
* HAIC.400.7 HAIC - CDI Case Report and Treatment Form  – 2025
* HAIC.400.11: HAIC Candidemia Case Report Form - 2024
* HAIC.400.11: HAIC Candidemia Case Report Form - 2025

**Note:** FN.200.1-200.8 FoodNet Variable List – Updates to one of the sex question values for the FoodNet Active Surveillance data collection instrument is being delayed due to the technical effort involved and is awaiting further guidance before revising the data dictionary. The change will be updated as soon as the technical issue has been resolved.

FoodNet Active Surveillance conducts secondary data collection.  Data collected by participating state and local surveillance are transmitted to FoodNet monthly in excel format.  The states transfer their local data into our ‘sex’ column using M or F, and coding any missing information as U, interpreted as unknown.  The U variable is mapped to missing when received at CDC and shared with any group requesting FoodNet data as a missing value.

Please check the boxes below if your request includes:

**X Revision of an existing question(s)**

 Deletion of an existing question(s)

**Description of Changes to Burden:**

**There is no change in Burden Hours associated with the modifications made to comply with EO 14168**

**Explanation for Program Changes or Adjustments**

|  |
| --- |
| **FN.200.9 - HUS Surveillance Case Report Form**  |
| **Type of Change**  | **Itemized Changes / Justification**  | **Impact to Burden**  |
| Administrative  | Question 9A.  Sex: □ Female □ Male  Changes:  * Removed “Unknown” option

**Justification**: The value of  “Unknown” was removed from the CRF to comply with the “Defending Women” Executive Order.  | No impact to burden.  |
| **HAIC.400.1 – HAIC- 2024 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF)**  |
| **Type of Change**  | **Itemized Changes / Justification**  | **Impact to Burden**  |
| Administrative  | Question 7: Sex **Changes:** * Changed question text from “Sex at birth” to “Sex”
* Changed “Unknown” option to “Missing value”
* Removed the option for “Transgender”

 **Justification**: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order.  Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is beingabstracted, does not document male or female sex.   There is no expected burden change based on this change.  Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2024.  Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data  | **None**  |
| **HAIC.400.1 – HAIC- 2025 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF)**  |
| **Type of Change**  | **Itemized Change / Justification**  | **Impact to Burden**  |
| Administrative  | Question 7: Sex **Changes:** * Changed question text from “Sex at birth” to “Sex”
* Changed “Unknown” option to “Missing value”
* Removed the option for “Transgender”

 **Justification**: We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order.  Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is beingabstracted, does not document male or female sex.   There is no expected burden change based on this change.  Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2025.  Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data  | **None**  |
| **HAIC.400.4 Invasive Methicillin-Resistant *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2022**  |
| **Type of Change**  | **Itemized Changes / Justification**  | **Impact to Burden**  |
| Administrative  | Question 7.  Sex: **□** Yes **□** No **□** Missing Value **Changes:** * Changed question text for “Sex at birth” to “Sex”
* Renamed “unknown” checkbox to “missing value”
* Removed checkbox for transgender

**Justification:** We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order.  Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is beingabstracted, does not document male or female sex.   There is no expected burden change based on this change.  Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2022.  Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.  | **None**  |
| **HAIC.400.4 Invasive Methicillin-Sensitive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2022**  |
| **Type of Change**  | **Itemized Change / Justification**  | **Impact to Burden**  |
| Administrative  | Question 7.  Sex: **□** Yes **□** No **□** Missing Value **Changes:** * Changed question text for “Sex at birth” to “Sex”
* Renamed “unknown” checkbox to “missing value”
* Removed checkbox for transgender

**Justification:** We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order.  Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is beingabstracted, does not document male or female sex.   There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2022.  Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.  | **None**  |
| **HAIC.400.4 Invasive Methicillin-Resistant *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2023**  |
| **Type of Change**  | **Itemized Change / Justification**  | **Impact to Burden**  |
| Administrative  | Question 7.  Sex: **□** Yes **□** No **□** Missing Value **Changes:** * Changed question text for “Sex at birth” to “Sex”
* Renamed “unknown” checkbox to “missing value”
* Removed checkbox for transgender

