NATIONAL DISEASE SURVEILLANCE PROGRAM - II.
DISEASE SUMMARIES

OMB 0920-0004

REVISION

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National Disease Surveillance Program- II. Disease Summaries
OMB 0920-0004- Request for Revision

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- Revision includes a new respiratory form, form consolidation, minor revised language to improve clarity and the discontinuation of multiple previously approved forms.
- The data will be used to determine the prevalence of disease and planning and evaluating programs for prevention and control of infectious diseases. Disease incidence is needed to study present and emerging disease problems.
- The methodology for reporting varies depending on the occurrence, modes of transmission, infectious agents, and epidemiologic measures.
- The subpopulation is anyone who meets the criteria or case definitions for these diseases.
- Data collected as part of the CDC surveillance activities are published frequently in the *MMWR* and in the Surveillance Summaries published periodically as part of the *MMWR*. In addition, the data are included in the *MMWR* Annual Summary, in individual surveillance reports prepared on individual diseases under surveillance, and in journals related to individual diseases.

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a three-year approval for National Disease Surveillance Program - II. Disease Summaries, OMB Control Number 0920-0004. Expiration Date October 31, 2017. This is a revision of a previously approved information collection request.

Surveillance of the incidence and distribution of disease has been an important function of the U.S. Public Health Service since 1878. Through the years, PHS/CDC has formulated practical methods of disease control through field investigations. The CDC surveillance program is based on the premise that diseases cannot be diagnosed, prevented, or controlled until existing knowledge is expanded and new ideas developed and implemented. Over the years CDC's mandate has broadened to include preventive health activities thus expanding surveillance systems. This surveillance program is authorized under the provisions of Section 301 of the Public Health Service Act (42 USC 241) (Attachment A).

Data on disease and preventable conditions are collected in accordance with jointly approved plans by CDC and the Council of State and Territorial Epidemiologists (CSTE). Changes in the surveillance program and in reporting methods are affected in the same manner. In 1968, at the beginning of this surveillance program, CSTE and CDC decided which diseases warranted surveillance. These diseases are reviewed and revised based on variations in the public's health. Surveillance forms are distributed to State and local health department staff who voluntarily submit these reports to CDC on variable frequencies; weekly, monthly, or quarterly. CDC then calculates and publishes weekly statistics via the *Morbidity and Mortality Weekly Report* (MMWR), providing the states with timely aggregates of their submissions.

Since infectious disease agents and environmental hazards often cross geographical boundaries, public health departments have to be able to share data on certain conditions across jurisdictions and to coordinate program activities to prevent and control the conditions.

The following diseases/conditions are included in this program:

Influenza Virus
Caliciviruses
Respiratory and Enteric Viruses
Foodborne Outbreaks
Waterborne Outbreaks
Enteric Person-to-Person Outbreaks
Animal Contact Outbreaks
Enteric Environmental Contamination Outbreaks Other than Food/Water/Animal Contact
Enteric Outbreaks with Unknown Mode
Enteroviruses

Attachment C contains descriptive summaries of each disease under surveillance.

2. Purpose and Use of Information Collection

State and Territorial Epidemiologists are responsible for the collection, interpretation, and transmission of medical and epidemiologic information at the state level. State Health Departments submit the disease summaries to CDC and CDC tabulates, analyzes the data for trends, publishes, and distributes within the health community. By coordinating nationwide collection of epidemiological data, CDC is able to calculate annual between-state comparisons of diseases covered under this request.

As with the previous approval, these data are essential for measuring trends in diseases, evaluating the effectiveness of current preventive strategies, and determining the need to modify current preventive measures. Diseases included in this surveillance program are Influenza Virus, Caliciviruses, Respiratory and Enteric Viruses, Foodborne Outbreaks, Waterborne Outbreaks, and Enteroviruses. Proposed revisions include form consolidation, minor revised language, and rewording to improve clarity and readability of the data collection forms and the discontinuation of multiple previously approved influenza collection instruments, and the National Respiratory & Enteric Virus Surveillance System (NREVSS) Laboratory Assessment (CDC 55.83). CDC requests the use of a new form, Suspect Respiratory Virus Patient Form, to assist health departments and clinical sites when they submit specimens to the CDC lab for viral pathogen identification. The data will enable rapid detection and characterization of outbreaks of known pathogens, as well as potential newly emerging viral pathogens. The frequency of response for each form will depend on the disease and surveillance need. This represents a 7,116 burden hour reduction since last approval. This reduction in burden hours is primarily attributed to the discontinuation of previously approved forms and formatting changes to existing forms. The total burden estimate for all collection instruments in this revision request is 24,805. There are no costs to the respondents other than their time.

3. Use of Improved Information Technology and Burden Reduction

The methodology for reporting varies depending on the occurrence, modes of transmission, infectious agents, and epidemiologic measures. For example, the reporting of the Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form is reported as needed via facsimile transmission, email, or direct data entry via the Internet.

