

Explanation for Program Changes or Adjustments

There are 13 total forms being changed as a part of this non substantive change request. This change request includes minor revised language, formatting and rewording to improve clarity and readability of the data collection forms.

In response to the Notice of Decision published in the Federal Register on March 29, 2024 regarding the update of the Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15), the EIP programs (ABCs, FoodNet, FluSurv-NET, and HAIC) under OMB 0920-0978 will comply with the updated standards set for Federal data on Race and Ethnicity by and/or before the March 2029 deadline.

FluSurv-NET has incorporated the updated race and ethnicity (R/E) data standards in their data collection forms as part of a recently approved Revision. The remaining 3 EIP programs (ABCs, FoodNET, and HAIC) will update the R/E variable in a subsequent Non-Substantive Change Request by and/or before the March 2029 deadline in efforts to maintain data integrity. Maintaining data integrity and consistency is paramount to quality data analysis therefore, waiting to incorporate the race and ethnicity changes for ABCs, FoodNET and HAIC would ensure that the race ethnicity data variable will possess consistent parameters and will be easier for analysis. Within this Change Request a few of the data collection tools have updated the R/E variable. The remaining data collection tools will be ultimately updated before the March 2029 deadline.

Details of each collection instrument are as follows:

ABCs:

This non-substantive change request includes minor proposed changes to 3 approved data collection tools (form/s) detailed below:

Approved Forms:

- 1) ABC.100.1 ABCs Case Report Form
- 2) ABC.100.2 ABCs Invasive Pneumococcal Disease in Children and Adults Case Report Form
- 3) ABC.100.5 ABCs Neonatal Infection Expanded Tracking Form

ABCs Case Report Form (ABC.100.1)		
Type of Change	Itemized Changes / Justification	Impact to Burden
Revision	2025 Active Bacterial Core surveillance (ABCs) Case Report Justification: Updated header to reflect surveillance year	No change to burden
Revision	CDC logo Justification: Updated HHS/CDC logo with the latest CDC logo	No change to burden
Revision	REV 2024 Justification: Updated footnote to reflect last year form was updated	No change to burden
Addition/Revision/Deletion	11. Race and/or Ethnicity (Check all that apply) ☐ Unknown ☐ American Indian or Alaska Native ☐ Asian ☐ Black or African American ☐ Hispanic or Latino ☐ Middle Eastern or North African ☐ Native Hawaiian or Pacific Islander ☐ White Justification: Combined questions 11a. Ethnic origin and 11b. Race to follow recent update to OMB standards for collecting race and ethnicity data.	No change to burden
Revision	18a. Where was the patient a resident at time of initial culture? ☐ Correctional or detention facility Justification: Revised response option from "Incarcerated" to "Correctional or detention facility" to be in line with CDC inclusive language.	No change to burden
Revision	21. Type of insurance: (Check all that apply) ☐ Correctional or detention facility	No change to burden

	Justification: Revised response option from “Incarcerated” to “Correctional or detention facility” to be in line with CDC inclusive language.	
Addition/Revision/Deletion	27. Underlying causes or prior illnesses (check all that apply) ☐ Any complement inhibitor – N.men. only (specify): _____ Justification: Revised response options from “Eculizumab (Soliris)” and “Ravulizumab (Ultomiris)” to “Any complement inhibitor” with an option to specify complement inhibitor to better capture information on additional complement inhibitors that are currently available and will become available in the future.	No change to burden
Revision	Q27b. Smoking (Check all that apply) ☐ None documented Justification: Updated wording of the response option “None” to “None documented” for clarification purposes	No change to burden
Revision	Q27c. Alcohol abuse ☐ None documented Justification: Updated wording of the response option “No” to “None documented” for clarification purposes	No change to burden
Revision	Q27d. Other substances (Check all that apply) ☐ None documented Justification: Updated wording of the response option “None” to “None documented” for clarification purposes	No change to burden
ABCs Invasive Pneumococcal Disease in Children and Adults Case Report Form (ABC.100.2)		
Type of Change	Itemized Change / Justification	Impact to Burden
Revision	CDC logo Justification: Updated HHS/CDC logo with the latest CDC logo	No change to burden
Revision	Pneumococcal conjugate vaccine name ☐ Prevnar™ (PCV7) ☐ Prevnar 13™ (PCV13) ☐ Vaxneuvance™ (PCV15) ☐ Prevnar 20™ (PCV20)	No change to burden

	☐ CAPVAXIVE™ (PCV21) ☐ Other _____ ☐ Unknown Justification: Added CAPVAXIVE™ (PCV21) as an additional response option. ACIP recommended PCV21 as an option to the current PCV recommendation in June 2024.	
Revision	RSV vaccine RSVpreF (ABRYSVOTM, mRESVIA, or AREXVY) Justification: Updated label for RSV vaccine to include recently approved RSV vaccine, mRESVIA	No change to burden
Revision	9-2024 Justification: Updated footnote to reflect last month and year form was updated	No change to burden
ABCs Neonatal Infection Expanded Tracking Form (ABC.100.5)		
Revision	CDC logo Justification: Updated HHS/CDC logo with the latest CDC logo	No change to burden
Revision	09/2024 Justification: Updated footnote to reflect last month and year form was updated	No change to burden
Addition/Revision	Date & Time of positive culture Justification: Added field to record time of culture in addition to the existing date of culture question to be able to capture timing of disease onset more precisely.	No change to burden
Deletion	6. Outcome Justification: Removed outcome. It's already covered in another question on a different form.	1 minute decrease
Addition	6. Was patient admitted to the ICU during hospitalization? If yes, date and time of admission and discharge. Justification: This question was added to get a better understanding timing and severity of disease onset.	1 minute increase

