**Description of Changes**

**ABCs:**

The changes made to the data elements under this non-substantive request will aid in improving surveillance efficiency and data quality to clarify the burden of disease and possible risk factors for disease. This information can be used to inform strategies for preventing disease and negative outcomes. Specifically, changes were made for clarification purposes, to improve efficiency, and to assist data collectors in capturing data in a standardized fashion to improve accuracy.

The data collection tools for which approval for changes are being sought include:

1. 2023 ABCs Case Report Form
2. 2023 ABCs Neonatal Infection Expanded Tracking Form
3. **2023 ABCs Case Report Form:**There is no impact on burden due to the changes on this form. Change includes:

* **Removed Question 24d.** “Mark if this is a GBS Blood Spot Study case that lives outside ABCs catchment area.” ***Justification:*** GBS Blood Spot Study enrollment ended at the end of 2022 and Q24d is no longer needed on the ABCs core case report form.
* **Updated Question 31 value label for one response option**. Type of meningococcal vaccine updated from “ACWY conjugate (Menactra, Menveo, MenHibrix)” to “ACWY conjugate (Menactra, Menveo, MenHibrix, MenQuadfi)”. ***Justification:*** Included clarification that MenQuadfi should also be indicated as ACWY conjugate vaccine.

1. **2023 ABCs Neonatal Infection Expanded Tracking Form:**There is no impact on burden due to the changes on this form. Change includes:

* **Added additional response option ‘unknown’ for Question 13** “Maternal Blood Type”
* **Added additional response option ‘unknown’ for Question 18** “Type of rupture”
* **Added additional response option ‘Gentamicin’ for Question 21b** “Name of antibiotic”
* **Added additional response option ‘unknown’ for Question 24** “Did mother have chorioamnionitis or suspected chorioamnionitis?”

**Food Net:**

The changes made to the data elements under this non-substantive request will aid in improving surveillance efficiency and data quality to clarify the burden of disease and possible risk factors for disease. This information can be used to inform strategies for preventing disease and negative outcomes. Specifically, changes were made for clarification purposes, to improve efficiency, and to assist data collectors in capturing data in a standardized fashion to improve accuracy.

The data collection tools for which approval for changes are being sought include:

1. FoodNet Active Surveillance Data Elements List
2. FoodNet Hemolytic Uremic Syndrome Data Elements List
3. FoodNet Clinical Laboratory Practices and Testing Volume
4. **FoodNet Active Surveillance Data Elements List**

There is no impact on burden due to the changes on these data elements. Changes were made to streamline, collect level of detail needed, for consistency with the FDD MMG, and to identify communities with increased vulnerability and incidence with more specificity than our current county and zipcode variables.

The following data elements have been added:

1. **CTNO2020 (2020 Census Tract Number)**
   1. 00000000000-99999999999

The following data elements have value set changes:

1. **AgClinicTestType**
   1. Techlab Shiga Toxin Quik Chek
2. **AgSphlTestType**
   1. Techlab Shiga Toxin Quik Chek
3. **PcrClinicTestType**
   1. BioFire Filmarray Blood Culture Identification 2 (BCID2)
   2. Karius Test
   3. Vik or Scientific Gastro-ID
4. **PcrSphlTestType**
   1. BioFire Filmarray Blood Culture Identification 2 (BCID2)
   2. Karius Test
   3. Vik or Scientific Gastro-ID
5. **SpecSrce**
   1. Product of conception

The following data elements have variable label changes:

1. **EforsNum**
   1. CDC NORS outbreak ID number
2. **Immigrate**
   1. Did case-patient immigrate to the U.S.? (within 30 days of onset for *Salmonella* Typhi, Paratyphi, & *Listeria*, 14 days for *Cyclospora*, and 7 days for all other pathogens)
3. **TravelInt**
   1. Did the case patient travel internationally? (within 300 days of onset for *Salmonella* Typhi, Paratyphi, & *Listeria*, 14 days for *Cyclospora*, and 7 days for all other pathogens)

The following data elements have comment changes:

1. **Homeless**
   1. [collect for *Shigella* cases, optional for all other pathogens]
2. **FoodNet Clinical Laboratory Practices and Testing Volume** The burden has been reduced due to the changes on these data elements. Changes were made to improve efficiency of the data collection tool and to streamline the data collection process while maintaining the level of detail needed.

The following data elements have been removed:

* 1. **ChngTestMeth (During the past 6 months, has your laboratory changed testing methods used for detecting each pathogen)\***
  2. **Entericscrn (Is each pathogen part of your laboratory’s routing (approx >80%) enteric screen?)\***
  3. **IDCx (How often does your laboratory use culture to initially detect each pathogen?)\***
  4. **IDPCR (How often does your laboratory use PCR test to initially detect each pathogen?)\***
  5. **IDAG (How often does your laboratory use Antigen test (ELISA, lateral flow) to initially detect each pathogen?)\***
  6. **IDother (How often does your laboratory use another CIDT test to initially detect each pathogen?)\***
  7. **IDOtherSpec (If other CIDT method used, please specify)\***
  8. **Pcrbrand (What is the brand name of the PCR test for each pathogen?)\***
  9. **IsolateSubmit (How often are isolates submitted to the public health laboratory?)\***
  10. **StoolSubmit (How often are stools submitted to the public health laboratory?)\***
  11. **BrothSubmit (How often are broth submitted to the public health laboratory?)\***
  12. **BloodSubmit (How often are blood samples submitted to the public health laboratory?)**
  13. **CSFSubmit (How often are CSF samples submitted to the public health laboratory?)**

**\* Data elements were each asked for the following pathogens: Campylobacter, STEC (E.coli O157 and/or Shiga toxin), Salmonella, Shigella, Vibrio, Yersinia, Listeria, Cyclospora, and Norovirus**

The following data elements have been added:

