Non-Substantive Change Request to National Disease Surveillance Program - II. Disease Summaries OMB Control Number 0920-0004

Program Contact

Kristin Pope Associate Director, Office of Policy National Center for Immunization and Respiratory Diseases Centers for Disease Control and Prevention 1600 Clifton Road, N.E., MS C12 Atlanta, Georgia 30333

Phone: (404) 639.8714 Email: kfp7@cdc.gov

Submission Date: December 17, 2014

Circumstances of Change Request for OMB 0920-0004

CDC requests approval for a non-substantive change to OMB Control No. 0920-0004 National Disease Surveillance Program - II. Disease Summaries. Non-substantive changes are included in the following forms:

Attachment D, Foodborne Disease Transmission_Person to Person_Animal Contact (CDC 52.13)

Attachment J, Influenza-Associated Pediatric Mortality Case Report Form

Attachment T, Antiviral Resistant Influenza Infection Case Report Form

Attachment Z, Waterborne Diseases Outbreak Form (CDC 52.12)

State and Territorial Epidemiologists are responsible for the collection, interpretation and transmission of medical and epidemiologic information at the state level. Disease Summaries are submitted by State Health Departments to CDC where the data are tabulated, analyzed for trends, published, and distributed within the health community. By coordinating nationwide collection of epidemiological data, CDC is able to calculate annual between-state comparisons of diseases. These data are essential on the Local, State, and Federal levels for measuring trends in diseases, evaluating the effectiveness of current preventive strategies, and determining the need for modifying current preventive measures.

Overall, these changes include adding, deleting and reformatting. The modifications in Attachment D, Foodborne Disease Transmission_Person to Person_Animal Contact (CDC 52.13), Attachment Z, Waterborne Diseases Outbreak Form (CDC 52.12) and Attachment T, Antiviral Resistant Influenza Infection Case Report Form are needed primarily to reduce confusion and more effectively respond to the questions. Additionally, the selections regarding influenza testing results were expanded in Attachment J, Influenza-Associated Pediatric Mortality Case Report Form, to include the capacity for laboratories to differentiate lineages of influenza B viruses which will provide information on influenza viruses that are causing mortality in children under 18 years of age.

Estimates of annualized burden hours for this change request remain the same. The total burden estimate for all forms included in OMB Control No. 0920-0004 is 31,922 hours (see Table 1).

Description of Changes

This is a request to modify 4 currently approved information collection tools. The changes to each form are as follows.

- 1) Foodborne Disease Transmission Person to Person Animal Contact (CDC 52.13)
 - a) Under the General Section, Geographic location, Reporting State and Reporting County variables have been modified to Exposure State and Exposure County
 - b) Under the Reporting Agency Section, Reporting State option has been added.
 - c) Under the Etiology Section:
 - i) Removed question Etiology known? Yes/ No
 - ii) Modified Question 1 from "If etiology is unknown, were patient specimens collected (Yes/No/Unknown)" to "Were any specimens collected and tested? (Yes/ No/ Unknown)"
 - iii) Removed "If yes" from "How many specimens of each type were tested? "
 - iv) Added table to Question 2 to include three columns: Type of sample, Tested?(Yes/No/Unknown), and No. of specimens tested

- v) Modified Question 3 to include "Unknown"
- vi) Added Question 4 "Test Types"
- vii) Added Question 5, "Is there at least one confirmed or suspected outbreak etiology(s)? Yes, No (unknown etiology)"
- viii) Etiology table: Options for column 6 have been updated to include water sample and animal specimen.
- ix) Isolates/Strains table: Under the first column included Accession ID as an option (State Lab ID/Accession ID/CaliciNet Key)
- d) Under Food Section:
 - i) Contaminated food imported to US, modified to include "Unknown" as an option
 - ii) School Questions Question 2 School Characteristics, removed preschool as an option

2) <u>Influenza-Associated Pediatric Mortality Case Report Form</u>

 Under Influenza Testing Section, added additional Result Options. The selections regarding influenza testing results were expanded to include the capacity for laboratories to differentiate lineages of influenza B viruses which will provide additional information on influenza viruses that are causing mortality in children under 18 years of age.