FoodNet

This non-substantive change request includes minor proposed changes to 1 approved data collection tools (form/s) detailed below:

Approved Forms:

4) FN200.1-FN200.8 (FoodNet Active Surveillance Data Elements List)

FoodNet Active Surveillance Data Elements List		
Type of Change	Itemized Changes / Justification	Impact to Burden
Removed the following <i>Campylobacter</i> species specific variables: SpeciesClinic, SpeciesSPHL	FoodNet discontinued data collection and transmission for <i>Campylobacter</i> cases without an isolate at the state public health lab beginning in 2024. Data will continue to be collected and transmitted for <i>Campylobacter</i> cases with an isolate at the state public health lab.	Reduced burden for <i>Campylobacter</i> cases without an isolate.
Removed the following eCEA variables: AR_antacid_any, AR_antacid_any_1, AR_antacid_any_2, AR_antacid_any_3, AR_Diet_veal, AR_probiotic_use30	eCEA data transmission to CDC will be reduced, reducing the number of variables transmitted to CDC for <i>Salmonella</i> , <i>Campylobacter</i> , and <i>Shigella</i> cases.	Reduced burden for <i>Salmonella</i> , <i>Campylobacter</i> , and <i>Shigella</i> cases.
Removed the following CEA variables: CEA_Beef, CEA_Chicken, CEA_Dairy, CEA_Dog, CEA_Eggs, CEA_Fish, CEA_Lettuce, CEA_Live_poultry, CEA_Milk_raw, CEA_Pig, CEA_Pork, CEA_Reptile_amphib, CEA_Ruminants, CEA_Seafd, CEA_Turkey.	CEA data transmission to CDC will be discontinued, reducing the number of variables transmitted to CDC for <i>Salmonella</i> and <i>Campylobacter</i> .	Reduced burden for <i>Salmonella</i> and <i>Campylobacter</i> cases.
Value set change for variable DxO157TestType	The value of “Meridian ImmunoCard STAT! E. coli O157 Plus” was added for the variable DxO157TestType to assist data collectors in capturing data in a standardized fashion to improve accuracy,	No impact to burden.
Value set change for variable Pathogen	The value of “ETEC” was removed from the variable Pathogen, as Enterotoxigenic <i>E. coli</i> (ETEC) data transmission to CDC has been discontinued.	No impact to burden.

FluSurv-NET

This non-substantive change request includes minor proposed changes to 1 approved data collection tools (form/s) detailed below:

Approved Forms:

1) FSN 300.1 2024-25 Influenza Hospitalization Surveillance Network (FluSurv-NET) Case Report Form

Influenza Hospitalization Surveillance Network (FluSurv-NET) Case Report Form		
Type of Change	Itemized Changes / Justification	Impact to Burden
Non-substantive change (clarification)	D. Influenza Testing Results Test 1-4: (bolded text reflects added clarification) - Rapid Antigen - Standard/Rapid Molecular Assay - Viral Culture - Fluorescent Antibody - Method Unknown/Provider note only Justification - Maintained all existing options and added “Provider note only” to the existing “Method Unknown” to clarify this includes any influenza test results noted in the chart by a provider	No change to burden
Non-substantive change (clarification)	G. Admission and Patient History 1. Reason for admission (Select all that apply) Justification Allowing selection of any reason for admission to reduce burden on sites to make the determination of the reason for admission.	No change to burden
Non-substantive change (clarification)	J. Influenza Treatment 1. Did the patient receive treatment for influenza during the course of illness? - Yes - No - Unknown Justification - Added “during the course of illness” to the question to clarify the time frame during which to collect whether antiviral treatment was administered to be consistent with our instructions.	No change to burden
Non-substantive change	N. Pregnancy Information	No change to burden

(correction)	2. Total # of pregnancies to date that reached viable gestational age as of date of admission (Parity, P)” Justification • The definition for parity was previously incorrect, so it has been changed from “Total # of pregnancies to date that resulted in a live birth as a date of admission (Parity, P)” to “total # of pregnancies to date that reached viable gestational age as of date of admission (Parity, P)” to correctly describe parity.	
--------------	---	--

HAIC

This non-substantive change request includes minor proposed changes to 8 approved data collection tools (form/s) detailed below:

Approved Forms:

- 1) HAIC.400.1–Multi-Site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form
- 2) HAIC.400.4–Invasive *Staphylococcus aureus* Healthcare-Associated Infections Community Interface (HAIC) Case Report - 2025
- 3) HAIC.400.6–2024 HAIC Invasive *Staphylococcus aureus* Supplemental Surveillance Officer Survey
- 4) HAIC.400.7 - CDI Case Report and Treatment Form
- 5) HAIC.400.8 - Annual Survey of Laboratory Testing Practices for *C. difficile* Infections
- 6) HAIC.400.9 - HAIC- CDI Annual Surveillance Officers Survey
- 7) HAIC.400.11 HAIC Candidemia CRF
- 8) HAIC.400.12 Laboratory Testing Practices for Candidemia

