Emerging Infections Program
OMB Control No. 0920-0978

Non-Substantive Change Request
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Contact:
Lee Samuel
Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases
Office of the Director
1600 Clifton Rd
Atlanta GA 30333
404-718-1616
llj3@cdc.gov

Background

The National Center for National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) of the Centers for Disease Control and Prevention (CDC) is requesting approval of non-substantive changes to seven data collection forms that have previously been approved under OMB no. 0920-0978—expiration date 2/28/2019—and the addition of one new form.

These forms are used to conduct surveillance to determine the incidence and epidemiologic characteristics of invasive disease due to specific active core bacterial infections, non-invasive Pneumoccocal Pneumonia, *H. influenzae*, specific foodborne diseases that is captured within FoodNet, Influenza (specifically for the All Age Influenza Hospitalization Surveillance (Flu Hosp) project *Clostridium difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), and Multi-Site Resistant Gram-Negative *Bacilli* infections (MuGSI).

The forms for which approval for changes are being sought include:

1. 2016 ABCs Case Report Form **(Attachment 1)**
2. 2016 ABCs Non-Invasive Pneumococcal Pneumonia **(Attachment 2)**
3. 2015 ABCs *H. influenzae* Neonatal Sepsis Expanded Surveillance Form (New form) **(Attachment 3)**
4. 2016 FoodNet Surveillance Variable List **(Attachment 4)**
5. 2015-2016 FluSurv-NET Influenza Surveillance Project Case Report Form **(Attachment 5)**
6. 2016 *Clostridium difficile* Infection (CDI) Case Report Form **(Attachment 6)**
7. 2016 Invasive Methicillin-Resistant *Staphylococcus aureus* (MRSA) Case Report Form **(Attachment 7)**
8. 2016 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form **(Attachment 8)**

Description of Changes

Minor changes are being requested for the 2016 ABCs Case Report Form, the 2014 ABCs Invasive Methicillin-resistant *Staphylococcus aureus* Case Report Form, the 2016 ABCs Non Invasive Pneumoccocal Pneumonia in order to streamline and enhance disease surveillance for the pathogens under surveillance. Additionally, a new form has been added: 2015 ABCs *Haemophilus. influenzae* Neonatal Sepsis Expanded Surveillance. The burden associated with this inclusion is minimal as it is only for 10 hours (see Table A.1) and is an extension to the case report form when the criteria is met. Criteria include infants less than 30 days or less and pregnant and postpartum women who have tested positive for H. influenza identified on the case report form that is already approved by OMB under this package. *See Appendix A. for background statement on Haemophilus influenzae serotype b (Hib).*

Minor changes are being requested for the 2016 FoodNet Variable list in order to improve disease surveillance under FoodNet surveillance.

There is no impact on burden due to the changes on the *2015-16 FluSurv-NET Influenza Surveillance Project_Case Report Form.* Minor changes have been made to 1) Better capture information regarding signs/symptoms at the time of admission, question E2 was expanded to include the following additional sign/symptoms commonly noted in the medical chart: Fatigue/weakness and URI/ILI. The original intent of the question was preserved. 2) The underlying medical condition variable Atrial Fibrillation for question E10e is currently a variable collected on the Microsoft Access database. This variable reflects responses commonly written in the "Other: specify" field in the CRF. It was added back to easily capture this information on the paper case report form.

Minor changes are being requested for the 2016 CDI Case Report Form to improve surveillance for CDI. The changes from the previously approved forms will have minimal impact on the burden of data collection. Minor changes are being requested for the 2016 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form. The requested changes will have no impact on the burden of data collection. Minor changes are being requested for the 2016 Invasive Methicillin-Resistant *Staphylococcus aureus* (MRSA) Case Report Form

in order to enhance disease surveillance. The requested changes will have minimal impact on data collection burden.

In total, this non-substantive change request accounts for an additional 51 burden hours to this collection per year.