Historically, use of data collected by the foodborne disease outbreak system was slowed because of the time required for data entry and coding once the forms were received. In 1998, CDC introduced electronic reporting of foodborne outbreak data through the electronic Foodborne Outbreak Reporting System (eFORS). eFORS was a web-based reporting system that collected the same information as the paper form, and was used by local, county, or state organizations to enter, edit, analyze, and transmit data electronically to other state or federal offices. Beginning in 1998, all reports were entered into eFORS. In 2009, this system was phased out in lieu of the National Outbreak Reporting System (NORS). NORS allows ongoing reporting of foodborne-associated outbreaks, in addition to the following modes of transmission: waterborne, person-to-person contact, animal contact, environmental contamination other than food/water/animal contact, and unknown mode of transmission.
Similar to foodborne disease outbreak reporting, waterborne disease outbreak data were initially collected through a paper-based reporting system. NORS included a waterborne disease outbreak reporting module that is accessible to local, county, and state organizations to enter, edit, analyze, and transmit data electronically to CDC. A PDF of the CDC 52.12 form matches the NORS interface and serves as a training device and a guide to health departments that routinely investigate outbreaks, however, report submissions occur only through NORS.

The National Enterovirus Surveillance System (NESS) uses an MS Excel spreadsheet to list each detection report. The report is completed either on a monthly or a quarterly basis by the respondents, and then emailed to the coordinator for entry into an MS Access database. The same data may also be reported through a secure web-based platform called NESSweb.

The National Respiratory and Enteric Virus Surveillance System (NREVSS) reporting is conducted weekly using a secure CDC website. Staff report that electronic reporting allows immediate processing

and analysis of national trends and allows for data correction by participating centers.

For virologic surveillance data collected through the U.S. World Health Organization (WHO) Collaborating Laboratories system, data is transmitted from participating laboratories using PHIN-MS, PHLIS2, or a secure password-protected CDC website. For data collected through the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), reporting is conducted by enrolled healthcare providers each week using a secure password-protected CDC website. This electronic reporting allows for immediate processing and analysis of virologic and ILINet surveillance data. A small number (less than 3%) of enrolled ILINet providers submit their weekly data to CDC via facsimile transmission. Individual case report forms for human infections with novel influenza A viruses, also including a separate report form for cases with severe outcomes, and for influenza-associated pediatric deaths are submitted on the CDC Secure Access Management System (SAMS) from state and select local health departments. Data collected on the Antiviral Resistant Influenza Infection Case Report Form and the U.S. WHO Collaborating Laboratories Testing Methods Assessment are submitted to the domestic surveillance team via facsimile transmission or email.

The information requested is the minimum amount required to maintain surveillance of these selected diseases.

4. Efforts to Identify Duplication and Use of Similar Information

The specific variables included in this information collection request are not included in any other nationwide disease-specific surveillance system. While similar information may be collected from limited geographic areas or collected in one-time studies, for most diseases, sampling would not be sufficient for the states' need of conducting prevention or control programs. The surveillance systems in this request collect data from all states and territories of the U.S. in a uniform manner.

5. Impact on Small Businesses and Other Small Entities

This collection of information will not involve small businesses or other small entities.

6. Consequences of Collecting Information Less Frequently

Disease reporting varies to the extent that diseases differ in occurrence, modes of transmission, infectious agents, patient's susceptibility and resistance, control of patient's contacts and the immediate environment, and epidemiologic measures. The first step in the control of a given disease is its rapid identification followed by notification to the local health authority that a case of disease exists within a particular jurisdiction. Prompt notification to CDC allows for identification of epidemics and outbreaks so that immediate prevention and control measures can be taken. The submission frequency requested in this package is dependent on the particular epidemiology of the disease in question and is addressed individually for each form.

For example, timely collection of information allows rapid analysis of data to detect unusual disease clusters, which is necessary to recognize foodborne outbreaks. A statistical algorithm that detects unusual clusters is applied to information collected in PHLIS.

CDC is responsible for surveillance of influenza with the goal of determining the impact of the disease on the U.S. population and developing improved prevention and control measures. Influenza types A and B viruses are responsible for epidemics of respiratory illness that occur almost every winter in temperate climates and are often associated with increased rates of hospitalization and death. The estimated rates of influenza-associated hospitalizations and influenza-related deaths vary substantially

from one influenza season to the next, depending, in part, on the characteristics of the circulating influenza virus strains. The emergence of new strains of influenza, such as influenza A (H1N1) pdm09 virus, influenza A (H3N2) variant virus, and influenza A (H7N9) virus necessitate annual virologic and epidemiologic surveillance.