HAIC.400.1 – HAIC- Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form (CRF)		
Type of Change	Itemized Changes / Justification	Impact to Burden
Administrative	2025 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Healthcare-Associated Infections Community Interface (HAIC) Case Report Form Changes: Updated year to 2025 Justification: Updated to reflect the surveillance year.	None
Administrative	Question 8. Race and/or Ethnicity (<i>Check all that apply</i>) Changes: - Combined questions 8a. Ethnic Origin and 8b. Race - Added an option for “Middle Eastern or North African” Justification: Updated to reflect new OMB Standards (Statistical Policy Directive No. 15)	None
Administrative	Question 12. Location of Specimen Collection: Changes: - Removed free-text field for “Other (Specify)” - Changed “Other (Specify)” to “Other” Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses.	None
Administrative/Language Modification & Addition of Response Options	Question 13. Where was the patient located on the 3rd calendar day before the DISC? Changes: - Changed “Incarcerated” to “Correctional or detention facility” - Added option for “Drug/alcohol rehabilitation” - Added option for “Not born yet”	None

	- Removed free-text field for “Other (Specify)” - Changed “Other (Specify)” to “Other” Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. The additional options offered on the form have been derived from analyzing previous free-text responses, aiming to standardize and streamline data collection. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses.	
Administrative/Language Modification & Addition of Response Options	Question 16. Patient Outcome: Changes: - Added an option for “Hospitalized > 1 year” - Removed free-text field for “Other (Specify)” - Changed “Other (Specify)” to “Other” - Added option for “Homeless” - Added option for “Correctional or detention facility” - Added option for “Drug/alcohol rehabilitation” Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. The additional options offered on the form have been derived from analyzing previous free-text responses, aiming to standardize and streamline data collection. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses.	None
Administrative/Language Modification & Addition of Response Options	Question 18. Underlying Conditions: (Neurologic Condition) Changes: - Neurologic Condition - Removed “Other (specify)” and free-text field - Added checkbox for “Paresis” - Added checkbox for “Spinal cord injury” - Skin Condition - Removed “Other (specify)” and free-text field - Add checkbox for “Blistering disease” - Add checkbox for “Eczema” - Add checkbox for “Psoriasis” Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. The additional options offered on the form have been derived from analyzing previous free-text responses, aiming to standardize and streamline data collection. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses.	None
Administrative/Language Modification & Deletion	Question 19. Substance Use: Changes: - Smoking - Changed “None” to “None	Decrease

	documented” - Alcohol Abuse - Changed “No” to “None documented” - Other Substances - Removed the table containing many options for various types of substance use and mode of delivery - Removed “During the current hospitalization, did the patient receive medication assisted treatment (MAT) for opioid use disorder?” - Added option for “Opioid use disorder” - Added option for “Injection drug use” - Changed “None” to “None documented” Justification: The changes from “None” or “No” to “None documented” are clarifications. Detailed questions about various types of substance use were removed because they were less relevant to routine surveillance. Replacing the substance use table with concise checkbox options for the two most relevant and frequent substances used and removing the question regarding MAT will streamline data collection.	
Administrative/Deletion	Question 24b. If Yes, check all antimicrobials used in the 30 days before the DISC: Changes: - Removed “Ceftizoxime” - Removed “Doripenem” Justification: These antimicrobial agents are infrequently reported and/or no longer available for use in the United States.	None
Deletion	Question 25a. 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? Changes: Removed the entire question Justification: The data collected through this question are now less important for routine surveillance.	Decrease
Deletion	Question 25b. Specimen collection dates for positive tests in the 90 days before or the day of the DISC: Changes: Removed the entire question Justification: The data collected through this question are now less important for routine surveillance.	Decrease
Deletion	Question 25c. COVID-Net case ID in the year before or day of DISC: Changes: Removed the entire question Justification: The data collected through this question are now less important for routine surveillance.	Decrease
Administrative	Questions 26–30 Changes:	None

	Updated to Questions 25–29 to reflect the removal of Questions 25a.–25c. Justification: Updated numbering is necessary to ensure a continuous count of questions.	
Administrative/Addition of a Response Option	Question 26b. (Formerly 27b.) If Yes, what testing method was used? Changes: Added “CARBA-5” as an option Justification: The use of this testing method assay has become more frequent in the U.S. warranting inclusion as a standard response option.	None
Administrative/Addition of a Response Option	Question 28. (Formerly 29.) Susceptibility Results: Changes: Added “Sulbactam/Durlobactam” Justification: In 2023, this drug combination was approved for use in the USA, therefore, has been added as a response option.	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	Invasive <i>Staphylococcus aureus</i> Healthcare-Associated Infections Community Interface (HAIC) Case Report - 2025 Changes: Updated year to 2025 Justification: Updated to reflect the surveillance year.	None
Administrative/Language Modification	Question 7 Sex at Birth: ☐ Male ☐ Female ☐ Unknown ☐ Check if transgender Changes: Use ‘transgender’ instead of ‘transgendered’ Justification: Grammatical correction	None
Administrative & Addition of a Response Option	Question 10. Race and/or Ethnicity (<i>Check all that apply</i>) Changes: - Combined questions 10. Race and 11. Ethnic Origin - Removed “Other” from “Native Hawaiian or Pacific Islander” checkbox - Added an option for “Middle Eastern or North African” Justification: Updated to reflect new OMB Standards (Statistical Policy Directive No. 15)	None
Administrative	Questions 11–15 Changes: Updated numbering of Questions 12–15a (numbering of prior form) to reflect the removal of Question 11.	None

