

**0920-0004 National Disease Surveillance Program II-Disease Summaries**

**(Expiration 10/31/2017)**

**Non-Substantive Change Request**

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This is a nonmaterial/non-substantive change request for OMB Control No. 0920-0004, expiration date 10/31/2017. This ICR covers the reporting of foodborne, enteric person-to-person, animal contact, environmental contamination other than food/water, other/unknown modes of transmission, and waterborne outbreak data from 59 sites (50 US states, the District of Columbia, five US territories, and three Freely Associated States) to the National Outbreak Reporting System (NORS).

CDC requests OMB approval for non-substantive changes to two forms included in ICR No. 0920-0004:

- Form 52.13, Foodborne Disease Transmission\_Person to Person\_Animal Contact (Attachment A)
- Form 52.12, Waterborne Diseases Outbreak Form (Attachment B)

The requested changes would increase the total number of estimated annualized burden hours for this information collection by 91 hours. The requested changes would increase the estimated cost burden by \$8,251. However, this increase is due primarily to updated wage estimates, not a substantial increase to the burden.

### **CDC Form 52.13, Foodborne Disease Transmission Person to Person Animal Contact (Attachment A)**

**Description/Justification of changes:** Data elements requiring change will improve clarification and readability of the data collection form; see table below. Most changes to the form are label changes that will improve clarity and accuracy of the question asked. These label changes should not impact the burden on reporters except through improved readability.

- We request the addition of questions on antimicrobial susceptibility testing. Reporters should have this information readily available from the investigation and it would not increase the burden to report. These questions are important for linking to the National Antimicrobial Resistance Monitoring System and provide data on antimicrobial resistance in outbreaks. Monitoring antimicrobial resistance has become a priority for CDC and the nation. Collecting these data will aid in efforts to monitor this emerging problem.
- We request to add questions to clarify if a food vehicle was identified or suspected and if there was a kitchen manager certified in food safety located at the location of preparation. These additional questions would not add burden to the reporter as they would be answered in the outbreak investigation.
- In addition, we would remove the Additional *Salmonella* Questions.
- We request the addition of nine questions to the animal contact section. These questions would be answered by the outbreak investigation and should not add burden on reporting. Although these are nine additional questions, the time burden is estimated based on the longest possible form entry, which is foodborne. The animal contact section is much shorter than the foodborne section, allowing the time burden to fall within the estimated 20 minutes.
- We request the addition of questions to gain further data on *Shigella* outbreaks. These three questions will only be asked if the etiology of the outbreak is *Shigella* and the mode of transmission is person-to-person or unknown. These additional questions will not affect the burden of reporting because they will not be completed for foodborne outbreaks.

The data collection changes are summarized in the table below.

**Proposed Form Changes: CDC 52.13**

<b>Section</b>	<b>Current Question/Item</b>	<b>Requested Change</b>
General	Signs or Symptoms, 'Feature'	Change 'Feature' to 'Sign or Symptom'
General	Asymptomatic as a sign or symptom	Remove this as a printed option.
General	Environmental Health Specialists Network	Change to 'Other System IDs'
General	EHS-Net Evaluation ID	Change to 'NEARS ID'
General		Add under 'Other System IDs,' OHHABS ID
General	Reporting State	Change to Reporting site
Etiology		Add 'Clinical and Environmental Testing' subheading
Etiology	Were any specimens collected and tested?	Change specimens to samples
Etiology	How many specimens of each type were tested?	Change specimens to samples
Etiology		Add: Was antimicrobial susceptibility testing (AST) performed? [Yes, no, unknown]
Etiology		Add: If yes, where was AST performed? [clinical lab, PHL, CDC-NARMS, other, unknown]
Etiology		If yes, were any antimicrobial resistant isolates associated with the outbreak? [Yes, no, unknown]
Etiology		Add: CDC System to Isolates/Strains table
Etiology	State lab ID/Accession ID/CaliciNet key	State lab ID/Accession ID/CaliciNet key/PulseNet key
Etiology	CaliciNet sequenced region/other molecular designation 1	CaliciNet sequenced region/whole genome sequencing ID
Etiology	CaliciNet sequenced region/other molecular designation 2	CaliciNet sequenced region/other molecular designation
Settings	Major and other setting of Exposure picklist values.	Add: unknown, Shelter/group home/transitional housing as options.
Settings		Add: Specify setting [free text] field
Settings		Add: Further <i>Shigella</i> Questions subheading
Settings		Add: 1. Did any case-patients report travel prior to illness onset? [Yes, No; Unsure/unknown] If yes, was travel international, domestic, or both? [International, Domestic, Both, Unknown] 2. Were any confirmed, suspected, or probable case-patients immunocompromised (e.g., HIV/AIDS)? [Yes, No, Unsure/Unknown] 3. Were there any confirmed, suspected, or probable cases among men who have sex with men? [Yes, No, Unsure/Unknown]
Animal Contact		Add: Animal vehicle undetermined [checkbox]; Reason(s) animal contact, but undetermined vehicle
Animal Contact		Add: Animal type ( <i>specify</i> )
Animal Contact		Add: Confirmed or suspected vehicle
Animal Contact		Add: Reason(s) confirmed or suspected
Animal Contact		Add: Did any cases have exposure to livestock or household pets that were experiencing diarrhea? [Yes, No, Unknown]
Animal Contact		Add: Was pet food or animal feed implicated as a potential source of the outbreak? [Yes, no,