1. **Campy\_practices** **(When does your lab test stool for Campylobacter?)**
   1. On all stool specimens submitted
   2. Only when specifically requested/ordered
   3. Only for specific projects/outbreaks
   4. Other (specify)
2. **Stec\_practices** **(When does your lab test stool for STEC?)**
   1. On all stool specimens submitted
   2. Only when specifically requested/ordered
   3. Only for specific projects/outbreaks
   4. Other (specify)
3. **Salm\_practices** **(When does your lab test stool for Salmonella?)**
   1. On all stool specimens submitted
   2. Only when specifically requested/ordered
   3. Only for specific projects/outbreaks
   4. Other (specify)
4. **Shig\_practices** **(When does your lab test stool for Shigella?)**
   1. On all stool specimens submitted
   2. Only when specifically requested/ordered
   3. Only for specific projects/outbreaks
   4. Other (specify)
5. **Vib\_practices** **(When does your lab test stool for Vibrio?)**
   1. On all stool specimens submitted
   2. Only when specifically requested/ordered
   3. Only for specific projects/outbreaks
   4. Other (specify)
6. **Yers\_practices** **(When does your lab test stool for Yersinia?)**
   1. On all stool specimens submitted
   2. Only when specifically requested/ordered
   3. Only for specific projects/outbreaks
   4. Other (specify)
7. **Cyclo\_practices** **(When does your lab test stool for Cyclospora?)**
   1. On all stool specimens submitted
   2. Only when specifically requested/ordered
   3. Only for specific projects/outbreaks
   4. Other (specify)
8. **Noro\_practices** **(When does your lab test stool for norovirus?)**
   1. On all stool specimens submitted
   2. Only when specifically requested/ordered
   3. Only for specific projects/outbreaks
   4. Other (specify)
9. **Practices\_other (If other, specify protocol for determining when stool specimens are tested for enteric pathogens)** 
   1. [Free text field]
10. **Campy\_methods (What methods are initially used to detect Campylobacter in stool specimens?)**
    1. Stool culture
    2. Multiplex PCR/NAAT gastrointestinal panel
    3. Stool immunoassay EIP microplate or lateral flow assay)
    4. Other CIDT test (specify)
11. **Stec\_methods (What methods are initially used to detect STEC in stool specimens?)**
    1. Stool culture
    2. Multiplex PCR/NAAT gastrointestinal panel
    3. Stool immunoassay EIP microplate or lateral flow assay)
    4. Other CIDT test (specify)
12. **Salm\_methods (What methods are initially used to detect Salmonella in stool specimens?)**
    1. Stool culture
    2. Multiplex PCR/NAAT gastrointestinal panel
    3. Stool immunoassay EIP microplate or lateral flow assay)
    4. Other CIDT test (specify)
13. **Shig\_methods (What methods are initially used to detect Shigella in stool specimens?)**
    1. Stool culture
    2. Multiplex PCR/NAAT gastrointestinal panel
    3. Stool immunoassay EIP microplate or lateral flow assay)
    4. Other CIDT test (specify)
14. **Vib\_methods (What methods are initially used to detect Vibrio in stool specimens?)**
    1. Stool culture
    2. Multiplex PCR/NAAT gastrointestinal panel
    3. Stool immunoassay EIP microplate or lateral flow assay)
    4. Other CIDT test (specify)
15. **Yers\_methods (What methods are initially used to detect Yersinia in stool specimens?)**
    1. Stool culture
    2. Multiplex PCR/NAAT gastrointestinal panel
    3. Stool immunoassay EIP microplate or lateral flow assay)
    4. Other CIDT test (specify)
16. **Methods\_other (If other CIDT used, specify)**
    1. [Free text field]
17. **Cyclo\_methods (What methods are used to detect Cyclospora in stool specimens?)**
    1. Microscopy
    2. PCR
    3. Other (specify)
18. **Cyclo\_cidt\_other** **(If other test, specify)**
    1. [Free text field]
19. **Pcr\_brand (What is the brand name of the PCR used to detect Campylobacter, STEC, Salmonella, Shigella, Vibrio, Yersinia, or Cyclospora?)**
    1. Biocode Gastrointestinal Pathogen Panel (GPP)
    2. BioFire FilmArray Gastrointestinal (GI)
    3. BD Max Enteric Bacterial and/or BD Max Extended Enteric Bacterial
    4. Great Basin Scientific Stool
    5. Hologic Prodesse ProGastro SSCS
    6. Luminex Verigene Enteric Pathogens
    7. Luminex xTAG Gastrointestinal Pathogens
    8. Medical Diagnostics
    9. Laboratory-developed test (LDT)
    10. Multiple PCR tests are used (specify)
    11. Other commercially available PCR test (specify)
20. **Pcr\_brand\_multiple (If multiple PCR tests are used, specify)**
    1. [Free text field]
21. **Pcr\_brand\_other (If other PCR used, specify)**
    1. [Free text field]
22. **Campy\_submission (Which specimens are sent to the PHL when Campylobacter is detected?)**
    1. Isolates
    2. Stool/transport media
    3. Broth
    4. No specimens are sent to the PHL
23. **Stec\_submission (Which specimens are sent to the PHL when STEC is detected?)**
    1. Isolates
    2. Stool/transport media
    3. Broth
    4. No specimens are sent to the PHL
24. **Salm\_submission (Which specimens are sent to the PHL when Salmonella is detected?)**
    1. Isolates
    2. Stool/transport media
    3. Broth
    4. No specimens are sent to the PHL
25. **Shig\_submission (Which specimens are sent to the PHL when Shigella is detected?)**
    1. Isolates
    2. Stool/transport media
    3. Broth
    4. No specimens are sent to the PHL
26. **Vib\_submission (Which specimens are sent to the PHL when Vibrio is detected?)**
    1. Isolates
    2. Stool/transport media
    3. Broth
    4. No specimens are sent to the PHL
27. **Yers\_submission (Which specimens are sent to the PHL when Yersinia is detected?)**
    1. Isolates
    2. Stool/transport media
    3. Broth
    4. No specimens are sent to the PHL
28. **List\_submission (Which specimens are sent to the PHL when Listeria is detected?)**
    1. Isolates
    2. Stool/transport media
    3. Broth
    4. No specimens are sent to the PHL
29. **FoodNet Hemolytic Uremic Syndrome Data Elements List**

There is no impact on burden due to the changes on these data elements. Changes were made to streamline and collect the level of detail needed to improve accuracy.

The following data elements have been added to the case report form:

1. **Atypical (Did the clinical providers confirm or suspect this is a case of atypical HUS based on laboratory testing or other clinical features?)**
   1. Yes; No
2. **Atypicaldetails (If yes, provide laboratory values or other pertinent information)**
   1. [Free text field]

**FluSurv-Net:**

The changes made to the FluSurv-NET forms under this non-substantive request will aid in improving surveillance efficiency and data quality to clarify the burden of disease and possible risk factors for disease. This information can be used to inform strategies for preventing disease and negative outcomes. Specifically, changes were made for clarification purposes, to assist data collectors in capturing data in a standardized fashion to improve accuracy.