	Justification: Updated numbering is necessary to ensure a continuous count of questions.	
Administrative	Question 17. Was incident specimen collected 3 or more calendar days after hospital admission? Changes: Removed references to MRSA in checkbox options Justification: The CRF captures MRSA <u>or</u> MSSA so the references to MRSA were not correct	None
Administrative	Question 19. Location of Specimen Collection Changes: - Removed free-text field for “Other (Specify)” - Changed “Other (Specify)” to “Other” Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses.	None
Administrative/Language Modification & Addition of a Response Option	Question 23. Where was the patient located on the 3rd calendar day before the DISC? Changes: - Changed “Incarcerated” to “Correctional or detention facility” - Added option for “Drug/alcohol rehabilitation” - Removed free-text field for “Other (Specify)” - Changed “Other (Specify)” to “Other” Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. The additional options offered on the form have been derived from analyzing previous free-text responses, aiming to standardize and streamline data collection. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses.	None
Administrative/Language Modification & Addition of Response Options	Question 29. Underlying Conditions: (Neurologic Condition and Skin Condition) Changes: - Neurologic Condition - Removed “Other (specify)” and free-text field - Added checkbox for “Paresis” - Added checkbox for “Spinal cord injury” - Skin Condition - Removed “Other (specify)” and free-text field - Add checkbox for “Blistering disease” - Add checkbox for “Eczema” - Add checkbox for “Psoriasis” Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. The additional options offered on the form have been derived from analyzing previous	None

	free-text responses, aiming to standardize and streamline data collection. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses.	
Administrative/Language Modification	Question 19. Substance Use: Changes: - Smoking - Changed “None” to “None documented” - Alcohol Abuse - Changed “No” to “None documented” - Other Substances - Changed “No” to “None documented” Justification: The changes from “None” or “No” to “None documented” are clarifications.	None
Administrative/Language Modification & Addition of Response Options	Question 30. Patient Outcome: Changes: - Added an option for “Hospitalized > 1 year” - Removed free-text field for “Other (Specify)” - Changed “Other (Specify)” to “Other” - Added option for “Homeless” - Added option for “Correctional or detention facility” - Added option for “Drug/alcohol rehabilitation” Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. The additional options offered on the form have been derived from analyzing previous free-text responses, aiming to standardize and streamline data collection. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses.	None

HAIC.400.6–2024 HAIC Invasive *Staphylococcus aureus* Supplemental Surveillance Officer Survey

Type of Change	Itemized Change / Justification	Impact to Burden
Administrative	Title: 2024 HAIC Invasive <i>Staphylococcus aureus</i> Supplemental Surveillance Officer Survey Introductory text: Please answer the following questions for the year 2024 Surveillance Area Characteristics Section Question 3: Did you site send MRSA/MSSA isolates to CDC for characterization in 2024? Lab Participation Section Introductory text: Please answer the following questions for the year 2024 Question 4: Indicate the percentage contribution of each case finding method to your site’s total SA case counts (100%) in 2024	None

	Question 6: Did any labs drop out of participation in 2024? Question 7: In 2024, did you identify any labs, regardless of location, which identify invasive SA isolates from persons who are residents of your catchment area? Data Edits Section Question 2: Did your site complete CRF re-abstractions during 2024? Ascertainment of Surveillance Area and Case Audits Section Question 1: How did your site define an audit case in 2024? Question 2: Indicate the percentage contribution of each case finding method to your site’s audit counts (100%) in 2024. Question 3d. How many laboratories did you audit in 2024? Question 4. In 2024, did your site update its inventory of facilities within the EIP catchment area? Geocoding Section Question 1. Did your site geocode SA cases in 2024? Vital Records Linkages Did your site link SA cases to vital records (mortality matching) in 2024? Changes: • Updated year to 2024 Justification: Updated to reflect the surveillance year.	
Administrative	Lab Participation Section Question 4a: Do you expect this distribution and/or percentage values to change in 2025? Changes: • Updated year to 2025 Justification: Updated to reflect the appropriate year	None
Administrative	Lab Participation Section Question 5c: How important is electronic messaging for your site (1—not important at all; 5—very high priority) ☐ 1 – not important at all ☐ 2 ☐ 3 ☐ 4 ☐ 5 – very high priority Changes: • Added checkbox options (previously used free text field for capturing a value of 1 to 5) Justification: Checkboxes for the 5 options helps eliminate data entry errors	None
Administration	Ascertainment of Surveillance Area* and Case Audits* Section Introductory text: <i>*“Case ascertainment” should include ongoing attempts to identify new or additional laboratories inside and outside of your defined catchment area which may be processing MRSA/MSSA specimens for surveillance area residents.</i>	None

	<i>*Audits of all laboratories both within the HAIC MRSA/MSSA surveillance area and those outside are required once a year. The purpose of the audit is to ensure that all cases of invasive MRSA/MSSA are being captured. The primary data source at every reporting laboratory (e.g. laboratory log slips/log book, computer-generated electronic printouts, case reports, line lists) should be reviewed for invasive MRSA/MSSA cases and compared to the list of cases that were reported to the surveillance personnel.</i> Updates: Previous text reading “MRSA” updated to “MRSA/MSSA”. Replaced “ABCs” with “HAIC” Justification: MRSA was updated to MRSA/MSSA to more accurately reflect the data captured by the surveillance program. ABC’s was replaced with HAIC because the surveillance program is now based in HAIC (no longer a part of EIP ABCs)	
--	---	--