Influenza surveillance data are used to determine influenza vaccine composition for the following year and permits rapid detection of influenza virus circulation and the degree to which vaccine virus strains match circulating wild type virus strains. It provides data used in determining influenza-associated morbidity, mortality, and economic loss. Furthermore, it may assist in the control of the disease by affording the opportunity for rapid preventive action, for example, by chemoprophylaxis of high-risk persons who have not received the vaccine. Circulating influenza viruses are constantly changing and annual monitoring for antiviral resistant influenza viruses is needed as this information is critical to antiviral recommendations and guidance. In addition to monitoring annual influenza epidemics, this system is in place to detect viruses with pandemic potential and track the course of the next influenza pandemic.

Monthly or quarterly reports of enterovirus detections in the US via the National Enterovirus Surveillance System (NESS) aids in establishing seasonal trends. Each year, the peak activity occurs in the summer months. However, varying types of enteroviruses in a given year may result in earlier or later peak activity.

The weekly reports collected via National Respiratory and Enteric Virus Surveillance System (NREVSS) are analyzed by CDC staff and the results are immediately updated on a public CDC website. Real-time data allow physicians and public health officials to make decisions based on the most up to date surveillance reports of viral activity in their area.

The National Adenovirus Type Reporting System (NATRS) is a passive surveillance mechanism to collect adenovirus typing data on a quarterly basis from laboratories in the US. When available, this granular data enhances adenovirus circulation data already collected by NREVSS. The objective is to document the types of adenovirus circulating in the US and identify any emergent or severe adenovirus infections by using a simple, voluntary reporting mechanism. Transmission, seasonality, and clinical course vary greatly according to the specific types of adenovirus that may cause infection in humans. A vaccine that protects against several adenovirus types is currently available to US military recruits. The effect of this vaccine on overall circulation of adenovirus types in specific settings is unknown and warrants monitoring.

There is a need for real-time monitoring for the emergence of MERS-CoV in the US due to the uncertainty and threat to human health. Less frequent data collection could result in missing the initial cases of MERS-CoV occurring in the US delaying the public health response to this emerging virus in the human population.

The Suspect Respiratory Virus Patient Form will be made available to health departments and clinical sites when they submit specimens to the CDC lab for viral pathogen identification. Submission of specimens is typically only done for severe cases of unknown etiology, particularly when a cluster of similar cases are noted, requiring further investigation. The data provided will enable rapid detection and characterization of outbreaks of known pathogens, as well as potential newly emerging viral pathogens.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

As described in section A.6, in order to permit rapid response to public health problems and prompt initiation of prevention and control measures, respondents may be required to report information more often than quarterly. Surveillance reports are submitted as soon as possible after an epidemiologic investigation and delays in reporting could result in serious public health consequences. There are no other special circumstances.

This request fully complies with regulation 5 CFR 1320.5 with the exception to quarterly reporting.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A 60-day Federal Register Notice (Attachment B) was published in the *Federal Register* on 04/19/2017, Vol 82, No. 74, pp. 18459-18460. CDC did not receive public comments related to this notice.

B. Consult Outside the Agency: The Council of State and Territorial Epidemiologists (CSTE) are routinely consulted regarding the availability of data, the frequency of collection, and the revisions of any forms. CDC has collaborated with CSTE since CSTE's inception in 1951, and it is through the CSTE annual conference that the cooperation of all states is maintained. Although formal CSTE meetings are usually held only once a year, communication between CDC and CSTE groups and individual members of those organizations continue on a regular basis throughout the year. Jeff Engle is the Executive Director (jengle@cste.org).

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Protection of the Privacy and Confidentiality of Information Provided to Respondents

The NCIRD Information Systems Security Officer reviewed this submission and determined that it is not applicable to the Privacy Act because the information is not retrieved by personal identifiers. However, personally identifiable information (PII) is collected on some of the forms.

For the diarrheal disease case surveillance, identifiers are maintained at the state or local health department, and information is encrypted before data are transmitted to CDC. CDC does not have the capability of un-encrypting identifiers.

State and local health departments use personally identifiable information to support local disease control activities related to foodborne, person-to-person, animal contact, environmental, unknown, and waterborne outbreaks, however, personally identifiable information related to outbreak surveillance is not submitted to CDC. Non-identifiable data relating to foodborne, person-to-person, animal contact, environmental, unknown, and waterborne outbreaks are submitted to CDC via a secure system called NORS (National Outbreak Reporting System).

NREVSS data are collected through a secure website within the CDC. No identifiers or demographics are included in this surveillance system. The respondents only submit the total number of tests performed for each virus and the total number of positive results each week. No person-level data is

collected. Once entry is complete, the data are housed on a secure SQL server, accessible only by the Office of Informatics technical developer and the NREVSS coordinator.