Additionally, during the 2009 H1N1 pandemic, additional sites were added to the network to increase geographic representativeness and were funded through a cooperative agreement with the Council of State and Territorial Epidemiologists (CSTE). The four additional FluSurv-NET sites currently funded through CSTE Influenza Hospitalization Surveillance Project (IHSP) include Iowa, Michigan, Ohio and Utah. Together, the EIP and IHSP sites which contribute to FluSurv-NET surveillance include all 10 HHS regions and represent about 9% of the US population. During the 2009 H1N1 pandemic, FluSurv-NET data were used to identify groups at highest risk for influenza-associated hospitalizations (e.g., pregnant women during the 2009 H1N1 pandemic), mathematically model the morbidity and mortality burden of the influenza pandemic and provide data for several peer-reviewed journal articles describing seasonal and pandemic influenza among high risk groups in the population.

Upon verification of an influenza positive laboratory result and confirmation of residence within the pre-defined FluSurv-NET catchment area, each FluSurv-NET site conducts data abstraction of the medical chart and laboratory report to complete the project’s standardized case report form. Influenza vaccination status is an important piece of information that is used to evaluate the influenza vaccine program. To obtain as complete an influenza vaccine history as possible sites will use the following sources to collect this information: 1) review the patient’s medical chart, 2) consult the state vaccination registry, 3) contact the patient’s provider via fax or telephone and/or 4) contact the patient or their proxy. If providers and/or patients or proxies need to be contacted, a Consent Form and Provider Vaccination History Fax Form will be used to obtain influenza vaccination history. In the setting of the ongoing COVID-19 pandemic, it is important to understand the impact of COVID-19 on other respiratory viruses including influenza. During the 2022-23 influenza season, we will add an optional supplemental form to collect COVID-19 vaccination status on FluSurv-NET cases through automated linkage of cases to state immunization registries. To better understand how influenza testing practices may impact influenza hospitalization rates, all sites are also asked to conduct laboratory surveys to determine what processes are in place to conduct influenza testing and what types of influenza tests are performed at each participating FluSurv-NET laboratory at the beginning of each season. Additionally, FluSurv-NET sites will continue to routinely geocode cases using an EIP-wide protocol. The geocoded data will be linked to demographic information from the census so that social determinants of public health interest, including health disparities related to influenza, can be more completely described among cases. Data collection instruments used across all FluSurv-NET sites, including EIP and IHSP sites, are identical. Therefore, these IHSP sites are being added to this non-substantive request.

1. **FluSurv-NET Influenza Hospitalization Surveillance Case Report Form:** For the upcoming 2022-23 influenza season, we made minor changes to the case report form and will continue to harmonize data elements with those collected on the COVID-NET and RSV-NET CRFs. There is no impact on burden due to changes to this form. Changes include:

* For Section C, Enrollment Information, we updated the Race categories to follow the OMB requirements and allowing multiple race checkboxes to be selected: White, Black, Asian, Native Hawaiian or Other Pacific Islander, American Indian or Alaska Native, Multiracial, not otherwise specified, Not specified.
* For Section C, Enrollment Information, we deleted “Admission Type”.
* For Section H, Underlying Medical Conditions, we moved pregnancy status to Section C, Enrollment Information, and we changed the age range for women of child-bearing age from 15-44 years of age to 15-49 years of age.
* For section H, Underlying Medical Conditions, we added a new header category to capture “Mental Health Conditions” including Anxiety disorder, Bipolar disorder, Depression, and Schizophrenia spectrum disorder, which can pose as a higher risk for severe COVID-19 outcomes.
* For Section I, Bacterial Pathogens, we changed the timeframe for culture tests in question 1 to “Were any culture tests performed within 3 days prior to or 3 days following admission?”.
* For Section I, Bacterial Pathogens, we reordered questions for specimen source, date of specimen collection for culture, result of culture, pathogen identified, and *Staphylococcus aureus* type for clarity.
* For Section I, Bacterial Pathogens, we changed the options for result of culture: Positive, Negative, Unknown.
* For Section J, Viral Pathogens, we changed the timeframe for viral respiratory pathogen testing in question 1 to “Was patient tested for any of the following viral respiratory pathogens within 14 days prior to admission or ≤3days after admission?”.
* For Section K, Influenza Treatment, we deleted the question “Treatment End Date”.
* For Section M, Discharge Summary, we added a new discharge diagnosis checkbox “Mucormycosis”.

1. **COVID-19 Vaccination Status on FluSurv-NET Cases:** To better understand vaccination practices among persons hospitalized with influenza, and to assess the impact of COVID-19 vaccination status on FluSurv-NET cases, we have added a new optional section to the main FluSurv-NET case report form to collect COVID-19 vaccination data. All COVID-19 vaccination data will be obtained through automated linkage of Flu-Surv-NET cases to vaccination data from state immunization systems. This, this data collection will not impact burden for the overall project (see form)
2. **FluSurv-NET – Laboratory Survey:** Minimal changes are being made to the lab survey to update laboratory kit names and to clarify existing questions. There is no impact to burden due to changes to this form.

* For question 4a, we added new rapid antigen tests: BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B (Becton Dicinson & Co.), SARS-CoV-2 & Flu A/A Rapid Antigen Test (Roche)
* For questions 5a and 5b, we deleted molecular assay kit names that no longer exist: Cepheid Xpert Flu/RSV XC Assay, (Cepheid), Verigene Respiratory Virus Nucleic Acid Test (Nanosphere, Inc), Verigene Respiratory Virus Plus Nucleic Acid Test (RV+), (Luminex)
* For questions 5a and 5b, we added new molecular assay kit names: Alinity M Resp-4 Plex Assay (Abbott), Aptima SARS-CoV-2/Flu/A/B,
* For questions 5a and 5b, we renamed the FilmArray kit names to BioFire kit names manufactured by Biomerieux.
* For questions 6a, 6b, and 7, we added a new checkbox “Rapid Molecular Assay (e.g. RT-PCR, NAAT) – dualplex/multiplex”.

1. **Patient/Proxy Influenza Vaccination Phone Script and Consent Form (Pediatric/Adult) in English and Spanish**

The Spanish form has been deleted because it is used exceedingly rarely. Not sure it makes sense to count burden for this form separately. We either use the English or the Spanish Form or the Pediatric or Adult form for cases (we don’t use more than one of these for each case)

**HAIC:**

The changes made to all forms under this non-substantive request will aid in improving surveillance efficiency and data quality to clarify the burden of disease and possible risk factors for disease. This information can be used to inform strategies for preventing disease and negative outcomes. Specifically, changes were made for clarification purposes, to assist data collectors in capturing data in a standardized fashion to improve accuracy.