HAIC.400.7 - CDI Case Report and Treatment Form

Administrative	Specimen ID Change: Moved to section of unnumbered data fields that are not transmitted to CDC Justification: CDC no longer needs to receive this data, so it will be made an optional field for local data collection.	Decrease
Deletion	Phone number Change: Removed from section of unnumbered fields not transmitted to CDC Justification: This field is no longer needed. This was an optional field and data were never sent to CDC. Removal does not impact burden.	None
Administrative	Questions 3-6 Change: Updated numbering of Questions 4-6b (numbering of prior form) to reflect the removal of the specimen ID field. Justification: Updated numbering is necessary to ensure a continuous count of questions.	None
Administrative	Question 13. Race and/or Ethnicity Changes: • Combined questions 13. Ethnic Origin and 14. Race • Added an option for “Middle Eastern or North African” • Removed “Other” from “Native Hawaiian or Pacific Islander” checkbox Justification: Updated to reflect new OMB Standards (Statistical Policy Directive No. 15)	None
Administrative	Questions 14 and 14a. Change: Updated numbering of Questions 15 and 15a	None

	(numbering of prior form) to adjust for the change of the race and ethnicity questions from 2 questions to 1. Justification: Updated numbering is necessary to ensure a continuous count of questions.	
Administrative/Language Modification & Added a Response Option	Question 15. Where was the patient located on the 3rd calendar day before the DISC? Changes: • Changed “Incarcerated” to “Correctional or detention facility” • Added option for “Drug/alcohol rehabilitation” • Removed free-text field for “Other (Specify)” • Changed “Other (Specify)” to “Other” • Updated numbering of Question 16 (numbering of prior form) to adjust for the change of the race and ethnicity questions from 2 questions to 1. Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. The additional options offered on the form have been derived from analyzing previous free-text responses, aiming to standardize and streamline data collection. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses. Updated numbering is necessary to ensure a continuous count of questions.	None
Administrative	15a. Was the patient transferred from this hospital? Change: Updated numbering of Question 16a (numbering of prior form) to adjust for the change of the race and ethnicity questions from 2 questions to 1. Justification: Updated numbering is necessary to ensure a continuous count of questions.	None
Administrative	16. Location of incident <i>C. diff</i>+ stool collection Changes: • Removed free-text field for “Other (Specify)” • Changed “Other (Specify)” to “Other” • Updated numbering of Question 17 (numbering of prior form) to adjust for the change of the race and ethnicity questions from 2 questions to 1. Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses. Updated numbering is necessary to ensure a continuous count of questions.	None
Administrative	Questions 17a-17c Changes: • Updated numbering of Questions 20a-20c	None

	(numbering of prior form) Added the time period for each question Justification: Moved questions earlier in the form to improve flow and help inform later questions. Updated numbering is necessary to ensure a continuous count of questions. Added “in the 12 weeks before DISC” to each question to clarify time period being referenced.	
Administrative/Language Modification	18. Epiclass questions Change: Wording change to question and header. Justification: All of question 18 (18a-118d), including the header, was revised to accommodate a new sampling scheme. This new sampling scheme is an adjustment to the types of case sampled under the prior sampling scheme to enable a more representative sample of cases while not changing the burden of data collection.	None
Administrative/Language Modification	18a. Was incident C. diff+ stool collected at least 3 calendar days after the date of hospital admission? Changes: Wording change to “Yes” response option. Justification: Changes to language for the response option branching logic to guide implementation of the new sampling scheme, as reported above 18.	None
Administrative/Language Modification	18b. Was incident C. diff+ stool collected in an outpatient setting for a LTCF resident, or in a LTCF or LTACH? Changes: - Breaking up the “Yes” response into two more nuanced “Yes” response options - Wording change of “No” response Justification: Changes to language for the response option branching logic to guide implementation of the new sampling scheme, as reported above 18.	None
Administrative/Language Modification	18c. Was the patient admitted from a LTCF or a LTACH? Changes: - Breaking up the “Yes” response into two more nuanced “Yes” response options - Wording change of “No” response Justification: Changes to language for the response option branching logic to guide implementation of the new sampling scheme, as reported above 18.	None
Addition	18d. Did patient have a previous hospitalization or overnight stay in a LTCF or LTACH in the 12 weeks before the DISC? Changes: New question Justification: Changes to language for the response option	None

	branching logic to guide implementation of the new sampling scheme, as reported above 18. This question is new but the response to this question is informed by responses to Question 17 so there will not be any additional burden.	
Administrative/Language Modification	18e. Was this case sampled for full CRF? Changes: • Changed to remove word from the question • Updated numbering of Question 18d (numbering of prior form) Justification: Changes to language for the question to guide implementation of the new sampling scheme, as reported above 18.	None
Administrative/Language Modification & Added Response Options	Question 19. Patient Outcome: Changes: • Added an option for “Hospitalized > 1 year” • Removed free-text field for “Other (Specify)” • Changed “Other (Specify)” to “Other” • Added option for “Homeless” • Added option for “Correctional or detention facility” • Added option for “Drug/alcohol rehabilitation” Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. The additional options offered on the form have been derived from analyzing previous free-text responses, aiming to standardize and streamline data collection. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses.	None
Administrative/Language Modification	Questions 20a-20d Changes: • Updated numbering of Questions 20d-20g (numbering of prior form) • Removed the header above these questions • Added the time period for each question Justification: Updated numbering is necessary to ensure a continuous count of questions. Removed the header and added “in the 12 weeks before DISC” to each question to clarify time period being referenced.	None
Administrative/Language Modification & Addition of Response Options	Question 21. Underlying Conditions: (Neurologic Condition and Skin Condition) Changes: • Neurologic Condition - o Removed “Other (specify)” and free-text field - o Added checkbox for “Paresis” - o Added checkbox for “Spinal cord injury” • Skin Condition - o Removed “Other (specify)” and free-	None