Data collection for NATRS, the Suspect Respiratory Virus Patient Form, the National Enterovirus Surveillance System, and the Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form includes age, gender, state of residence, and optional information on broad clinical outcomes. A locally assigned patient ID and/or specimen ID may be submitted for NATRS, the Suspect Respiratory Virus Patient Form, and the Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form. This number, typically assigned by a state or local health department or possibly by a hospital, may be used by CDC to group results together that were submitted for a single person or to report test results for a specific specimen back to the health department or submitting laboratory which will maintain the link to personal identifiers as needed. The data for NESS are not identifiable and does not include any identifier that could be traced back to the patient.

Data collected through the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) do not involve the collection of individually identifiable information. Submission of data through PHLIP_HL7 messaging and PHIN-MS submit the influenza laboratory results of testing on the patient level, and submitting laboratories have the option of including information on age, gender, and state of residence. Case report forms for influenza-associated pediatric deaths and human infections with novel influenza A viruses are collected through the CDC Secure Access Management System (SAMS) from state and select local health departments. Data collection for influenza-associated pediatric deaths and human infections with novel influenza A viruses will include age, gender, race, ethnicity, state and county of residence, date of birth, and date of death. Data collection for antiviral-resistant influenza infections will include age, gender, race, ethnicity, and state and county of residence. This data will be faxed or emailed to the influenza antiviral resistance coordinator. Once submitted data from all surveillance systems are received at CDC, the data is stored on secure SQL servers and access to databases are limited to select domestic influenza surveillance staff.

Records are safeguarded appropriately. Access is limited to personnel whose official job duties require them to use the records. Paper forms are kept in locked file cabinets in a locked room. Computer files are password protected. State health departments reporting patient names electronically encrypt identifiers before sending them to CDC.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

A CDC human subjects advisor has determined that the activities in 0920-0004 are considered routine surveillance activities. Consistent with current CDC policy, routine surveillance activities do not meet the regulatory definition of research, and are therefore outside the scope of IRB review requirements. (Attachment DD)

Sensitive Questions

Epidemiologic characteristics such as age, sex, and geographic location are routinely collected because of their significance in resolving public health problems. Some forms also include race and ethnicity data, which may be considered sensitive by some persons, but are routinely collected in HHS/CDC data collections. CDC does not collect race/ethnicity information on the following forms: foodborne outbreaks, aggregated influenza surveillance, waterborne disease outbreaks, and CaliciNet, because, race/ethnicity are not key risk factors for contracting these diseases. If race/ethnicity is not an integral

part of epidemiologic investigation, it is not collected. Clinical laboratory data are collected and reported when that information is essential to proper identification and control of the particular health problem. Only the minimum data necessary is collected on all surveillance forms.

12. Estimates of Annualized Burden Hours and Costs

A. The total burden estimate in Table 1 for all forms is 24,801. The frequency of response for each form will depend on the disease and surveillance need. This represents a 7,211 burden hour reduction since last approval. This reduction in burden hours is attributed primarily to the discontinuation of previously approved forms and formatting changes to existing forms. Current burden estimates are based on previous experience and feedback from stakeholders using these instruments.

Table 1 – Estimate of Annualized Burden Hours

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Avg. Burden per Response (in hours)**	**Total Burden Hours**
Epidemiologist	Attachment D_NORS Foodborne Disease Transmission_ Person to Person Disease Transmission_ Animal Contact_Environmental Contamination_Unknown Transmission Mode_52.13	54	37	20/60	666
Epidemiologist	Attachment E_WHO COLLABORATING CENTER FOR INFLUENZA Influenza Virus Surveillance	53	52	10/60	459
Epidemiologist	Attachment F_U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment	113	1	10/60	19
Epidemiologist	Attachment G-US Outpatient Influenza-like Illness Surveillance Network (ILINet) Weekly_CDC 55.20	1,800	52	10/60	15,600
Epidemiologist	Attachment H_US Outpatient Influenza-like Illness Surveillance Network (ILINet) Workfolder 55.20E	1,800	1	5/60	150
Epidemiologist	Attachment J_Influenza-Associated Pediatric Mortality_ Case Report Form	57	2	30/60	57

Epidemiologist	Attachment K_Human Infection with Novel Influenza A Virus Case Report Form	57	2	30/60	57
Epidemiologist	Attachment M_Human Infection with Novel Influenza A Virus Severe Outcomes	57	1	90/60	86
Epidemiologist	Attachment P_Novel Influenza A Virus Case Screening Form	57	1	15/60	14
Epidemiologist	Attachment T_Antiviral Resistant Influenza Infection Case Report Form	57	3	30/60	86
Epidemiologist	Attachment U_National Respiratory & Enteric Virus Surveillance System (NREVSS) (55.83A, B, D) (electronic)	550	52	15/60	7,150
Epidemiologist	Attachment V_National Enterovirus Surveillance Report: (CDC 55.9) (electronic)	20	12	15/60	60
Epidemiologist	Attachment W_National Adenovirus Type Reporting System (NATRS)	13	4	15/60	13
Epidemiologist	Attachment X_Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form	57	3	25/60	71
Epidemiologist	Attachment Y_Viral Gastroenteritis Outbreak Submission Form	20	5	5/60	8
Epidemiologist	Attachment Z_NORS Waterborne Disease Transmission Form_52.12.	59	1	20/60	20
Epidemiologist	Attachment AA_Influenza Virus (Electronic, Year Round), PHLIP_HL7 messaging Data Elements	57	52	5/60	247
Epidemiologist	Attachment BB_Influenza virus (electronic, year round) (PHIN-MS)	3	52	5/60	13
Epidemiologist	Attachment CC_Suspect Respiratory Virus Patient Form	10	5	30/60	25
Total					24801