		<p>unknown]</p> <p>If yes, please specify:  Prepackaged pet food  Pet treats or chews  Homemade pet food  Commercially prepared 'raw' pet food  Frozen or fresh feeder rodents  Blended feed  Other (specify)  Unknown</p>
Animal Contact	Setting of Exposure	<p>Setting of Exposure (check all that apply):  [Removed from table format]  Agricultural feed store  Animal shelter or sanctuary  Camp  Child day care  Farm/dairy  Festival or fair  Hospital  Laboratory  Live animal market  Long-term care/nursing home/assisted living facility  Pet store or other retail location  Petting zoo  Prison/jail  Private home/residence  School/college/university  Veterinary clinic  Zoo or animal exhibit  Other (specify)  Unknown</p>
Animal Contact		<p>Add: What prevention measures or recommendations were used to stop the outbreak and prevent additional infections (check all that apply)?  Handwashing  Quarantine/stop movement  Venue or event closure  Removal of animals from setting  None  Other (specify)  Unknown</p>
Animal Contact		<p>Add: Was the Compendium of Measures to Prevent Disease Associated with Animals in Public Settings used in the investigation? [Yes, no, unknown]</p>
Food		<p>Add: Reasons foodborne, but undetermined vehicle</p>
Food		<p>Add to food grid: Confirmed or suspected vehicle</p>
Food		<p>Was there a kitchen manager certified in food safety at the location of preparation? [yes, no, unknown]</p>
Food	Confirmed or suspected point of contamination	<p>Add: unknown option</p>
Food	Was food worker implicated as the source of	<p>Add: unknown option</p>

	contamination	
Food	*If multiple schools are involved, please answer according to the most affected school.	Edit: *If multiple schools are involved, please answer for the school with the most cases.
Food	Additional <i>Salmonella</i> Questions	Remove entire section

### Burden

The estimated number of annualized burden hours is expected to increase by 90 hours, from 576 hours to 666 hours.

The change to the annualized burden hours is minimal because the reporting agencies currently collect these data elements for foodborne, person-to-person, and animal contact outbreaks. Therefore, the effort to include these additional data elements does not require up-front cost in hours. In addition, the changes to the annual submissions to CDC are not expected to change after these changes are implemented. There is an increase from 32 responses per respondent to 37 in 2016. This increase is based on median number of reports submitted by each state and territory in 2015; the number of reported outbreaks often fluctuates each year.

The burden hours were estimated based on the average time to complete the common data collection fields by multiple team members.

In the 0920-0004 revision approved in October, 2014, \$23.20 was used for the mean hourly wage of state workers. In this change request, we are using the most recent data which indicates that the mean hourly wage of state epidemiologists is \$32.15 (source: <http://www.bls.gov/oes/current/oes191041.htm#ind>).

In the approved ICR, the estimated burden for the completion of Form 52.13 was \$13,363.20. The estimated burden now is \$21,411.90, an increase of \$8,048.80. The increase in cost is not likely to have been incurred over this short time span, rather the updated cost is a more accurate representation of the true burden than previously estimated.

Estimates of Annualized Burden Hours (requested changes are highlighted)

Respondents	Form name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Approved burden (in hours)	Requested Burden (in hours)
Epidemiologist	CDC Form 52.13	54	37 (+5)	20/60	576	666 (+90)

Estimates of Annualized Cost Burden (requested changes are highlighted)

Respondents	Total Burden Hours	Hourly Wage Rate	Approved cost to respondents	Requested Respondent Cost
Epidemiologist	666 (+90)	\$32.15 (+\$8.95)	\$13,363.20	\$21,411.90 (+8,048.80)

**CDC Form 52.12, Waterborne Diseases Outbreak Form (Attachment B)**

The Waterborne Disease and Outbreak Surveillance System (WBDOSS) is a collaboration between the Centers for Disease Control (CDC), the Council of State and Territorial Epidemiologists (CSTE), and the Environmental Protection Agency (EPA). This system tracks and analyzes waterborne disease outbreaks in the United States. WBDOSS has received disease outbreak reports through the electronic National Outbreak Reporting System (NORS) since a revised form was approved by the Office of Management and Budget (OMB) in 2009. NORS variables correspond to variables in the CDC 52.12 form.