	text field - o Add checkbox for “Blistering disease” - o Add checkbox for “Eczema” - o Add checkbox for “Psoriasis” Justification: The inconsistent nature of data collected in free-text fields make analysis challenging. The additional options offered on the form have been derived from analyzing previous free-text responses, aiming to standardize and streamline data collection. Where possible, free-text fields are removed from this form to ensure an efficient user experience and subsequent data analyses.	
Administrative/Language Modification	Question 23. Substance Use: Changes: • Smoking - o Changed “None” to “None documented” • Alcohol Abuse - o Changed “No” to “None documented” • Other Substances - o Removed the table containing many options for various types of substance use and mode of delivery - o Removed “During the current hospitalization, did the patient receive medication assisted treatment (MAT) for opioid use disorder?” - o Added option for “Opioid use disorder” - o Added option for “Injection drug use” • Changed “None” to “None documented” Justification: The changes from “None” or “No” to “None documented” are clarifications. Detailed questions about various types of substance use were removed because they were less relevant to routine surveillance. Replacing the substance use table with concise checkbox options for the two most relevant substance use and removing the question regarding MAT will streamline data collection.	Decrease
Addition	Question 29: Did provider indicate that patient may be colonized by <i>C. difficile</i>? Change: New question. Justification: This data was previously reported in the comments field on the form. The inconsistent nature of data collected in free-text fields make analysis challenging. We added this question to standardize and streamline data collection.	None
Administrative	Questions 29-34 Change: Updated numbering of Questions 29-33 (numbering of prior form) to adjust for the addition of a new Question 29 Justification: Updated numbering is necessary to ensure a continuous count of questions.	None

Addition	Question 35. Antimotility agents in the 6 calendar days before, day of, or 6 days after DISC Change: New question Justification: The addition of this question will enable us to collect data on medications that impact the clinical course of <i>C. difficile</i>. This change will have minimal impact on burden and does not alter the scope in any way.	Increase <0.5 mins
Administrative	Questions 36a-36c Change: Updated numbering of Questions 34a-34c (numbering of prior form) to adjust for the addition of two new questions Justification: Updated numbering is necessary to ensure a continuous count of questions.	None
Administrative	Question 36d. If Yes, check all antimicrobials used in the 30 days before the DISC: Changes: • Removed “Ceftizoxime” • Removed “Doripenem” • Updated numbering of Question 34d (numbering of prior form) to adjust for the addition of two new questions Justification: These antimicrobial agents are infrequently reported and/or no longer available for use in the United States. Updated numbering is necessary to ensure a continuous count of questions.	None
Administrative	Questions 36e-37b Change: Updated numbering of Questions 34e-35b (numbering of prior form) to adjust for the addition of two new questions Justification: Updated numbering is necessary to ensure a continuous count of questions.	None
Administrative/Language Modification & Addition of Response Options	Question 37c. Adjunctive therapy Changes: • Added “Adjunctive therapy” as header to question • Changed wording of “stool transplant” to “conventional FMT” • Added Rebyota, Vowst, Bezlotoxumab, Other (specify), and Unknown as response options • Updated numbering of Question 35c (numbering of prior form) to adjust for the addition of two new questions Justification: Added header to capture all types of adjunctive therapy under this question. Changed wording of stool transplant to reflect correct terminology. Other medications newly listed on the form were previously captured as free text under “other” medication courses. The inconsistent nature of data collected in free-text fields make analysis challenging. The additional options offered on the form have been derived from analyzing previous free-text responses, aiming to standardize and streamline data collection. Updated numbering is necessary	None

	to ensure a continuous count of questions.	
Deletion	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? Changes: Removed the entire question Justification: The data collected through this question are now less important for routine surveillance.	Decrease
Deletion	Question 36a. Specimen collection dates for positive tests in the 90 days before or the day of the DISC: Changes: Removed the entire question Justification: The data collected through this question are now less important for routine surveillance.	Decrease
Deletion	Question 37. COVID-Net case ID in the year before or day of DISC: Changes: Removed the entire question Justification: The data collected through this question are now less important for routine surveillance.	Decrease

HAIC.400.8 - Annual Survey of Laboratory Testing Practices for C. difficile Infections

Administrative	Questions: Was this a new laboratory in 2024? How often did you receive line lists from this lab in 2024? How did you receive line lists from this lab in 2024? Did you receive specimens from this lab in 2024? Was this lab audited in 2024? Types of facilities in your catchment area served by this lab in 2024 Did your laboratory ever send specimens off-site for Clostridioides difficile testing in 2024? Questions 2a, 3a, 3b, 4b, 5a, 5b, 6, 7, 7a, 8 Change: Updated year to 2024 Justification: Updated to reflect the appropriate year of data collection	None
----------------	--	------

HAIC.400.9 - HAIC- CDI Annual Surveillance Officers Survey

Administrative	Questions 2, 3, 10, 13 Change: Updated year to 2024 Justification: Updated to reflect the appropriate year of data collection	None
----------------	---	------