B. The proposed estimated annual cost is $828,238.95. This represents an increase of $87,671.75 from the previous submission and can be attributed primarily to increase in the 2015 median pay of $33.39 for an epidemiologist. This information is based on data from the Bureau of Labor Statistics website (see https://www.bls.gov/ooh/life-physical-and-social-science/epidemiologists.htm).

Table 2- Estimated Annualized Burden Costs

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Avg. Burden per Response (in hours)**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Epidemiologist	Att D_NORS Foodborne Disease Transmission_ 52.13	54	37	20/60	666	$33.39	$22,237.74
Epidemiologist	Att E_WHO Collaborating Center for Influenza_Influenza Virus Surveillance	53	52	10/60	460	$33.39	$15,359.40
Epidemiologist	Att F_U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment	113	1	10/60	19	$33.39	$634.41
Epidemiologist	Att G_US Outpatient Influenza-like Illness Surveillance Network (ILINet) Weekly_CDC 55.20	1,800	52	10/60	15600	$33.39	$520,884.00
Epidemiologist	Att H_US Outpatient Influenza-like Illness Surveillance Network (ILINet) Workfolder 55.20E	1800	1	5/60	150	$33.39	$5,008.50
Epidemiologist	Att J_Influenza-Associated Pediatric Mortality_Case Report Form	57	2	30/60	57	$33.39	$1,903.23
Epidemiologist	Att K_Human Infection with Novel Influenza A Virus Case Report Form	57	2	30/60	57	$33.39	$1,903.23
Epidemiologist	Att M_Human	57	1	1.5/60	86	$33.39	$2,871.54

	Infection with Novel Influenza A Virus Severe Outcomes						
Epidemiologist	Att P_Novel Influenza A Virus Case Screening Form	57	1	15/60	15	$33.39	$500.85
Epidemiologist	Att T_Antiviral Resistant Influenza Infection Case Report Form	57	3	30/60	86	$33.39	$2,871.54
Epidemiologist	Att U_National Respiratory & Enteric Virus Surveillance System (NREVSS) (55.83A, B, D) (electronic)	550	52	15/60	7150	$33.39	$238,738.50
Epidemiologist	Att V_National Enterovirus Surveillance Report: (CDC 55.9) (electronic)	20	12	15/60	60	$33.39	$2,003.40
Epidemiologist	Att W_National Adenovirus Type Reporting System (NATRS)	13	4	15/60	13	$33.39	$434.07
Epidemiologist	Att X_Middle East Respiratory Syndrome Coronavirus (MERS) Patient Under Investigation (PUI) Form	57	3	25/60	72	$33.39	$2,404.08
Epidemiologist	Att Y_Viral Gastroenteritis Outbreak Submission Form	20	5	5/60	9	$33.39	$300.51
Epidemiologist	Att Z_NORS Waterborne Disease Transmission Form_52.12	59	1	20/60	20	$33.39	$667.80
Epidemiologist	Att AA_Influenza Virus (Electronic, Year Round), PHLIP_HL7 messaging Data Elements	57	52	5/60	247	$33.39	$8,247.33

Epidemiologist	Att BB_Influenza virus (electronic, year round) (PHIN-MS)	3	52	5/60	13	$33.39	$434.07
Epidemiologist	Attachment CC_Suspect Respiratory Virus Patient Form	10	5	30/60	25	$33.39	$834.75
Total							$828,238.95

13. Estimates of Other Total Annual Cost Burden to Respondents or Record-keepers

There are no capital and maintenance costs incurred by respondents

14. Annualized Cost to the Government

Each data case report results in action taken by multiple programs in response to the required CDC mandate in maintaining preventive health activities and surveillance systems. The action taken will vary, depending on the specifics of the data reporting involving multiple staff. Estimates for the foodborne and waterborne activities estimate $1,285,000.00. The foodborne and waterborne estimates include $900,000.00 for personnel across 2 CIOs (NCIRD and NCEZID) and 385,000.00 for Information Technology. Influenza activities estimate $8,120,000.00. The influenza estimate includes $7.55M for the Epidemiology and Laboratory Capacity (ELC) cooperative agreement to support epi and laboratory personnel in all 50 states, plus territories, Information Technology at $346,000.00, additional personnel costs of $765,746.00 and $9,500.00 for computers, printing and phones. NESS, NATRS, MERS and remaining collection activities estimate $260, 000.00. The overall incurred costs include staff support, platform maintenance and computer resources and some printing and miscellaneous expense such as phone calls. These costs more accurately reflect cooperative agreement funding and program costs to the federal government since the last revision. The estimated annual cost to the government is $9,665,000.00.