1. **Invasive MRSA Infection Case Report Form**

Justification

We are adding the variable planning region because one site is moving away from county designated areas to planning regions to maintain consistency with census area designations.

A review of SARS-CoV-2 data in the NNDSS system showed that most non-demographic variables were missing. Therefore, linking between iSA and NNDSS would not be useful and we opted to stop collecting NNDSS IDs in question 34a. We have also removed the SARS-COV-2 test type from question 34a. As the COVID-19 pandemic evolves, more and more people are able to use at-home and mail-in tests. Though they may verbally report the results to their clinicians, the type of at-home test is often not specified in medical records. Because reports of positive at home tests are less likely to be recorded in medical records if they occurred further back in time, we have changed the time period for reporting positive SARS-CoV-2 tests from 1 year to 90 days.

Description of Changes

Minimal changes are being requested for the 2023 Methicillin-resistant *Staphylococcus aureus* (MRSA) Case Report Form.  We are proposing the following changes: addition of the variable planning region, deletion of five NNDSS ID variables related to positive SARS-CoV-2 tests, deletion of the test type variable for the most recent positive SARS-CoV-2 test specimen collection, and addition of the first positive SARS-CoV-2 test date. Additionally, we have shortened the time period for question 34a from one year to 90 days.

Detailed Description of Changes

1. Changes to the 2022 Methicillin-resistant *Staphylococcus aureus* (MRSA) Case Report Form includes:
   1. Title
      * Changed the year from 2022 to 2023
   2. Question 2a
      * Added planning region
   3. Question 34a: SARS-CoV-2
      * Updated the time period of the question from 1 year to 90 days
      * Update wording of follow up question
      * Removed test type question
      * Added date of first positive test
      * Removed 5 NNDSS IDs
2. **Invasive MSSA Infections Case Report Form**

Justification

We are adding the variable planning region because one site is moving away from county designated areas to planning regions to maintain consistency with census area designations.

A review of SARS-CoV-2 data in the NNDSS system showed that most non-demographic variables were missing. Therefore, linking between iSA and NNDSS would not be useful and we opted to stop collecting NNDSS IDs in question 34a. We have also removed the SARS-COV-2 test type from question 34a. As the COVID-19 pandemic evolves, more and more people are able to use at-home and mail-in tests. Though they may verbally report the results to their clinicians, the type of at-home test is often not specified in medical records. Because reports of positive at home tests are less likely to be recorded in medical records if they occurred further back in time, we have changed the time period for reporting positive SARS-CoV-2 tests from 1 year to 90 days.

Description of Changes

Minimal changes are being requested for the 2023 Methicillin-sensitive *Staphylococcus aureus* (MSSA) Case Report Form.  We are proposing the following changes: addition of the variable planning region, deletion of five NNDSS ID variables related to positive SARS-CoV-2 tests, deletion of the test type variable for the most recent positive SARS-CoV-2 test specimen collection, and addition of the first positive SARS-CoV-2 test date. Additionally, we have shortened the time period for question 34a from one year to 90 days.

Detailed Description of Changes

1. Changes to the 2022 Methicillin-sensitive *Staphylococcus aureus* (MSSA) Case Report Form includes:
   1. Title
      1. Changed the year from 2022 to 2023
   2. Question 2a
      1. Added planning region
   3. Question 34a: SARS-CoV-2
      1. Updated the time period of the question from 1 year to 90 days
      2. Update wording of follow up question
      3. Removed test type question
      4. Added date of first positive test
      5. Removed 5 NNDSS IDs
2. **Extended-Spectrum Beta-Lactamase (ESBL)-Producing Enterobacterales / Invasive *Escherichia coli* (iEC) Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF)**

Justification for Changes:

The proposed changes will allow the Emerging Infection Program (EIP) sites to report positive SARS-CoV-2 tests for cases in the 90 days before DISC, rather than the prior year, and report the date of specimen collection for the first and most recent positive SARS-CoV-2 tests.

Description of Changes

For the 2023 Extended-Spectrum Beta-Lactamase (ESBL)-Producing Enterobacterales / Invasive *Escherichia coli* (iEC) Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF), we are proposing the following changes: 1) Update “Enterobacteriaceae” to “Enterobacterales”; 2) Update the language for Q25a and Q25b; and 3) Add the date of specimen collection for the first and most recent positive SARS-Cov-2 test in Q24b.

Detailed Description of Changes

1. Changes to the Extended-Spectrum Beta-Lactamase (ESBL)-Producing Enterobacterales / Invasive *Escherichia coli* (iEC) include:
   1. Q24a: Did the patient have a positive test(s) for SARS-CoV-2 (molecular assay, antigen, or other viral test, excluding serology) in the 90 days before or day of the DISC?
      1. Updated the text for this question
   2. Q24b: Specimen collection dates for positive tests in the 90 days before or day of DISC
      1. Updated the text for this question
      2. Modified the table to only collect the date of specimen collection for the first and most recent positive SARS-CoV-2 test
2. **Carbapenem-Resistant Enterobacterales (CRE) and Carbapenem-Resistant *Acinetobacter baumannii* (CRAB) Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF)**

Justification for Changes:

The proposed changes will allow the Emerging Infection Program (EIP) sites to report the planning region, specify when the CRAB case did not have any risk factors for Q23b, report positive SARS-CoV-2 tests for cases in the 90 days before DISC, rather than the prior year, and report the date of specimen collection for the first and most recent positive SARS-CoV-2 tests.

Description of Changes

For the 2023 Carbapenem-Resistant Enterobacterales (CRE) and Carbapenem-Resistant *Acinetobacter baumannii* (CRAB) Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF), we are proposing the following changes: 1) Update the year to “2023”; 2) Update “Enterobacteriaceae” to “Enterobacterales”; 3) Added “Planning region” question; 4) Add a “None” checkbox for Q23b; 5) Update the language for Q24a and Q24b; and 6) Added the date of specimen collection for the first and most recent positive SARS-Cov-2 test in Q24b.

Estimated Change in Burden:

The requested changes will have minimal impact on the burden of data collection and are anticipated to have no impact on the time expected to complete the case report form because these data are already included in the reports received to complete other sections of the case report form.