HAIC.400.11 HAIC Candidemia CRF

Type of Change	Itemized Changes / Justification	Impact to Burden
Administrative	Updating the year i.Title: Year changed from 2024 to 2025. ii.Footnotes: changed version year to 2025	None

	iii.Changed last updated date from 07/29/2023 to 7/29/2024 Justification: Updating to reflect the new year and date.	
Administrative	Question 19: Race i.Race and/or ethnicity combined into one question ii.Changed “check all that apply” to “select all that apply” iii.Added response options for “Hispanic or Latino” and “Middle Eastern or North African” Justification: Justification: Updated to reflect new OMB Standards (Statistical Policy Directive No. 15)	None
Deletion	Question: 20: Ethnic origin Removed question since race and ethnicity are now combined into one question above. Justification: Race and ethnicity are now combined into one question.	None
Administrative	Question: 21: Changed question number by 1 Justification: Updated numbering is necessary to ensure a continuous count of questions.	None
Administrative/Language Modification & Additional Response Option	Question: 22: Location of specimen collection i.Changed question number by 1 ii.Added response option for “Burn Unit” under “Hospital Inpatient” category iii.Removed the ‘specify’ text field from the ‘other’ response option Justification: i. Updated numbering is necessary to ensure a continuous count of questions. ii.Added to enable capture of cases identified in this setting. iii.We removed the “specify” text fields for four questions. These text fields are difficult to clean and rarely used for analyses. For this reason, commonly reported answers in the text fields were added as response options for each given question.	None
Administrative	Question: 23: Changed question number by 1 Justification: Updated numbering is necessary to ensure a continuous count of questions.	None
Administrative & Addition of a Response Option	Question 24: Antifungal susceptibility testing i.Changed question number by 1 ii.Added a response option for a new antifungal “Rezafungin (Rezzayo)” Justification: i. Updated numbering is necessary to ensure a continuous count of questions. ii. Rezafungin, is a newly approved antifungal medication, a	None

	response option has been added to capture data for it.	
Administrative	Question 25-29a : Changed question number by 1 Justification: Updated numbering is necessary to ensure a continuous count of questions.	None
Administrative/Language Modification	Question 30: Types of infection i.Changed question number by 1 ii.Added “suspected or confirmed” to question wording. Justification: i. Updated numbering is necessary to ensure a continuous count of questions. ii. added two words to the original question to clarify what should be entered.	None
Addition	Question 30 New question: <i>C. auris</i> colonization. Added a question to capture if patient is known to be colonized with <i>C. auris</i> before candidemia diagnosis. Justification: Patients with candidemia from <i>C. auris</i> may be known to be colonized first. This question aims to capture this information. Surveillance staff already review these test results in the patient’s medical chart so this change will have minimal impact on burden and does not alter the scope in any way.	Increase <0.5 mins
Administrative/Language Modification & Additional Response Option	Questions 31c: Patient location 3rd day before the DISC i.Changed the response option “Incarcerated” to “Correctional or detention facility” ii.Added response options for “Drug/alcohol rehabilitation” and “Not born yet” iii.Removed the “specify” text field from the “Other” response option Justification: i: Revised phrasing to be in line with CDC inclusive language. ii:Included addition options for another location patients may have been in and to include newborn babies. iii: We removed the “specify” text fields for four questions. These text fields are difficult to clean and rarely used for analyses. For this reason, commonly reported answers in the text fields were added as response options for each given question. For example, for the patient’s location on the third day before the incident specimen collection date, the “specify” free text field was removed but a response option for “drug/alcohol rehabilitation” was added since it was commonly reported.	None
Administrative/ Additional Response Option	Question 35: Patient outcome i.Added response option for “Hospitalized >1 year”. ii.Rearranged order of response options. Justification:	None

	i.To capture if a patient was hospitalized for more than 1 year, a corresponding response option was added to the patient outcome question. Previously, sites were asked to report this in a text field but adding it as a separate response option is a cleaner and easier way to make sure this scenario is accurately captured on the CRF. ii.The response options for this question were also rearranged in more logical manner.	
Administrative/ Addition of a Response Option	Question 35a: Discharge location i.Removed the “specify” text field from the “Other” response option ii.Added response options for “Drug/alcohol rehabilitation” and “Correctional or detention facility” Justification: i.We removed the “specify” text fields for four questions that were difficult to clean and rarely used for analyses. ii.For this reason, commonly reported answers in the text fields were added as response options for each given question. For example, for the patient’s location on the third day before the incident specimen collection date, the “specify” free text field was removed but a response option for “drug/alcohol rehabilitation” was added since it was commonly reported.	None
Administrative/ Additional Response Options	Question 40: Underlying conditions i.Added response options for “Blistering disease”, “Eczema”, and “Psoriasis” under “Skin Condition”. ii.Removed the “Other (specify)” response option under “Skin Condition”. iii.Added response options for “Paresis” and “Spinal cord injury” under “Neurologic Condition”. iv.Removed the “Other (specify)” response option under “Neurologic Condition”. Justification: ii and iv: removed the “specify” text fields for questions that were difficult to clean and rarely used for analyses. i and iv: added response options for commonly reported “blistering diseases”, “paresis” and “skin conditions” that were commonly reported under Other (specify).	None
Administrative/Language Modification	Question 41: Smoking Changed the wording of the response option “None” to “None documented” for clarification purposes Justification: The “No” or “None” response option for the question about smoking were changed to “None documented” for clarification purposes.	None
Administrative//Language Modification	Question 42: Alcohol abuse Changed the wording of the response option “No” to “None documented” for clarification purposes,	None