15. Explanation for Program Changes and Adjustments

This is a request for a revision as the ICR is due to expire on October 31, 2017. The majority of the collection activities remain the same, however, there are multiple proposed revisions including form consolidation, minor revised language, and rewording to improve clarity and readability of the data collection forms and the discontinuation of multiple previously approved influenza collection instruments, and the National Respiratory & Enteric Virus Surveillance System (NREVSS) Laboratory Assessment (CDC 55.83). CDC is also requesting the use of a new form, Suspect Respiratory Virus Patient Form. Details of each collection instrument for the revision is as follows:

Attachment D, NORS Foodborne Disease Transmission_ Person to Person Disease Transmission_ Animal Contact Environmental Contamination Unknown Transmission Mode (CDC52.13)

A non-substantive change request was OMB approved on 12/23/2016. In summary, that non-substantive change request included label changes to improve clarification and readability of the data collection form, and the addition of questions on antimicrobial susceptibility testing. These questions are important for linking to the National Antimicrobial Resistance_Monitoring System and provide data on antimicrobial resistance in outbreaks. Approved in the non-substantive change request was the overall burden that increased from 576 to 666 due to the increase in the number of responses per respondent. The basis for the increase from 32 responses per respondent to 37 in 2016 was based on median number

of reports submitted by each state and territory in 2015; the number of reported outbreaks often fluctuates each year.
For this revision, the name of the form is now reflected throughout the ICR, NORS Foodborne Disease Transmission_ Person to Person Disease Transmission_Animal Contact_Environmental Contamination_Unknown Transmission Mode_52.13.

Attachment E, WHO COLLABORATING CENTER FOR INFLUENZA Influenza Virus Surveillance (CDC 55.31)
For this revision, changes include the removal of internet; year round and the CDC 55.31 from the name of the form, an increase in the number of respondents from 35 to 53 for a total burden increase from 303 to 460. The increase is due to more collaborating laboratories located in the United States being enrolled to participate in virologic surveillance and allows for greater geographic representation.

Attachment F, U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment
For this revision, the number 55.31 is removed from the title of the form. Additional changes include an increase in the number of respondents from 87 to 113 for a total burden increase from 15 to 19. The change burden accounts for all WHO collaborating laboratories. The increase equates to number of respondents indicated in Attachment E, Attachment AA and Attachment BB.

Attachment G, U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) Weekly (CDC 55.20)
Minor revisions were made to this form. In addition to collecting data on influenza-like illness (ILI) by age group, providers will have the option to report the total number of patients seen by age group. This information assists in calculating the age-group specific impact of circulating influenza viruses on outpatient visits for ILI. No change to number of respondents, number of responses per respondent nor the average burden per response.

Attachment H, U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) Workfolder; CDC 55.20E
CDC 55.20E form is included as a work folder with CDC 55.20. These reporting forms are used to collect data on influenza-like illness (ILI) by age group and the total number of patients seen for any reason from participating healthcare providers. CDC 55.20E is used by the healthcare provider to track data that is submitted to CDC in the weekly ILI report and accounts for the entire influenza season. It is also used by CDC for data verification purposes. For this revision, there aren't any changes to the actual form however, CDC has accounted for 55.20E separately in the burden table for easier tracking. This is only submitted once a year when the log has been completed.

Attachment I, U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet); daily ILINet Reports of Influenza-like Illness (ILI)
This form is discontinued.

Attachment J_Influenza-Associated Pediatric Mortality Case Report Form
Minor edits were made to this form. In the influenza testing question (q15), there was a change in labeling of influenza A (H1) to influenza A (H1) (prior to 2010) to avoid confusion with influenza A (H1N1)pdm09 virus. In the influenza vaccine history section, one question was rephrased to better reflect recommendations made by the Advisory Committee on Advisory Practices (ACIP) and two questions were added to inquire if immunization records or information about influenza vaccination were available and if so, the sources of information (q25a and q25b). No change in burden.

Attachment K, Human Infection with Novel Influenza A Virus Case Report Form
For this revision, Human Infection with Novel Influenza A Virus with Suspected Avian Source was incorporated into the Human Infection with Novel Influenza A Virus Case Report Form for easier reporting as this form is now delineated by suspected source of infection (i.e. avian versus swine). The reduction in number of responses per respondent is due to more recent data that shows a reduction in number of responses in number of human infection cases reported to CDC. For example, in 2012 there were over 309 human infections with novel influenza A viruses reported whereas from 2013-2016, an average of 11 cases were reported to CDC per calendar year.