3) Antiviral Resistant Influenza Infection Case Report Form

- a) Under Specimen Information Section:
 - i) Zanamivir Resistance (Yes/No/Unknown) has been added
 - ii) Specimen Type has been modified to Influenza Type/Subtype
- b) Under Basic Information Section:
 - i) Modified "Is Sex Known? Yes/No" question to an "Unknown" option
 - ii) Modified "Is Race Known? Yes/No" question to an "Unknown" option
 - iii) Modified "Is Ethnicity Known? Yes/No" question to an "Unknown" option
- c) Moved Immunosuppression Details from end of document to after Section III.
- d) Under IV. Hospitalization Patient Information Section
 - i) Removed "Mechanically Ventilated Yes/No/Unknown"
 - ii) Removed "On Vasopressors? Yes/No/Unknown"
 - iii) Removed "Renal Failure requiring Dialysis? Yes/No/Unknown"
- e) VII. Clinical Illness Section
 - i) Removed Question 2, 3, 4, 5, 7, 8, 9, 10, 11
- f) VIII. Transmission History
 - i) Removed Question 2 "How many people live in your household?"
- g) Removed self-reported antiviral consent form /telephone script
- 4) Waterborne Diseases Outbreak Form (CDC 52.12)

- a) Under the General Section, Geographic location, Reporting State and Reporting County variables have been modified to Exposure State and Exposure County
- b) Under the Reporting Agency Section, Reporting State has been added
- c) Under Water –General Section, Symptoms/Conditionsvariables have been removed
- d) Under Water Etiology & Lab:
 - i) Outbreak Etiology Section 'Confirmed as Etiology' column: "Yes" variables have been modified to 'Confirmed' and 'Suspected'
 - ii) Outbreak Etiology Section 'Total # Tested' and 'Total # Positive' has been modified to include "Primary Cases" for clarification
 - iii) Test Types Section: under DNA or RNA Amplication/Detection, the text in the second variable has been changed from "TR-PCR" to "RT-PCR".
 - iv) Test Types Section: Phage Typing variable has been removed
- e) Under the Water Samples, Microbiology or Chemical/Toxin Analysis Section, a 'No' option has been added to each row for the 'Test Results Positive' question.
- f) Under the Recreational Water Treated Venue Section:
 - i) Under Implicated Water Recreational Water Venue Description, the sixth data row has been deleted
 - ii) A header "Implicated Water Water Treatment Description" has been added above the second table
 - iii) The 8th data row included in table "Implicated Water Water Treatment Description" has been deleted
 - iv) A header "Implicated Water Fill Water Description" has been added above the third table.

Burden

Estimates of Annualized Burden Hours for this change request remain the same.

The total burden estimate for all forms is 31,922 hours in Table 1.

Table 1 – Estimate of Annualized Burden Hours

Type of Respondents State Epidemiologists Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
Foodborne Disease Transmission_Person to Person_Animal Contact CDC 52.13	54	32	20/60	576

WHO Collaborating Center for Influenza: Influenza Virus Surveillance (Internet; year round) (CDC 55.31) U.S. WHO Collaborating	35 87	52 1	10/60	303 15
Laboratories Influenza Testing Methods Assessment	07		10/00	13
US Outpatient Influenza- like Illness Surveillance Network (ILINet) Weekly (CDC 55.20)	1,800	52	10/60	15,600
US Outpatient Influenza- like Illness Surveillance Network (ILINet) Daily ILINet, Reports of Influenza-Like Illness (ILI)	75	365	10/60	4,563
Influenza-Associated Pediatric Mortality_Case Report Form	57	2	30/60	57
Human Infection with Novel Influenza A Virus Case Report Form	57	6	30/60	171
Human Infection with Novel Influenza A Virus with Suspected Avian Source	57	1	30/60	29
Human Infection with Novel Influenza A Virus Severe Outcomes	57	1	1.5/60	86
Novel Influenza A Virus Infection Contact Tracing Form	57	1	30/60	29
Novel Influenza A Virus Case Status Summary	57	1	15/60	14
Novel Influenza A Virus Case Screening Form	57	1	15/60	14

122 CMRS - City health officers or vital statistics registrars Daily Mortality Report	58	365	12/60	4,234
122 CMRS - City health officers or vital statistics registrars Weekly Mortality Report	122	52	12/60	1,269
Aggregate Hospitalization and Death Reporting Activity Weekly Report Form	56	52	10/60	485
Antiviral Resistant Influenza Infection Case Report Form	57	3	30/60	86
National Respiratory & Enteric Virus Surveillance System (NREVSS) (CDC 55.83 Lab Assessment Form, 55.83A, B, D) (electronic)	300	52	15/60	3900
National Enterovirus Surveillance Report: (CDC 55.9) (electronic)	25	12	15/60	75
Adenovirus Typing Report Form	25	12	15/60	75
Middle East Respiratory Syndrome Coronavirus (MERS) Patient Under Investigation (PUI) Form	57	3	25/60	71
Form for Submitting Specimens From Suspected Norovirus Outbreaks	20	5	15/60	25
Waterborne Disease Transmission CDC 52.12.	57	1	20/60	19

Influenza Virus	49	52	5/60	212
(Electronic, Year Round),				
PHLIP_HL7 messaging				
Data Elements				
-Influenza virus	3	52	5/60	13
(electronic, year round)		3_	3, 33	
(PHIN-MS)				
Total				31,921