Detailed Description of Changes

1. 2016 ABCs Case Report Form

There is no impact on burden due to the changes on this form. The changes include:

1. Question 18b, adding space to collect Facility ID
2. Question 22a – Adding the question:
    - "If survived, discharged to: Home, LTC/SNF, LTAC, Other, Unknown" and will need to specify the facility ID for LTC/SNF and LTAC options.
3. Question 24c. Adding the checkbox:
    - "Mark if this is a HiNSES fetal death with placenta and/or amniotic fluid isolate, a stillbirth or neonate <22 weks gestation.
4. Question 27 - Adding/removing underlying causes or prior illnesses.
5. Question 31a – changing question to below and adding more dose fields as well as vaccine type column to table.
    - "Did patient receive meningococcal vaccine?"
6. Question 31b – adding the question:
    - "If survived, did patient have any of the following sequelae evident upon discharge?" plus checkbox options (see crosswalk table).

2. 2016 Surveillance for Non-invasive Pneumococcal Pneumonia (SNiPP) Case Report Form

There is minor impact on burden due to an increase in the number of respondents per response from 100 to 125. The changes include:

1. Title of the form is changing from "Non-Bacteremic Pneumococcal Disease" to "Non-Invasive Pneumococcal Pneumonia"
2. Increase in the number of responses per respondent from 100 to 125 which leads to an increase of 41 burden hours/year.

3. 2015 ABCs *H. influenzae* Neonatal Sepsis Expanded Surveillance Form

This is a new form. The burden associated with this inclusion is minimal as it is only for 10 hours and is an extension to the case report form when the criteria is met. Criteria include infants less than 30 days or less and pregnant and postpartum women who have tested positive for H. influenza identified on the case report form that is already approved by OMB under this package.

4. 2016 FoodNet Variable list changes include:

1. Dropped 5 variables ('Comorb1-Comorb5') which collected information on underlying conditions for Listeria cases.
    - Reasons: the information was not being collected consistently by all sites, we were not using it at CDC, and there is a plan to incorporate these fields into the national case report form for Listeria.
2. Added 1 variable 'CEA_Sampled'
    - Reason: this variable indicates whether or not a case was selected to be interviewed for case exposure data. It will used to create a denominator to evaluate whether we are meeting performance standards for collection of CEA data. It will only be filled out in sites that have sampling schemes for CEA cases.
3. Revised our picklist for an existing variable ('OutFetal') which indicates the outcome of the pregnancy in the event of a pregnancy-associated Listeria case.

- Reason: to make the categories consistent with those on the national case report form for Listeria.

5. 2015-16 FluSurv-NET Influenza Surveillance Project Case Report Form

There is no impact on burden due to the changes on this form.

1. To better capture information regarding signs/symptoms at the time of admission, question E2 was expanded to include the following additional sign/symptoms commonly noted in the medical chart: Fatigue/weakness and URI/ILI. The original intent of the question was preserved.
2. The underlying medical condition variable Atrial Fibrillation for question E10e is currently a variable collected on the Microsoft Access database. This variable reflects responses commonly written in the "Other: specify" field in the CRF. It was added back to easily capture this information on the paper case report form.

6. 2016 CDI Case Report Form changes include:

1. Question 8c: Location of stool collection
    - A line has been added to capture the Facility ID for each of the following locations: Hospital Inpatient, Long Term Acute Care Hospital, and Long Term Care/Skilled Nursing Facility
2. Question 10: Where was the patient a resident 4 days prior to stool collection?
    - A line has been added to capture the Facility ID for each of the following locations: Hospital Inpatient, Long Term Acute Care Hospital, and Long Term Care/Skilled Nursing Facility
3. Question 12: Was patient admitted due to CDI?
    - The question was rewritten to read as follows: "Was CDI a primary or contributing reason for patient's admission?
4. Question 11c: Was the patient admitted from Long Term Care Facility/Skilled Nursing Facility or another acute care setting?
    - A line has been added to capture the Facility ID of where the patient was admitted from, if the response to the question is "Yes"
5. Question 14: Exclusion criteria for CA-CDI
    - A line has been added to capture the Facility ID for each of the following locations where the patient had an overnight stay in the prior 12 weeks of stool collection: Hospital, Long Term Acute Care Hospital, and Long Term Care/Skilled Nursing Facility
6. Question 16: Patient outcome
    - A line has been added to capture the Facility ID for each of the following locations where a patient who had survived was discharged to: Long Term Acute Care Hospital and Long Term Care/Skilled Nursing Facility
7. Question 20.1: Laboratory Findings a. Albumin < 2.5g/dl
    - Changed the order of the boxes for the responses in order to be in alignment with the other questions in this section
8. Question 24d: Antimicrobial therapy
    - Removed the following 5 antibiotics from the previous list: Cefaclor, Cefprozil, Ceftizoxime, Ofloxacin and Ticarcillin/Clavulanic Acid. Replaced the 5 antibiotics with the following: Ampicillin, Aztreonam, Cefoxitin, Rifampin and Rifaximin.
9. Question 24: Medications taken 12 weeks prior to incident stool collection date
    - Added a separate part to Q24 (part e) to ask if the patient was treated for previous suspected or confirmed CDI in the prior 12 weeks, and added check boxes for medications that were taken for prior CDI treatment. This part was added to streamline the process for capturing prior antibiotic treatment for CDI.