Attachment L, Human Infection with Novel Influenza A Virus With Suspected Avian Source
This form is discontinued. The specific avian exposure questions were incorporated into attachment K, Human Infection with Novel Influenza A Virus Case Report Form as noted above.

Attachment M, Human Infection with Novel Influenza A Virus Severe Outcomes
No Change.

Attachment N, Novel Influenza A Virus Infection Contact Tracing Form
This form is discontinued.

Attachment O, Novel Influenza A Virus Case Status Summary
This form is discontinued.

Attachment P, Novel Influenza A Virus Case Screening Form
Burden change reflects fraction round up to whole number.

Attachment Q, 122 CMRS City Health Officers or Vital Statistics Daily Mortality Report
This form is discontinued. CDC retired the 122 CMRS City Health Officers or Vital Statistics Daily Mortality Report.

Attachment R, 122 CMRS City Health Officers or Vital Statistics Weekly Mortality Report
This form is discontinued. CDC retired the 122 CMRS City Health Officers or Vital Statistics Daily Mortality Report.

Attachment S, Aggregate Hospitalization & Death Reporting Activity Weekly Report Form
This form is discontinued. It was originally used during the 2009 influenza A (H1N1)pdm09 pandemic and the subsequent 2010-2011 influenza season.

Attachment T, Antiviral Resistant Influenza Infection Case Report Form
No change.

Attachment U, National Respiratory & Enteric Virus Surveillance System (NREVSS) Laboratory Assessment (CDC 55.83) (electronic)
This form (55.83) is discontinued. Program determined that form 55.83 compared to 55.83 A, B, D was rarely used. Burden for 55.83 A, B, D is combined on the burden table.

Attachment U1, NREVSS Antigen Detection Worksheet (CDC 55.83A) (electronic)
Revisions include calendar updates for the 2016-2017 season. On the cover page, a previous gray scale

image of the CDC building is replaced with a color image. The increase in burden is due to increase in number of respondents.

Attachment U2, NREVSS Virus Isolation (Culture) Worksheet (CDC 55.83B) (electronic)
Revisions include calendar updates for the 2016-2017 season. On the cover sheet, a new graphic image for Participating Laboratories box and color image CDC building replaces a grayscale image from previous form. The increase in burden is due to increase in number of respondents.

Attachment U3, NREVSS Polymerase Chain Reaction (PCR) Worksheet (CDC 55.83D) (electronic)
Revisions include calendar updates for the 2016-2017 season. On the cover page, a previous gray scale image of the CDC building is replaced with a color image. The increase in burden is due to increase in number of respondents.

Attachment V, National Enterovirus Surveillance System (NESS) Report (CDC 55.9) (electronic)
No change to the collection instrument. Currently approximately 10-20 labs participate in NESS, thus the number of respondents has changed from 25 to 20 to more accurately reflect the number of respondents submitting at this time.

Attachment W, National Adenovirus Type Reporting System (NATRS) Form
Revisions include a minor name change from *Adenovirus Typing Form* to *National Adenovirus Type Reporting System (NATRS) Form*. Formatting has been changed and fields have been added to note unique patient and specimen IDs, and if the specimen was sent elsewhere for typing. Existing variables have been updated and/or reformatted to simplify data entry for the reporter. Changes include: Date of report to CDC (col B) was previously called "Report Date" which was filled out by the submitter and will now be filled out by NATRS coordinator. For Specimen type (col J), added "serum", "urine", and "blood" to options, clarified NP/OP swab to "NP and/or OP swab", clarified NP/OP wash "NP and/or OP wash". Under AdV species (cols O and Q), program added "species G" to options, AdV type (cols P and R) was reformatted into a drop down with list of known types, including an option for "undetermined". For Outbreak type (col z), program added "community" to options. Footnotes were also added to provide additional clarification during data entry for the reporter, specifically Age type (col G): footnote added "if patient age is 0-2 years, please list age in months", Patient ID (col C) and Specimen ID (col D): footnote added "Please enter unique patient level identifier and laboratory specimen identifier(s). If entering >1 specimen per patient, epidemiologic and clinical data may be entered for the first line only." Burden has changed to reflect an accurate number of respondents from 25 to 13 and the number of responses per respondent has changed from 12 to 4 reflecting quarterly submission.

Attachment X, Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form
Revisions include a name modification from *Middle East Respiratory Syndrome Coronavirus (MERS) Patient Under Investigation (PUI) Form* to *Middle East Respiratory Syndrome (MERS) Patient Under Investigation (PUI) Short Form*. Content changes are based on feedback from public health partners, healthcare providers and professional organizations and include the newly revised PUI case definition, collection of additional information on healthcare worker status, comorbid conditions, and other respiratory pathogens such as rhinovirus and/or enterovirus, coronavirus, influenza PCR / influenza rapid test, *Chlaymdophila pneumoniae*, and *Mycoplasma pneumoniae* and whether a serum specimen was collected for serologic testing. Overall, the form was simplified, and the sections on infection control and personal protective equipment were deleted.