**Justification:** We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order.  Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is beingabstracted, does not document male or female sex.   There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2023.  Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.  | **None**  |
| **HAIC.400.4 Invasive Methicillin-Sensitive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2023**  |
| **Type of Change**  | **Itemized Change / Justification**  | **Impact to Burden**  |
| Administrative  | Question 7.  Sex: **□** Yes **□** No **□** Missing Value **Changes:** * Changed question text for “Sex at birth” to “Sex”
* Renamed “unknown” checkbox to “missing value”
* Removed checkbox for transgender

**Justification:** We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order.  Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is beingabstracted, does not document male or female sex.   There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2023.  Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.  | **None**  |
| **HAIC.400.4 Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2024**  |
| **Type of Change**  | **Itemized Change / Justification**  | **Impact to Burden**  |
| Administrative  | Question 7.  Sex: **□** Yes **□** No **□** Missing Value **Changes:** * Changed question text for “Sex at birth” to “Sex”
* Renamed “unknown” checkbox to “missing value”
* Removed checkbox for transgender

**Justification:** We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order.  Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is beingabstracted, does not document male or female sex.   There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2024.  Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.  | **None**  |
| **HAIC.400.4 Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report – 2025**  |
| **Type of Change**  | **Itemized Change / Justification**  | **Impact to Burden**  |
| Administrative  | Question 7.  Sex: **□** Yes **□** No **□** Missing Value **Changes:** * Changed question text for “Sex at birth” to “Sex”
* Renamed “unknown” checkbox to “missing value”
* Removed checkbox for transgender

**Justification:** We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order.  Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record, that is beingabstracted, does not document male or female sex.   There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2025.  Our data collection forms are based on the date of culture, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.  | **None**  |
| **HAIC.400.7 HAIC - CDI Case Report and Treatment Form  – 2024**  |
| **Type of Change**  | **Itemized Changes / Justification**  | **Impact to Burden**  |
| Administrative  | Question 12.  Patient Sex: **□** Male **□** Female **□** Missing Value **Changes:** * Changed question text for “Sex at birth” to “Patient Sex”
* Renamed “unknown” checkbox to “missing value”
* Removed checkbox for transgender

**Justification:** We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order.  Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record that is beingabstracted does not document male or female sex.   There is no expected burden change based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2024.  Our data collection forms are based on the date of specimen collection for the case, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.    | **None**  |
| **HAIC.400.7 HAIC - CDI Case Report and Treatment Form  – 2025**  |
| **Type of Change**  | **Itemized Change / Justification**  | **Impact to Burden**  |
| Administrative  | Question 12.  Patient Sex: **□** Male **□** Female **□** Missing Value **Changes:** * Changed question text for “Sex at birth” to “Patient Sex”
* Renamed “unknown” checkbox to “missing value”
* Removed checkbox for transgender

**Justification:** We have removed the check box for “transgender” to be in compliant with the Defending Women Executive Order.  Additionally, seeing this data collection form is for a secondary data collection, a check box of “missing value” has been added for the situation where the medical record that is beingabstracted does not document male or female sex.   There is no expected burden change based on this change. Additionally, we are submitted this form as we are still in the process of collecting data from calendar year 2025.  Our data collection forms are based on the date of specimen collection for the case, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.  The 2025 form will also be used for 2026 data collection.   | **None**  |

|  |
| --- |
| **HAIC.400.11: HAIC Candidemia Case Report Form - 2024** |
| **Type of Change** | **Itemized Changes / Justification** | **Impact to Burden** |
| Administrative  | Question 15.  Sex: □ Female □ Male  Changes:  * Removed “Check if Transgender” option

Justification: We have removed the “Check if Transgender” option to be in compliance with the Defending Women Executive Order. There is no expected burden based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2024.  Our data collection forms are based on the date of specimen collection for the case, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.     | None  |
| **HAIC.400.11: HAIC Candidemia Case Report Form - 2025** |
| **Type of Change** | **Itemized Change / Justification** | **Impact to Burden** |
| Administrative  | Question 15.  Sex: □ Female □ Male  Changes:  * Removed “Check if Transgender” option

Justification: We have removed the “Check if Transgender” option to be in compliance with the Defending Women Executive Order.  There is no expected burden based on this change. Additionally, we are submitting this form as we are still in the process of collecting data from calendar year 2024.  Our data collection forms are based on the date of specimen collection for the case, and therefore in order to be compliant with the EO for all years of data under collection, this change is needed on historical forms.   | None  |