7. 2016 Invasive MRSA Case Report Form changes include:

1. The title has been changed from "Active Bacterial Core surveillance" to "Healthcare Associated Infections Community Interface" to reflect administrative changes in the program.
2. New question added, "if patient was hospitalized, was this patient admitted to the ICU during hospitalization?" to better capture the severity of illness
3. Added data element "facility ID" to questions 15, 16, 18, and 21 to allow sites to keep track of specific healthcare facilities where patients have been to for better data validation and to improve flexibility of data elements in the future. This information is already obtained during a regular course of operations, and this change gives sites a place on the form to note the information.

8. 2016 Multi-site Gram-Negative Surveillance Initiative (MuGSI) Case Report Form changes include:

1. Question 5: Where was the patient located on the 4th calendar day prior to the date of initial culture?
    - Two data entry lines for Facility ID next to the LTCF and LTACH check boxes. This is new data that is being captured, the user already knows these ids, we are just asking for them to record them.
    - Re-worded question: Was the patient transferred from this hospital? This data was previously being captured in a different way.
2. Question 10: Location of culture collection
    - Two data entry lines for Facility ID next to the LTCF and LTACH check boxes. This is new data that is being captured, the user already knows these ids, we are just asking for them to record them.
3. Question 12: Patient outcome, if survived, transferred to:
    - Two data entry lines for Facility ID next to the LTCF and LTACH check boxes. This is new data that is being captured, the user already knows these ids, we are just asking for them to record them.
4. Question 13c: Was the initial isolate tested for carbapenemases?
    - Added check box for “laboratory not testing”. This information was previously being tested under “unknown”. The “unknown” check box will be re-defined from the users prospective.
5. Question 13c: If yes, what testing method was used (check all that apply):
    - Adding two check boxes, one for “Carba-NP” and one for “Automated Molecular Assay”. These are new tests, and will reduce users burden because they will only have to check a box instead of writing in the test into the other specify each time.
    - Adding an “other specify” box for the “Automated Molecular Assay” check box only so that we can keep track of these types of tests. This is a very new test.
6. Question 14b: Record the colony count for the organism indicated in Q13a:
    - Adding a check box for “unknown” will save the user from having to write it in, when the value is unknown.
7. Question 15: Were cultures of other sterile site(s) or urine positive in the 30 days after the date of initial culture, for the same organism (Q13a)?
    - Question is being reworded to reduce confusion for users: Was the same organism (Q13a) cultured from a different sterile site or urine in the 30 days after the date of initial culture (or this current episode)?
8. Question 17d: If yes, specify organism, date of culture and stateid of the first positive Enterobacteriaceae culture in the year prior:
    - Question is being reworded to reduce confusion for users: If yes, specify organism, date of culture and stateid of the first positive Enterobacteriaceae culture in the year prior to the date of initial culture:
9. Question 21: Risk factors of interest
    - Adding “If known, prior facility id” for the following sub questions: “Residence in a LTCF within year before date of initial culture” and “Admitted to a LTACH within year

before initial culture date”. This is new data that is being captured, the user already knows these ids, we are just asking for them to record them.

9.