Detailed Description of Changes

1. Changes to the Carbapenem Resistant Enterobacteriaceae (CRE)/ Carbapenem Resistant *A. baumannii* (CRAB) Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form include:
   1. Q2a: County
      1. Updated the question number from 2 to 2a.
   2. Q2b: Planning region
      1. Added this question.
   3. Q23b:Risk factors in the 7 days before the DISC:
      1. Added a checkbox for “none”
   4. Q24a: Did the patient have a positive test(s) for SARS-CoV-2 (molecular assay, antigen, or other viral test, excluding serology) in the 90 days before or day of the DISC?
      1. Updated the text for this question
   5. Q24b: Specimen collection dates for positive tests in the 90 days before or day of DISC
      1. Updated the text for this question
      2. Modified the table to only collect the date of specimen collection for the first and most recent positive SARS-CoV-2 test
2. **CDI Case Report Form and Treatment Form**

**Justification**

For the 2023 *Clostridiodies difficile Infection* (CDI) Surveillance Emerging infection program Case Report Form (CRF), we are proposing several changes.

We will be adding a question about planning regions because one of our surveillance areas (Connecticut) is transitioning from counties to planning regions as county equivalents in 2023. We will be modifying two questions about testing for SARS-CoV2 to reduce the time period referenced in the question from one year to 90 days, removing a question about test type and adding an additional question about the first positive test in that 90 day period. We’re also removing a question that asked about NNDSS IDs. We will also be moving the SARS-CoV-2 testing fields and the COVID-NET ID field earlier in the form and will renumber several questions accordingly.

The requested changes will have minimal impact on the burden of data collection and are anticipated to have no impact on the time expected to complete the case report form.

**Description of Changes**

 The changes to the 2023 *Clostridiodies difficile* Infection (CDI) Surveillance Emerging infection program Case Report Form (CRF) include:

* Modifications of existing questions:
  + Question 6a. County
    - Changed question number
  + Question 36. Did the patient have a positive test(s) for SARS-CoV-2 (molecular assay, antigen, or other viral test; excluding serology) in the 90 days before or day of the DISC?
    - Changed question number
    - Changed time period of question from one year to 90 days
    - Changed wording to amend the tests under consideration
  + Question 36a. [Specimen collection dates for positive tests in the 90 days before or day of DISC] – Most recent positive test
    - Reworded
    - Changed time period of question from one year to 90 days
  + Question 38. Previous unique CDI episode
    - Changed question number
  + Question 39. Any recurrent C. diff+ episodes following this incident C. diff+ episode?
    - Changed question number
  + Question 39a. If YES, Date of first recurrent specimen
    - Changed question number
  + Question 40. CRF status
    - Changed question number
  + Question 41. Initials of SO
    - Changed question number
  + Question 42. Date of abstraction
    - Changed question number
* Addition of two questions
  + Question 6b. Planning region
  + Question 36a. [Specimen collection dates for positive tests in the 90 days before or day of DISC] - First positive test
* Removal of two questions
  + [If YES, complete below for most recent positive test for SARS CoV-2 in the year before or date of the DISC] - Test type
  + NNDSS IDs

1. **HAIC CDI Surveillance Officers Survey**

Justification:

We are requesting to change the wording of four questions to clarify that the survey is only capturing data on surveillance practices in 2022. There are no other changes to the survey. The requested changes will not change the burden of data collection for each response.

Description of Changes:

Changes to the CDI Surveillance Officers Survey Include:

Question 2. In 2022, did any laboratories drop out of participation?

* Changed year to 2022 to reflect change in survey year

Question 3. In 2022, did you identify any additional laboratories inside or outside of your catchment area which identify *C.diff* assays from persons who are residents of your catchment area?

* Changed year to 2022 to reflect change in survey year

Question 10. Did your site complete a physician/outpatient provider survey in 2022?

* Changed year to 2022 to reflect change in survey year

Question 13. For each facility that treated a case in 2022, please provide the following

* Changed year to 2022 to reflect change in survey year

1. **Annual Survey of Laboratory Testing Practices for *C. difficile* Infections**

Justification and Description of Changes

The primary change to this version of the survey is a consolidation of seven individual questions about current and former laboratory testing methodology into a single table with five columns; this change better reflects how survey respondents think about laboratory testing practices and will decrease the complexity and increase the quality of the resulting data. Note that this consolidation is listed in the description and crosswalk as a removal of the existing questions and an addition of new questions – there’s no direct way to compare. We are also making changes to the response options to a question about stool rejection policies to decrease the complexity there as well. Additionally, we’ve changed the year referenced in all questions to be 2022 instead of 2021 to reflect the change in the survey year. Finally, we’ve removed three questions about supply and staff shortages because the data re no longer needed. We expect that the burden will decrease by two minutes per response due to these changes all together.