	Justification: The “No” or “None” response option for the question about alcohol were changed to “None documented” for clarification purposes.	
Administrative//Language Modification	Question 43: Other substances Changed the wording of the response option “None to “None documented” for clarification purposes. Justification: The “No” or “None” response option for the question about other substances were changed to “None documented” for clarification purposes.	None
Administrative/ Addition of a Response Option	Question 59: Antifungal medication before the DISC Added a response option for a new antifungal “Rezafungin (Rezzayo)” Justification: Rezafungin, a newly approved antifungal medication, was added to two CRF questions to capture use and any associated resistance across candidemia cases.	None
Administrative/ Addition of a Response Option	Question 60: Antifungal medication after the DISC Added a response option for a new antifungal “Rezafungin (Rezzayo)” Justification: Rezafungin, a newly approved antifungal medication, was added to two CRF questions to capture use and any associated resistance across candidemia cases.	None
Addition	New question: Outbreak Added new question to capture if case is associated with a known outbreak Justification: Several species of candida responsible for causing candidemia can cause outbreaks in healthcare settings. Capturing this information will help us learn more about the epidemiology of these species. Surveillance staff already review the patient’s medical chart, where this information would be found. This addition has a minimal impact on burden and does not alter the scope in any way.	Increase <0.5 mins
Administrative Addition of a Response Option	Question 67: Antifungal medication table Added “Rezafungin (Rezzayo)= RZF” as an option to the antifungal medication list. Justification: Rezafungin, a newly approved antifungal medication, was added to two CRF questions to capture its use and any associated resistance across candidemia cases.	None
Administrative/ Addition of a Response Option	AFST results for additional <i>Candida</i> isolates Added a response option for a new antifungal “Rezafungin (Rezzayo)” Justification: Rezafungin, a newly approved antifungal medication, was added to the response to capture its usage and any associated resistance across candidemia cases.	None

HAIC.400.12 Laboratory Testing Practices for Candidemia

Type of Change	Itemized Change / Justification	Impact to Burden
Administrative	Title: i. Year changed from 2024 to 2025 Footnotes ii. Changed version year to 2025 Justification: Updating for the new year.	None
Deletion	Question 4: Blood culture system i. Removed response option for “Isolator tubes” since they are no longer manufactured. Justification: These are no longer manufactured so will not be needed as an option.	None
Administrative	Question 7: Yeast identification i. Updated branching logic Justification: Updated the branching logic to aid with clarification.	None
Administrative	Question 13: PCR molecular tests i. Updated question wording to remove “PCR” for clarity purposes ii. Updated branching logic for response options Justification: Updated phrasing and branching logic to improve clarification.	None
Administrative/Consolidation of Questions.	New question: Molecular tests i. Added a question to capture which molecular tests are used by the laboratory to identify <i>Candida</i> and the date that test started being used Justification: Instead of asking separate questions for each molecular test, one new question was created so survey participants to select from a list of tests. This new set-up allowed us to delete the 3 separate questions for the different molecular tests. Questions 14 - 16 have now been replaced with this one question.	None
Administrative/Language Change	Question 13b: Culture positive molecular tests Updated question wording to clarify question intent. Justification: Phrasing has been updated to make it more clear.	None
Deletion	Question 14-14b: T2Candida Panel i. Removed questions Justification: Deleted the individual questions. Questions 14 - 16 have now	None

	been replaced with this one question.	
Deletion	Question 15-15b: BioFire (FilmArray) i. Removed questions Justification: Deleted the individual questions. Questions 14 - 16 have now been replaced with this one question.	None
Deletion	Question 16: Other PCR molecular tests i. Removed question. Justification: Deleted individual questions. Questions 14 - 16 have now been replaced with this one question.	None
Administrative/Language Modification	Question 17: Future molecular test plans i. Changed question number by 3 ii. Updated question wording to remove “PCR” and add “GenMark” as test example for clarity purposes. Justification: Adjusted question number to account for deleted questions, removed phrasing to avoid confusing examples.	None
Administrative/Language Modification	Question 18: Antifungal susceptibility testing (AFST) i. Changed question number by 3 ii. Updated question wording to add AFST acronym Justification: Adjusted question number to account for deleted questions, included AFST acronym to improve clarity.	None
Administrative/Language Modification	Question 19: AFST location i. Changed question number by 3 ii. Removed unnecessary question wording since AFST is already defined in question above iii. Updated branching logic for response option Justification: Adjusted question number to account for deleted questions, removed unnecessary words in questions to improve clarity.	None
Administrative/Language Modification & Addition of a Response Option	Question 20: AFST by drug i. Changed question number by 3 ii. Removed unnecessary question wording since AFST is already defined iii. Added new response option for “Rezafungin” Justification: Adjusted question number to account for deleted questions, removed unnecessary words in questions to improve clarity, added a new response option so data can be captured for new	None

	drug rezafungin.	
Administrative/Language Modification	Question 21: AFST methods (excluding Amphotericin B) i.Changed question number by 3 ii.Updated response options for clarity purposes Justification: Adjusted question number to account for deleted questions, updated response options to improve clarity.	None
Administrative/ Language Modification	Question 22: AFST methods for Amphotericin B i.Changed question number by 3 ii.Updated response option for clarity purposes Justification: Adjusted question number to account for deleted questions, updated response options to improve clarity.	None
Administrative/ Language Modification	Question 23: AFST methods for Amphotericin B i.Changed question number by 3 ii.Removed unnecessary question wording since AFST is already defined Justification: Adjusted question number to account for deleted questions, updated response options to improve clarity.	None
Administrative	Questions 24-25 i.Changed question number by 3 Justification:Adjusted question number to account for deleted questions.	None
Administrative Language Modification	Question 26: Isolates for which AFST is automatically performed i.Changed question number by 3 ii.Removed unnecessary question wording since AFST is already defined Justification: Adjusted question number to account for deleted questions, removed unnecessary words in question.	None
Administrative	Question 27ai-27di: AFST performed by <i>Candida</i> spp. i. Changed question number by 3 ii.Updated branching logic for response options Justification: Adjusted question number to account for deleted questions, improved branching logic for responses.	None
Administrative	Question 28: Tracking trends	None

	i.Changed question number by 3 Justification: Adjusted question number to account for deleted questions.	
--	--	--