Cross walk of 2016 form changes

1. **2016 ABCs Case Report Form**

<table>
<tr><th>Current question</th><th>Requested change</th></tr>
<tr><td>18b. If resident of a facility, what was the name of the facility? _____</td><td>18b. If resident of a facility, what was the name of the facility? _____
Facility Id _____</td></tr>
<tr><td>N/A</td><td>22a. If survived, patient discharged to: □ Home □ LTC/SNF □ LTACH □ Other _____ □ Unknown
If discharged to LTC/SNF or LTACH, what is the Facility ID _____</td></tr>
<tr><td>N/A</td><td>24c. □ Mark if this is a HiNSES fetal death with placenta and/or amniotic fluid isolate, a stillbirth, or neonate <22 wks gestation.</td></tr>
<tr><td>27. Underlying causes or prior illnesses</td><td>27. Added: TIA, Chronic Liver Disease/cirrhosis, Connective Tissue Disease (Lupus, etc), Myocardial Infarction, Peptic Ulcer Disease, and Peripheral Vascular Disease.

Removed/Changed: Cirrhosis/Liver Failure, Systemic Lupus Erythematosus (SLE)</td></tr>
<tr><td>31. Did patient receive meningococcal vaccine? □ Yes □ No □ Unknown
If yes, please complete the following information:
<table>
<tr><th>Dose</th><th>Date</th><th>Vaccine Name</th><th>Manufacturer</th><th>Lot number</th></tr>
<tr><td>1</td><td></td><td></td><td></td><td></td></tr>
<tr><td>2</td><td></td><td></td><td></td><td></td></tr>
<tr><td>3</td><td></td><td></td><td></td><td></td></tr>
</table></td><td>31. Did patient receive meningococcal vaccine? □ Yes □ No □ Unknown If yes, complete the table:
<table>
<tr><th>Dose</th><th>Type</th><th>Date Given</th><th>Name</th><th>Manufacturer</th><th>Lot number</th></tr>
<tr><td>1</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>2</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>3</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>4</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>5</td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>6</td><td></td><td></td><td></td><td></td><td></td></tr>
</table>
Type Codes: 1= ACWY conjugate (Menactra, Menveo, MenHibrix) 2= ACWY polysaccharide (Menomune) 3= B (Bexsero, Trumenba) 9= Unknown</td></tr>
<tr><td>N/A</td><td>31b. If survived, did patient have any of the following sequelae evident upon discharge? (check all that apply)
□ None □ Unknown □ Hearing deficits □ Amputation (digit) □ Amputation (limb) □ Seizures □ Paralysis or spasticity □ Skin Scarring/necrosis</td></tr>
</table>

2. **2016 ABCs Non Invasive Pneumococcal Pneumonia Form**

Current item	Requested change
Title: Active Bacterial Core Surveillance (ABCs) Case Report Non-Bacteremic Pneumococcal Disease	Title: Surveillance for Non-Invasive Pneumococcal Pneumonia (SNiPP) Case Report Form

3. **2015 ABCs *H. influenzae* Neonatal Sepsis Expanded Surveillance Form**

This is a new form. The burden associated with this inclusion is minimal as it is only for 10 hours and is an extension to the case report form when the criteria is met. Criteria include infants less than 30 days or less and pregnant and postpartum women who have tested positive for H. influenza identified on the case report form that is already approved by OMB under this package.

4. **2014 FoodNet Variable list**

Current variable list	Requested change
Comorb1-Comorb5	DROPPED VARIABLE
CEA_Sampled	NEWLY ADDED VARIABLE
OutFetal Survived, no apparent illness; Survived, clinical infection; Live birth/neonatal death; Abortion/stillbirth; Induced abortion; Unknown; Abortion, otherwise undetermined; Live birth, otherwise undetermined; Survived, otherwise undetermined	OutFetal Still pregnant; Fetal death; Induced abortion; Delivery; Unknown

5. **2013-14 FluSurv-NET Influenza Surveillance Project Case Report Form**

Current question	Requested change
E2. Acute signs/symptoms at admission *[within 2 weeks prior to positive flu test]:* ☐ Altered mental status/confusion ☐ Chest pain ☐ Congested/runny nose ☐ Conjunctivitis/pink eye ☐ Cough ☐ Diarrhea ☐ Fever/chills ☐ Headache ☐ Myalgia/muscle aches ☐ Nausea/vomiting ☐ Rash	**E2. Acute signs/symptoms at admission *[within 2 weeks prior to positive flu test]:*** ☐ Altered mental status/confusion ☐ Chest pain ☐ Congested/runny nose ☐ Conjunctivitis/pink eye ☐ Cough ☐ Diarrhea ☐ Fatigue/weakness ☐ Fever/chills ☐ Headache ☐ Myalgia/muscle aches ☐ Nausea/vomiting