Attachment Y, Viral Gastroenteritis Outbreak Submission Form
Revisions include a name change from *Form for Submitting Specimens from Suspected Norovirus Outbreaks* to *Viral Gastroenteritis Outbreak Submission Form.* Other changes include the removal of multiple fields including Primary contact for clinical specimen: name, #, email, Specimens Collection for Type (Stool, Vomitus, Serum (acute), Serum (convalescent)), Number Collected, Any previous testing, if yes, details about results, Page 3 that included the specimen collection recommendations. Specimen Details (Specimen ID, Date of Collection, Date Onset, Age, Add'l Information) and Additional Comments. Due to these changes, there is a reduction in the average burden per response from 15 to 5. The total burden hours were reduced from 25 to 8.

Attachment Z, NORS Waterborne Disease Transmission Form (CDC 52.12)
A non-substantive change request was OMB approved on 12/23/2016. In summary, that non-substantive change request included a question to link to the One Health Harmful Algal Bloom System (OHHABS; OMB No. 0920-1105) and questions on antimicrobial susceptibility testing as these questions are important to link the OHHABS and the National Antimicrobial Resistance Monitoring System including data on antimicrobial resistance in outbreaks. For this revision, an additional word change on page 4 under Testing Information, question #2 uses the word "isolates" instead of "strains". Approved in the non-substantive change request was an increase in the number of respondents from 57 to 59 with a total burden increase from 19 to 20.

Attachment AA, Influenza Virus (Electronic, Year Round), PHLIP_HL7 messaging Data Elements
For this revision, changes include an increase in the number of respondents from 49 to 57 with a total burden increase from 212 to 247.

Attachment BB, Influenza virus (electronic, year round) (PHIN-MS)
No Change.

Attachment CC, Suspect Respiratory Virus Patient Form
This is a new form that is based upon forms that have been used for outbreak responses in the past. The new Suspect Respiratory Virus Patient Form will be requested from health departments and clinical sites when submitting specimens to the CDC lab for viral pathogen identification. This is typically submitted for severe cases of unknown etiology, particularly when a cluster of similar cases are noted. The data provided will enable rapid detection and characterization of outbreaks of known pathogens, as well as the emergence of potentially new vial pathogens.

16. Plan for Tabulation and Publication and Project Time Schedule
Data collected as part of the CDC surveillance activities are published frequently in the *MMWR* and in the Surveillance Summaries published periodically as part of the *MMWR*. In addition, the data are included in the *MMWR* Annual Summary, in individual surveillance reports prepared on individual diseases under surveillance, and in journals related to individual diseases.

Data collected through the influenza surveillance system are compiled and analyzed on a weekly basis and published in the weekly influenza surveillance report that is distributed to public health professionals, the media, as well as the general public (report is available online. In addition, summaries of influenza activity in the United States are published a minimum of four times a year in the MMWR. Aggregated datasets for laboratory, influenza-like illness, and influenza-associated pediatric death data for each season are also made available via the FluView Interactive website. Influenza surveillance data

are also periodically published in peer-reviewed journals.

Approximately every two years, a summary of enteroviral activity is reported in the MMWR. In years with a large burden of disease or with outbreaks of public interest, additional reports are published. Compiled data are also made available over the Internet (URL: https://www.cdc.gov/surveillance/ness/index.html).

Graphs are updated weekly on the CDC's public website for NREVSS. In addition, MMWR reports of viral activity are published each year for RSV, and occasionally for other viruses included in the surveillance system. Reports are also periodically published in peer-reviewed journals.

Adenovirus typing data collected by NATRS will be compiled and analyzed on a quarterly basis and may result in annual summary reports in the MMWR or in a peer-reviewed journal.

Data collected using the MERS-CoV PUI short form are used to monitor patients with suspected MERS-CoV in the United States. Periodically, these data will be analyzed and summarized for publication and presentations that apprise the US public health community of the MERS-CoV PUI domestic surveillance activities.

Upon receipt, data collected using the new Suspect Respiratory Virus Patient Form will be assessed in real-time to inform situational awareness of subject matter experts and to support the rapid detection of potential new outbreaks which may require a public health response and/or notification.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Many of the disease summary forms included in this request have required minor modifications since first approved, usually due to technology changes. Because of their long period of use, printed paper forms may still be in use. It is requested that permission be granted to exclude the expiration date from some disease summary forms included in this request.

18. Exceptions to Certification for Paperwork Reduction Act Submission

There are no exceptions to the certification.