* Modifications of existing questions:
  + Was this a new laboratory in 2022?
    - Changed time period of question
  + Did this lab participate in surveillance in 2022?
    - Changed time period of question
  + How often did you receive line lists from this lab in 2022?
    - Changed time period of question
  + How did you receive line lists from this lab in 2022?
    - Changed time period of question
  + Did you receive specimens from this lab in 2022?
    - Changed time period of question
  + Types of facilities in your catchment area served by this lab in 2022 (select all that apply):
    - Changed time period of question
  + 1. Did your laboratory ever send specimens off-site for *Clostridioides difficile* testing in 2022?
    - Changed time period of question
  + 3a. Which EIA test kit was used by your laboratory in 2022?
    - Changed time period of question
  + 3b. Which Nucleic Acid Amplification test was used by your laboratory in 2022?
    - Changed time period of question
  + 4a. If your laboratory used a multiplexed molecular diagnostic (e.g., Biofire Filmarray GI Panel, Luminex xTAG GPP) to test for several GI pathogens in 2022, did your laboratory suppress the *C. difficile* result so that clinicians could not see it?
    - Changed time period of question
  + 4b. If your laboratory used a multiplexed diagnostic in 2022 and the result was suppressed, where does the suppression occur?
    - Changed time period of question
  + 5a. If your laboratory used a nucleic acid amplification test (NAAT) (e.g., Cepheid Xpert *C. difficile*) as first line testing *followed* by a toxin EIA test (whenever NAAT result is positive) in 2022, did your laboratory suppress the positive NAAT result so that clinicians could not see it?
    - Changed time period of question
  + 5b. If your laboratory used NAAT as first line testing *followed* by confirmatory toxin EIA testing in 2022, and both the NAAT and toxin EIA results were released to the clinician, did your laboratory provide any comments to help the clinician interpret the test results (e.g., NAAT-positive only result might represent colonization, etc.)?
    - Changed time period of question
  + 6. What are the LOINC or internal testing codes associated with the tests your lab used in 2022 (e.g. LOINC codes 13957-6, 34713-8, or 54067-4)?
    - Changed time period of question
  + 7. Did your lab have a policy to reject stool specimens for *C. difficile* testing in 2022?
    - Changed time period of question
    - Changed response options
    - Renumbered question
  + 7a. Did your rejection policy for stool specimens change between January 1, 2022 and December 31, 2022?
    - Changed time period of question
    - Renumbered question
  + 8. How many stool samples did you test for *C. difficile* each month in 2022?
    - Changed question number
    - Renumbered question
* Removed:
  + 2. What type and order of testing was routinely used by your laboratory in standard testing for C. difficile on December 31, 2021?   
     1st line of testing: \_\_\_\_\_\_\_\_ 2nd line of testing: \_\_\_\_\_\_\_\_ 3rd line of testing: \_\_\_\_\_\_\_\_
  + 2a. Which specimens were used during your 2nd line of testing?
  + 2b. Which specimens were used during your 3rd line of testing?
  + 2c. Did your laboratory perform any onsite testing for C. difficile outside of your normal testing algorithm in 2021?
  + 7a. In 2021, did your laboratory experience any shortages in supplies, reagents, and/or test kits for performing C. difficile testing (e.g., NAAT or EIA reagents, swabs)?
  + 7b. If your laboratory experienced a supply shortage for C. difficile testing in 2021, how did the shortage affect your laboratory’s ability to perform C. difficile testing?
  + 7c. In 2021, did your laboratory experience a high demand for COVID-19 testing that limited the availability of staff (e.g., reduced staffing or work time) or the use of equipment to perform C. difficile testing?
  + 8. Did your lab testing algorithm for C. difficile change between January 1, 2021 and December 31, 2021?
  + What date did this change occur? \_\_\_\_\_\_ / \_\_\_\_\_\_ / \_\_\_\_\_
  + 8a. What was the previous type and order of testing performed by your lab in 2021 before it changed its testing algorithm?  
     1st line of testing: \_\_\_\_\_\_\_\_ 2nd line of testing: \_\_\_\_\_\_\_\_ 3rd line of testing: \_\_\_\_\_\_\_\_
  + 8b. Which specimens were used during your 2nd line of testing?
  + 8c. Which specimens were used during your 3rd line of testing?
* Added table
  + Headings
    - Did your laboratory use this testing method for Clostridioides difficile (C. difficile) in 2022?
    - Specify when you used this test (e.g. at provider request, for outpatients, for inpatients with a length of stay > 3 days, for every specimen received)
    - Did you use this testing method in this way for all of 2022?
    - What date did you change?
    - What test did you use in this situation before this date?
  + Rows
    - GDH and EIA for toxin simultaneously, followed by NAAT for discordant results
    - NAAT, followed by EIA for toxin and GDH simultaneously if NAAT positive
    - NAAT, followed by EIA for toxin if NAAT positive
    - GDH, followed by NAAT if GDH positive
    - GDH and EIA for toxin simultaneously, followed by cell cytotoxicity neutralization assay (cytotoxin)
    - GDH and EIA for toxin simultaneously
    - EIA for toxin
    - Cell cytotoxicity neutralization assay (cytotoxin)
    - C. difficile-specific NAAT (e.g., PCR, LAMP)
    - Multiplex GI panel NAAT
    - Toxigenic culture (C. difficile culture followed by detection of toxins)
    - Other (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **HAIC Candidemia Case Report** *(Attachment #14)*

Overall Description and Justification of Changes

Minimal changes are being requested for the 2023 Candidemia Case Report Form (CRF). We are proposing the following changes: 1) removal of six questions (including two sub-questions), 2) addition of six new questions (including two sub-questions), 3) addition of response options for two questions, 4) removal of a response option for one question, 5) minor rewording of the question and/or responses for four questions to increase clarity, and 6) subsequent renumbering of other questions as a result of removing and adding questions throughout the case report form.

We are removing the specimen collection site because this level of detail isn’t needed since our surveillance system only focuses on bloodstream infections. The question pertaining to C. diff infections is infrequently reported and has already been captured for several years with no major trend changes. We are also removing two questions about immunomodulatory drugs. Both were originally added to capture treatment for COVID-19 but these questions don’t broadly capture the wide breadth of available immunomodulatory drugs. One version of two invasive mechanical ventilation questions is also being removed on the case report form. Both questions capture the same condition but have two different time frames (2 days and 30 days before the date of incident specimen collection). We are removing the version with a 30-day time frame since the 2-day time frame is a lesser burden to collect.

Six new questions are being added to capture CIDT use, GI ostomies and echocardiograms as potential risk factors, and use of dilated fundoscopic eye exams for patients with candidemia. These questions are being added based on feedback from data abstractors and current literature. Two questions will now have a “Not applicable” or “None of the above” option to better account for cases don’t fall into the other response options. A response option under the drug substance’s mode of delivery question is being removed since it’s infrequently reported in candidemia patients and does not provide enough data for any sort of analyses. For questions with minor wording changes, these changes were made to increase clarity based on feedback from data abstractors.

The requested changes to the data collection form are not estimated to increase the time required for data collection or the overall burden estimate. We have updated the number of records in the burden table, resulting in no change in burden hours from the previous year.

Detailed Description of Changes

Changes to the Candidemia Case Report Form for 2023 include:

1. Title:
   * + Year changed from 2022 to 2023
2. Footnotes:
   * + Changed version year to 2023
     + Changed last updated date from ‘7/17/2021’ to ‘7/29/2022’
3. Question 23: Incident specimen collection site
   * + Removed question
4. Question 24-25
   * + Changed question number by 1
5. New Questions: CIDT, test type, result
6. Questions 30 and 30a: *C. diff* infection
   * + Removed questions
7. Question 31: Types of infection
   * + Changed to question number 30
     + Changed question wording from “following types of infection/colonization” to “following types of infection”
     + Added to and edited response options according to the following:
       1. Changed “abdominal” to “abdominal infection”
       2. Removed “GI tract” category option
       3. Changed “Candiduria” to “Urinary tract infection”
       4. Changed “Skin lesions/wounds” to “Skin/wound infection”
       5. Changed “Pulmonary” to “Pulmonary infection”
       6. Removed “Respiratory specimen with *Candida*” category option
       7. Changed “CNS involvement” to “CNS infection”
       8. Changed “Eyes (endophthalmitis or chorioretinitis)” to “Eyes” (and added separate category options for “Endophthalmitis” and “Chorioretinitis”)
8. Question 32-34
   * + Changed question number by 1
9. Question 35: Invasive mechanical ventilation
   * + Removed question since mechanical ventilation is already collected under another question with a shorter timeframe (2 days vs 30 days)
10. Question 36-37a
    * + Changed question number by 2
11. Question 38: ICD-10 codes
    * + Changed to question number 36
      + Added “Not applicable (i.e., patient not hospitalized)” response option
12. Question 39-44
    * + Changed question number by 2
13. Question 45: Other substances
    * + Removed “Skin popping” mode of delivery option
14. Question 46-50
    * + Changed question number by 2
15. New Question: GI tract ostomies
16. Question 51-53a
    * + Changed question number by 1
17. Question 53b: CVC removed
    * + Changed to question number 52b
      + Changed the wording of the question for clarification from ‘on the day of’ to ‘in the 2 days before’
18. Question 54-55
    * + Changed question number by 1
19. Question 56: Positive SARS-CoV-2 test result
    * + Changed the wording of the question for clarification from “(molecular assay, serology, or other confirmatory test)” to “(molecular assay, antigen, or other confirmatory test, excluding serology)”
20. Question 56a-58
    * + Changed question number by 1
21. Question 58a: Reason steroids were administered
    * + Changed to question number 57b
      + Changed the wording of the response option for clarification from ‘Steroid(s) given during hospitalization associated with candidemia episode, prior to *Candida* DISC’ to ‘Steroid(s) given, prior to *Candida* DISC, during hospitalization associated with candidemia episode’
      + Added “None of the above” response option
22. Question 59: Total parenteral nutrition
    * + Changed question number to 58
23. Question 60 and 60a: Immunomodulatory drugs
    * + Removed questions
24. Questions 61 - 63
    * + Changed question number by 2
25. New question: Echocardiogram
26. New question: Dilated fundoscopic eye exam
27. **Laboratory Testing Practices for Candidemia Questionnaire**

Overall Description and Justification of Changes

Minimal changes are being requested for the 2023 Candidemia Lab Survey. We are proposing the following changes: 1) addition of three new questions, 2) removal of two questions, 3) minor rewording of response options for 18 questions (including sub-questions), 4) minor rewording of 12 questions, and 5) renumbering of four questions due to the addition of new questions.

There were 2 new questions added assessing antifungal susceptibility testing (AFST) methods for Amphotericin B, how AFST results are reported when no breakpoints are available, and if laboratories are tracking susceptibility trends for *Candida* isolates tested in their lab. Two questions were removed. These questions assessed for what species Vitek is used for AFST and how categorical interpretations are determined. With the addition of the three new questions which incorporates these elements, the importance of collecting this additional information isn’t needed. There were 11 questions where “reflexively” was removed entirely or replaced with “always” for clarity. For the remaining questions where we have proposed minor changes to the question wording or response options, these changes were made to clarify question intent, accommodate changes in question numbers and/or update skip logic.

The requested changes to the survey tool are estimated to increase the time required for data collection by 1 minute per response. The new estimate is 14 minutes per response.

Detailed Description of Changes

Changes to the Candidemia Laboratory Survey for 2023 include:

1. Title:
   * + Year changed from 2022 to 2023
2. Question 1: Laboratory type
   * + Minor change to question wording (‘What kind of laboratory is this facility?’ to ‘What kind of laboratory is this?’)
3. Question 2: Blood cultures from LTCFs
   * + Minor change to question wording (‘Does this facility...’ to ‘Does this laboratory...’)
4. Question 5: Fungal cultures
   * + Minor change to question wording (‘What is the approximate volume of any type of fungal cultures performed annually in your laboratory?’ to ‘What is the approximate volume of fungal cultures ordered and performed annually in your laboratory for any specimen type?’)
5. Question 6: Fungal blood cultures
   * + Minor change to question wording (‘What is the approximate volume of fungal cultures performed annually in your laboratory?’ to ‘What is the approximate volume of fungal blood cultures ordered and performed annually in your laboratory?’)
6. Question 7: Fungal blood cultures
   * + Minor change to skip logic (‘-------- If No, SKIP TO QUESTION 15 --------’ to ‘-------- If No, SKIP TO QUESTION 18 --------’)
7. Question 10: Chromagar
   * + Minor change to question wording (‘Does this laboratory routinely use Chromagar…’ to ‘Does this laboratory routinely use chromogenic agar…’)
8. Question 11a: Species-level identification for blood isolates
   * + Minor change to wording of response options (‘Yes, reflexively’ to ‘Yes, always’)
9. Question 11b: Species-level identification for other normally sterile body site isolates
   * + Minor change to wording of response options (‘Yes, reflexively’ to ‘Yes, always’)
10. Question 11c: Species-level identification for abdominal isolates
    * + Minor change to wording of response options (‘Yes, reflexively’ to ‘Yes, always’)
11. Question 11d: Species-level identification for respiratory isolates
    * + Minor change to wording of response options (‘Yes, reflexively’ to ‘Yes, always’)
12. Question 11e: Species-level identification for urine isolates
    * + Minor change to wording of response options (‘Yes, reflexively’ to ‘Yes, always’)
13. Question 11f: Species-level identification for other isolates
    * + Minor change to wording of response options (‘Yes, reflexively’ to ‘Yes, always’)
14. Question 13: Culture independent diagnostic tests (CIDTs)
    * + Minor change to question wording (‘CIDT’ to ‘CIDTs’)
      + Minor change to skip logic (change instructions from ‘got to q14’ to ‘go to Q14’ and ‘got to q17’ to ‘go to Q17’)
15. Question 14: T2Candida Panel
    * + Minor change to skip logic (change instructions from ‘got to 12a’ to ‘go to Q14a’ and ‘go to 13’ to ‘go to Q15’)
16. Question 14b: T2Candida Panel culture
    * + Minor change to wording of question (‘If Yes, does this lab culture blood if you get a positive result on T2Candida Panel?’ to ‘If Yes and you get a positive result on T2Candida Panel, does this lab culture the blood to obtain an isolate?’)
      + Minor change to wording of response options (‘Yes, reflexively’ to ‘Yes, always’)
17. Question 15: BioFire
    * + Minor change to skip logic (change instructions from ‘go to 15a’ to ‘go to Q15a’ and ‘go to 16’ to ‘go to Q16’)
18. Question 15b: BioFire culture
    * + Minor change to wording of question (‘If Yes, does this lab reflexively culture blood if you get a positive result on BioFire?’ to ‘If Yes and you get a positive result on Biofire, does this lab culture the blood to obtain an isolate?’)
      + Minor change to wording of response options (‘Yes, reflexively’ to ‘Yes, always’)
19. Question 19: BioFire culture
    * + Minor change to skip logic (added ‘(go to Q20)’ to first response option and ‘(-------- If not an on-site laboratory, QUESTIONNAIRE COMPLETE --------)’ to second response option)
20. Question 21: AFST methods
    * + Changed question wording (‘What methods are used for AFST?’ to ‘What methods are used for AFST, excluding Amphotericin B?’)
      + Minor change to wording of response options
21. Question 21a: Species tested with Vitek for AFST
    * + Removed question
22. New question: AFST methods for Amphotericin B
    * + Added question 22 (‘What methods are used for AFST of Amphotericin B?’)
23. Question 22: AFST proficiency testing requirements
    * + Changed number of question to 23
24. Question 23: AFST results reported
    * + Changed number of question to 24
      + Changed question wording (‘How are results of AFST reported?’ to ‘How are results of AFST reported when breakpoints are available?’)
25. Question 23a: Categorical interpretation determination
    * + Removed question
26. New question: AFST results reported when no breakpoints
    * + Added question 25 (‘How are results of AFST reported when breakpoints aren’t available?’)
27. Question 24: Isolates types where AFST is performed automatically
    * + Changed number of question to 26
      + Changed question wording (‘…antifungal susceptibility testing (AFST) performed automatically/reflexively?’ to ‘…antifungal susceptibility testing (AFST) performed automatically?’)
28. Question 25: AFST performed for *Candida* spp.
    * + Changed number of question to 27
      + Minor change to question wording (‘How is AFST performed…’ to ‘When is AFST performed…’)
29. Question 25a: *C. albicans*
    * + Changed number of question to 27a
      + Updated skip logic (‘*Go to 21ai’* to *Go to 27ai’*)
      + Minor change to wording of response options (‘Performed automatically/reflexively’ to ‘Performed automatically’)
30. Question 25ai: AFST performed – *C. albicans*
    * + Changed number of question to 27ai
      + Minor change to wording of question (‘Drugs for which AFST is performed on *C. abicans’* to ‘Drugs for which AFST is performed on *C. albicans’*)
31. Question 25b: *C. glabrata*
    * + Changed number of question to 27b
      + Updated skip logic (‘*Go to 21bi’* to *Go to 27bi’*)
      + Minor change to wording of response options (‘Performed automatically/reflexively’ to ‘Performed automatically’)
32. Question 25c: AFST results reported – *C. parapsilosis*
    * + Changed number of question to 27c
      + Updated skip logic (‘*Go to 21ci’* to *Go to 27ci’*)
      + Minor change to wording of response options (‘Performed automatically/reflexively’)
33. Question 25d: AFST results reported – Other *Candida* spp.
    * + Changed number of question to 27d
      + Updated skip logic (‘*Go to 21di’* to *Go to 27di’*)
      + Minor change to wording of response options (‘Performed automatically/reflexively’ to ‘Performed automatically’)
34. New question: Tracking susceptibility trends
    * Added question 28 (‘Is this laboratory tracking susceptibility trends for *Candida* spp. isolates tested in your lab?’)
35. **HAIC** **Invasive Staphylococcus aureus Supplemental Surveillance Officer Survey**