☐ Seizures ☐ Shortness of breath/resp distress ☐ Sore throat ☐ Wheezing ☐ Other, non-respiratory	☐ Rash ☐ Seizures ☐ Shortness of breath/resp distress ☐ Sore throat ☐ URI/ILI ☐ Wheezing ☐ Other, non-respiratory
E10E. Cardiovascular Disease ☐ Yes ☐ No/Unknown ☐ Artherosclerotic cardiovascular disease (ASCVD) ☐ Cerebral vascular incident/Stroke ☐ Congenital heart disease ☐ Coronary artery disease (CAD) ☐ Heart failure/CHF ☐ Other, specify _____	**E10E. Cardiovascular Disease** ☐ Yes ☐ No/Unknown ☐ Artherosclerotic cardiovascular disease (ASCVD) ☐ Atrial Fibrillation ☐ Cerebral vascular incident/Stroke ☐ Congenital heart disease ☐ Coronary artery disease (CAD) ☐ Heart failure/CHF ☐ Other, specify _____

6. **<u>CDI Case Report Form:</u>**

Current question	**Requested change**
8c. Location of stool collection □ Hospital Inpatient □ Long Term Acute Care Hospital □ Emergency Room □ Long Term Care/Skilled Nursing Facility □ Outpatient □ Other (specify) _____ □ Unknown □ Observation Unit/CDU	8c. Location of stool collection □ Hospital Inpatient Facility ID _____ □ Long Term Acute Care Hospital Facility ID _____ □ Emergency Room □ Long Term Care/Skilled Nursing Facility Facility ID _____ □ Outpatient □ Other (specify) _____ □ Unknown □ Observation Unit/CDU
Q10. Where was the patient a resident 4 days prior to stool collection? □ Hospital Inpatient □ Long Term Acute Care Hospital □ Home □ Long Term Care/Skilled Nursing Facility □ Homeless □ Incarcerated □ Unknown □ Other (specify) _____	Q10. Where was the patient a resident 4 days prior to stool collection? □ Hospital Inpatient Facility ID _____ □ Long Term Acute Care Hospital Facility ID _____ □ Home □ Long Term Care/Skilled Nursing Facility Facility ID _____ □ Homeless □ Incarcerated □ Unknown □ Other (specify) _____
Q12. Was patient admitted due to CDI? □ Yes	Q12. Was CDI the primary or contributing reason for patient's admission?

□ No □ Unknown	□ Yes □ No □ Unknown
Q11. HCFO classification questions: c. If no, was the patient admitted from LTC/SNF or another acute care setting? □ Yes (HCFO) □ No (CO – complete CRF)	Q11. HCFO classification questions: c. If no, was the patient admitted from LTC/SNF or another acute care setting? □ Yes (HCFO) Facility ID _____ □ No (CO – complete CRF)
Q14. Exclusion criteria for CA-CDI (*check all that apply*) □ None □ Unknown □ Hospitalized (overnight) at any time in the 12 weeks prior to stool collection date. If yes, Date of most recent discharge: Date of Discharge Mo. Day Year □□ □□ □□□□ □ Overnight stay in LTACH at any time in the 12 weeks prior to stool collection date □ Residence in LTCF/SNF at any time in the 12 weeks prior to stool collection date	Q14. Exclusion criteria for CA-CDI □ None □ Unknown □ Hospitalized (overnight) at any time in the 12 weeks prior to stool collection date. If yes, Date of most recent discharge: Date of Discharge Mo. Day Year □□ □□ □□□□ Facility ID _____ □ Overnight stay in LTACH at any time in the 12 weeks prior to stool collection date Facility ID _____ □ Residence in LTCF/SNF at any time in the 12 weeks prior to stool collection date Facility ID _____
Q16. Patient outcome □ Unknown □ Survived Date of Discharge Mo. Day Year □□ □□ □□□□ □ Died Date of Death Mo. Day Year □□ □□ □□□□ If survived, patient was discharged to: □ Long Term Acute Care Hospital □ Home □ Long Term Care/Skilled Nursing Facility □ Other _____	Q16. Patient outcome □ Unknown □ Survived Date of Discharge Mo. Day Year □□ □□ □□□□ □ Died Date of Death Mo. Day Year □□ □□ □□□□ If survived, patient was discharged to: □ Long Term Acute Care Hospital Facility ID _____ □ Home □ Long Term Care/Skilled Nursing Facility