**Description/Justification of changes:** CDC requests revising Form 52.12 to include a new question to link to the One Health Harmful Algal Bloom System (OHHABS; OMB No. 0920-1105) and questions on antimicrobial susceptibility testing. Reporters would have this information available so it would not be expected to increase the burden to report. These questions are important for linking to the OHHABS and the National Antimicrobial Resistance Monitoring System, as well as providing data on antimicrobial resistance in outbreaks. Monitoring antimicrobial resistance has become a priority for CDC and the nation. Collecting these data will aid in efforts to monitor this emerging problem.

A complete list of changes to the form are detailed in the table below. Neither the actual annual number of reports nor the burden hours for users are expected to increase or decrease as a result of the changes present in the CDC 52.12, however updates have been made in the burden table to better reflect the maximum number of burden hours and cost burden independent of these changes. These updates are also described below.

Proposed Form Changes: CDC 52.12		
Section	Current Question/Item	Requested Change
General	Signs or Symptoms, 'Feature'	Change 'Feature' to 'Sign or Symptom'
General	Asymptomatic as a sign or symptom	Remove this as a printed option and delete the blank data entry row
General	Environmental Health Specialists Network	Change to 'Other System IDs'
General	EHS-Net Evaluation ID	Change to 'NEARS ID'
General		Add under 'Other System IDs,' OHHABS ID
General	Reporting State	Change to Reporting site
Water-General	Other, specify:	Delete the text field after "Other" and redirect respondents to enter other values in an existing remarks field
Water-Etiology & Lab	Test types	Change to "Testing Information"
Water-Etiology & Lab	Test Types	Add label to existing question "1. Test types (Select all test types used for clinical specimens)
Water-Etiology & Lab		Add question 2: "2. Was Antimicrobial Susceptibility Testing (AST) performed? With

		answer choices of "Yes, No, Unknown". Add sub-question: "If yes, where was AST performed?" with answer choices of "Clinical Lab, PHL, CDC-NARMS, Other, Unknown". Add another sub-question "If yes, were any antimicrobial resistant isolates associated with the outbreak?" with answer choices of "Yes, No, Unknown"
Other or Unknown Water	Contributing factors	Add three contributing factor options to the list on the form: -Ornamental fountain - presence of submerged lighting -Ornamental fountain - lack of a written cleaning and maintenance program -Ornamental fountain - presence of dirt, organic matter, or other debris in the water basin
Specimen type		Delete a data entry row

### Burden

The estimated number of annualized burden hours for this form is expected to increase by one hour. The change to the annualized burden hours and cost is minimal because the reporting agencies currently collect these data elements for waterborne disease outbreaks.

NORS supports outbreak reporting by 59 sites (50 US states, the District of Columbia, five US territories, and three Freely Associated States). Therefore, the number of estimated respondents has been updated from 57 to 59. Not all 59 report each year so this update presents a maximum rather than an actual annual number of respondents. The one hour increase in annualized burden (from 19 hours to 20 hours) is due to the additional two respondents.

In addition, the burden cost was based on the form being completed by an epidemiologist at the reporting site. In the most recent revision of 0920-0004, \$23.20 was used for the mean hourly wage of state workers. In this change request, we're using the most recent data which indicates that the mean hourly wage of state epidemiologists is \$32.15 (source: <http://www.bls.gov/oes/current/oes191041.htm#ind>). In the approved ICR, the total estimated burden was \$440.80. The estimated burden now is \$643.00, an increase of \$202.20. The slight increase in cost is not likely to have been incurred over this short time span, rather the updated cost is a more accurate representation of the true burden than previously estimated.

Estimates of Annualized Burden Hours (requested changes are highlighted)

Respondents	Form name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Approved burden (in hours)	Requested Burden (in hours)
Epidemiologist	CDC Form 52.12	59 (+2)	1	20/60	19	20 (+1)

Estimates of Annualized Cost Burden (requested changes are highlighted).

<b>Respondents</b>	<b>Total Burden Hours</b>	<b>Hourly Wage Rate</b>	<b>Approved cost to respondents</b>	<b>Requested Respondent Cost</b>
Epidemiologist	20 (+1)	\$32.15 (+\$8.95)	\$440.80	\$643.00 (+\$202.20)