Justification

Minor wording change to the first question in the COVID impact section was made to reflect the fact that some sites have had impacts beyond just delays in surveillance which are important for the program to document. We also updated the first question of the CDC responsibilities section to reflect staff turnover at CDC.

Description of Changes

We are requesting slight revisions to the wording of two questions for the 2022 invasive *Staphylococcus aureus* surveillance officer survey. The requested changes will have no impact on the burden of data collection.

Detailed Description of Changes

1. Changes to the 2022 invasive *Staphylococcus aureus* Surveillance Officer survey include:
   * 1. COVID-19 Impact section question 1
        1. Updated question wording
     2. CDC responsibilities question 1
        1. Changed question wording to reflect staff changes
2. **Healthcare-Associated Infections Community Interface (HAIC) *Staphylococcus aureus* Laboratory Survey: Use of Nucleic Acid Amplification Testing (NAAT)**

Justification

We have split a series of five questions about laboratory methods for detecting *S. aureus* from sterile site specimens into two series – one for each of two different testing methods – and added headers to these questions to better explain what we are referring to in each section. This improved layout will help reduce confusion for respondents and make survey analysis more straightforward. The addition of the question(s) about tests appearing on the surveillance line list and the question requesting an explanation for why isolates are not obtained were added because there is concern that the program may be undercounting cases as laboratory testing advances away from pure culture. The answers to these new questions will allow us to monitor if/when labs move away from our established isolate-based case definition and better understand the impact on our program.

Description of Changes

We are requesting to ask a series of 5 existing questions twice, once for each of two testing methods. Due to skip patterns, we do not expect that respondents will respond to both set of questions as most only use one of the two testing methods. Additionally, we would like to add three questions; given the skip patterns it is likely most respondents will only answer two of these new questions. We also have added two section headers and updated the wording of 4 questions to increase question clarity. Three questions have updated response options. Finally, we are requesting the removal of one question. The requested changes will have minimal or no impact on the burden of data collection.

Detailed Description of Changes

1. Changes to the 2023 invasive *Staphylococcus aureus* laboratory survey include:
   1. Question 2a
      1. Updated question number
   2. Question 3
      1. Updated question number
   3. Question 3a
      1. Updated question number
   4. Section header for Q4
      1. Added a section header for question 4
   5. Question 4 and 5d
      1. Question 3c from previous survey split into two questions
   6. Question 4a
      1. Added question
   7. Question 4b
      1. Updated question number
      2. Updated question wording/responses
   8. Question 4c
      1. Updated question number
      2. Updated question wording/responses
   9. Questions 4d and 5b
      1. Question 3b from previous survey split into two questions
      2. Added one new response option
   10. Question 4e
       1. Added question
   11. Questions 4f and 5e
       1. Question 3d from previous survey split into two questions
   12. Questions 4g and 5f
       1. Question 3e from previous survey split into two questions
   13. Questions 4h and 5g
       1. Question 3f from previous survey split into two questions
   14. Section header for Q5
       1. Added section header for question 5
   15. Question 5
       1. Updated question number
       2. Updated question wording
   16. Question 5a
       1. Updated question number
       2. Updated question wording
   17. Question 5c
       1. Added question
   18. Question 4
       1. Removed question