☐ Unknown	Facility ID _____ ☐ Other _____ ☐ Unknown
Q20.1 Laboratory Findings (*within 7 days before or after incident C. diff+ stool*): a Albumin ≤ 2.5g/dl: ☐ Yes ☐ Not Done ☐ No ☐ Information not available b White blood cell count ≤ 1,000/µl: ☐ Yes ☐ No ☐ Not Done ☐ Information not available c White blood cell count ≥ 15,000/µl: ☐ Yes ☐ No ☐ Not Done ☐ Information not available	Q20.1 Laboratory Findings (*within 7 days before or after incident C. diff+ stool*): a Albumin ≤ 2.5g/dl: ☐ Yes ☐ No ☐ Not Done ☐ Information not available b White blood cell count ≤ 1,000/µl: ☐ Yes ☐ No ☐ Not Done ☐ Information not available c White blood cell count ≥ 15,000/µl: ☐ Yes ☐ No ☐ Not Done ☐ Information not available
Q24d. Antimicrobial therapy (*check all that apply*) ☐ Yes, name unknown ☐ None ☐ Unknown ☐ Amikacin ☐ Amoxicillin ☐ Amoxicillin/Clavulanic Acid ☐ Amp/sulb ☐ Azithromycin ☐ Cefaclor ☐ Cefazolin ☐ Cefdinir ☐ Cefepime ☐ Cefotaxime ☐ Cefpodoxime ☐ Cefprozil ☐ Ceftazidime ☐ Ceftizoxime ☐ Ceftriaxone ☐ Cefuroxime ☐ Cephalexin ☐ Ciprofloxacin ☐ Clarithromycin ☐ Clindamycin ☐ Daptomycin ☐ Doxycycline ☐ Ertapenem ☐ Gentamicin ☐ Imipenem ☐ Levofloxacin ☐ Linezolid ☐ Meropenem ☐ Metronidazole ☐ Moxifloxacin ☐ Nitrofurantoin ☐ Ofloxacin ☐ Penicillin	Q24d. Antimicrobial therapy (*check all that apply*) ☐ Yes, name unknown ☐ None ☐ Unknown ☐ Amikacin ☐ Amoxicillin ☐ Amoxicillin/Clavulanic Acid ☐ Ampicillin ☐ Amp/sulb ☐ Azithromycin ☐ Aztreonam ☐ Cefazolin ☐ Cefdinir ☐ Cefepime ☐ Cefotaxime ☐ Cefoxitin ☐ Cefpodoxime ☐ Ceftazidime ☐ Ceftriaxone ☐ Cefuroxime ☐ Cephalexin ☐ Ciprofloxacin ☐ Clarithromycin ☐ Clindamycin ☐ Daptomycin ☐ Doxycycline ☐ Ertapenem ☐ Gentamicin ☐ Imipenem ☐ Levofloxacin ☐ Linezolid ☐ Meropenem ☐ Metronidazole ☐ Moxifloxacin ☐ Nitrofurantoin ☐ Penicillin ☐ Piperacillin-Tazobactam

□ Piperacillin-Tazobactam □ Tetracycline □ Ticarcillin/Clavulanic Acid □ Tigecycline □ Tobramycin □ Trimethoprim-Sulfamethoxazole □ Vancomycin (IV) □ Other (specify)_____	□ Rifampin □ Rifaximin □ Tetracycline □ Tigecycline □ Tobramycin □ Trimethoprim-Sulfamethoxazole □ Vancomycin (IV) □ Other (specify)_____
N/A	Q24e. Was patient treated for <u>previous</u> suspected or confirmed CDI in the <u>prior 12 weeks</u>? □ Yes □ No □ Unknown If YES, which medication was taken (check all that apply, or unknown if applicable): □ Metronidazole □ Vancomycin □ Fidaxomicin □ Other (specify):_____ □ Unknown

7. <u>Invasive MRSA Case Report Form</u>

Current question	**Requested change**
N/A	10b. If patient was hospitalized, was this patient admitted to the ICU during hospitalization?
15. Where was the patient located on the 4th calendar day prior to the date of initial culture? □ Long Term Care Facility □ Long Term Acute Care Hospital □ Hospital Inpatient	15. Where was the patient located on the 4th calendar day prior to the date of initial culture? □ Long Term Care Facility Facility ID _____ □ Long Term Acute Care Hospital Facility ID _____ □ Hospital Inpatient Facility ID _____
16. Location of culture collection: (Check one) □ LTCF □ LTACH	16. Location of culture collection: (Check one) □ LTCF Facility ID _____ □ LTACH Facility ID _____
18. Patient outcome: — If survived, was the patient transferred to a LTCF? □ Yes □ No — If survived, was the patient transferred to a LTACH? □ Yes □ No	18. Patient outcome: — If survived, was the patient transferred to a LTCF? □ Yes □ No If Yes, Facility ID _____ — If survived, was the patient transferred to a LTACH? □ Yes □ No If Yes, Facility ID _____

21. Prior healthcare exposure — healthcare-associated and community-associated: (check all that apply) □ Hospitalization within year before initial culture date. □ Residence in a long-term care facility within year before initial culture date. □ Admitted to a LTACH within year before initial culture date.	21. Prior healthcare exposure — healthcare-associated and community-associated: (check all that apply) □ Hospitalization within year before initial culture date. If known, Facility ID _____ □ Residence in a long-term care facility within year before initial culture date. If known, Facility ID _____ □ Admitted to a LTACH within year before initial culture date. If known, Facility ID _____

8. <u>MuGSI Case Report Form</u>

Current question	**Requested change**
5: Where was the patient location on the 4th calendar day prior to the date of initial culture? • LTCF • LTACH • Hospital Inpatient (If transferred, hospital ID_____)	5: Where was the patient location on the 4th calendar day prior to the date of initial culture? • LTCF Facility ID_____ • LTACH Facility ID_____ • Hospital Inpatient, Was the patient transferred from this facility? •Yes •No •Unknown Facility ID_____
10b: Location of culture collection • LTCF • LTACH	10b: Location of culture collection • LTCF Facility ID_____ • LTACH Facility ID_____
12: Patient outcome, If survived, transferred to • LTCF • LTACH	Add option to collect the provider ID for 12: Patient outcome, If survived, transferred to • LTCF Facility ID_____ • LTACH Facility ID_____
13c: Was the initial isolate tested for carbapenemase? • Yes • No • Unknown	13c: Was the initial isolate tested for carbapenemase? • Yes • No • Laboratory Not Testing • Unknown
Q13c: If yes, what testing method was used (check all that apply): • Modified Hodge Test • E Test • PCR • Other (specify):_____ • Unknown	Q13c: If yes, what testing method was used (check all that apply): • Automated Molecular Assay (specify):_____ • Carba-NP • E Test • PCR • Other (specify):_____ • Unknown

14b Record the colony count for the organism indicated in Q13a: _____	14b. Record the colony count for the organism indicated in Q13a: _____ •Unknown
15. Were cultures of OTHER sterile sites(s) or urine positive in the 30 days after the date of initial culture, for the SAME organism (Q13a)?	15. Was the same organism (Q13a) cultured from a different sterile site or urine in the 30 days after the date of initial culture (of this current episode)?
17d. If yes, specify organism, date of culture and stateid of the first positive Enterobacteriaceae culture in the year prior:	17d. If yes, specify organism, date of culture and stateid of the first positive Enterobacteriaceae culture in the year prior to the date of initial culture:
21. Risk Factors of Interest • Residence in LTCF within year before date of initial culture • Admitted to a LTACH within year before initial culture date	21. Risk Factors of Interest • Residence in LTCF within year before date of initial culture If known, prior facility ID:_____ • Admitted to a LTACH within year before initial culture date If known, prior facility ID:_____

Table A.1 Estimated Annualized Burden Hours
Items in Bold are forms for which we are requesting changes.
Items in Red are forms that impact the total burden.

Type of Respondent	Form Name	No. of respondents	No. of responses per respondent	Avg. burden per response (in hours)	Approved burden (in hours)	Requested burden (in hours)	+/-
State Health Department	**ABCs Case Report Form (Att. 1)**	**10**	**809**	**20/60**	**2697**	**2697**	
	Invasive Methicillin-resistant *Staphylococcus aureus* ABCs Case Report Form (Att. 7)	**10**	**609**	**20/60**	**2030**	**2030**	
	ABCs Invasive Pneumococcal Disease in Children Case Report Form	10	22	10/60	37	37	
	ABCs Non-Bacteremic Pneumococcal Disease Case Report Form (Att. 2)	**10**	**125**	**10/60**	**167**	**208**	**41**
	ABCs H. influenzae Neonatal Sepsis Expanded Surveillance Form (Att. 3)	**10**	**6**	**10/60**	**0**	**10**	**10**
	Neonatal Infection Expanded Tracking Form	10	37	20/60	123	123	
	ABCs Legionellosis Case Report Form	10	100	20/60	333	333	
	Campylobacter	10	637	20/60	2123	2123	

	Cryptosporidium	10	130	10/60	217	217	
	Cyclospora	10	3	10/60	5	5	
	Listeria monocytogenes	10	13	20/60	43	43	
	Salmonella	10	827	20/60	2757	2757	
	Shiga toxin producing E. coli	10	90	20/60	300	300	
	Shigella	10	178	10/60	297	297	
	Vibrio	10	20	10/60	33	33	
	Yersinia	10	16	10/60	27	27	
	Hemolytic Uremic Syndrome	10	10	1	100	100	
	Influenza Hospitalization Surveillance Project Case Report Form (Att. 5)	**10**	**400**	**15/60**	**1000**	**1000**	
	Influenza Hospitalization Surveillance Project Vaccination Telephone Survey	10	100	5/60	83	83	
	Influenza Hospitalization Surveillance Project Vaccination Telephone Survey Consent Form	10	100	5/60	83	83	
EIP site	**CDI Case Report Form (Att. 6)**	**10**	**1650**	**20/60**	**5500**	**5500**	
	CDI Treatment Form	10	1650	10/60	2750	2750	
	Resistant Gram-Negative Bacilli	**10**	**500**	**20/60**	**1667**	**1667**	

	Case Report Form (MuGSI) (Att. 8)						
Person(s) in the community infected with *C. difficile* (CDI Cases)	Screening Form	600	1	5/60	50	50	
	Telephone interview	500	1	40/60	333	333	
Total					**22,755**	**22,806**	**51**

In total, this non-substantive change request accounts for an additional 51 burden hours to this collection per year.

Appendix A.

Background: Haemophilus influenzae serotype b (Hib) was once the leading cause of bacterial meningitis in the United States with high rates of invasive Hib disease seen among children less than 5 years of age. Although the incidence of invasive Hib disease in children less than 5 years of age has decreased by 98% since the introduction of the Hib vaccine, *H. influenzae* (Hi) continues to cause invasive disease; in the post-vaccine era, non-typeable Hi now causes the majority of invasive disease in all age groups. The highest rates of invasive Hi disease are seen in infants <1 year of age (8.39 per 100,000); 48% of cases in this age group are neonates (<1 month of age) [ABC data, 2004-2013].

There are limited population-studies in the United States describing Hi disease in neonates; most data are from case-reports and suggest an association between neonatal Hi and premature rupture of the membranes, prematurity, and high morbidity and mortality. To our knowledge, there are no population-based studies in the United States looking at either maternal factors (signs of maternal infection or labor and delivery course) in neonatal Hi infections or Hi infection in pregnant or post-partum women and subsequent infection in neonates; several small population-based studies in Europe found a 6-25 fold increased risk of invasive Hi during pregnancy and an increased risk of pregnancy loss among women with invasive Hi.

Gathering extended data (prenatal history, labor and delivery course) for both neonates and pregnant and post-partum women with Hi disease will aid in better understanding the burden of disease and possible risk factors for disease. These data may inform possible strategies for preventing disease and negative outcomes.