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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Abstract – National Disease Surveillance Program - II. Disease Summaries
OMB 0920-0004

The Centers for Disease Control and Prevention (CDC) requests a three year approval for the Revision of National Disease Surveillance Program - II. Disease Summaries, OMB Control Number 0920-0004. Expiration Date August 31, 2014.

Proposed revisions include shifting information collection management responsibilities to the National Center for Immunization and Respiratory Diseases (NCIRD) and consolidating various forms to reflect more current technology trends. CDC also requests the use of 2 new Influenza forms to enhance surveillance and assist in understanding the complexities of these newer viruses: Human Infection with Novel Influenza A Virus Severe Outcomes; Human Infection with Novel Influenza A Virus with Suspected Avian Source. Due to the uncertainty regarding MERS-CoV and the potential threat to human health, CDC has developed a new form, Middle East Respiratory Syndrome Coronavirus (MERS-CoV) [Patient Under Investigation] form. The Adenovirus Typing Report Form allows for a passive surveillance mechanism that collects adenovirus typing data to enhance adenovirus circulation data already collected by the National Respiratory and Enteric Virus Surveillance System (NREVSS). The Harmful Algal Bloom-related Illness forms are being discontinued.

The methodology for reporting varies depending on the occurrence, modes of transmission, infectious agents, and epidemiologic measures. There is no cost to respondents other than their time.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

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. The Disease Summaries document (Attachment B) contains descriptive summaries of each disease/condition under surveillance. 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 effected in the same manner. At the beginning of this surveillance program in 1968, 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
Enteroviruses

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. 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 covered under this request.

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. For example, The National Respiratory and Enteric Virus Surveillance System (NREVSS) (Attachment U, U1, U2, U3) is an ongoing laboratory-based system that monitors laboratory detections of respiratory and enteric viruses such as respiratory syncytial virus, influenza virus, human parainfluenza viruses, human metapneumovirus, and rotavirus. This surveillance system plays an important role in determining seasonal and geographic trends of the leading causes of respiratory viral infections in children.

Another example of disease monitoring to better describe and respond to outbreaks is the addition of CaliciNet, a system to collect epidemiologic information on norovirus outbreaks. Norovirus outbreaks on cruise ships receive much publicity. Reporting of gastrointestinal outbreaks is required by law on cruise ships, but only foodborne outbreaks of gastroenteritis are reportable condition on land. Yet many norovirus outbreaks are not foodborne. CDC has been testing outbreaks for noroviruses for over 10 years, most recently using RT-PCR. Increasingly state public health laboratories have been testing for noroviruses, and currently three quarters of all norovirus outbreaks are diagnosed by the states and a quarter by CDC. RT-PCR has allowed for norovirus strains to be sequenced and the development of CaliciNet, a nationwide database of

norovirus sequences has allowed comparison of norovirus sequences from different outbreaks. For effective interpretation of the significance of similar sequences, however, some epidemiological information is required, and is collected by the form "Form for Submitting Specimens From Suspected Norovirus Outbreaks", Attachment Y. Data collected under CalicNet will allow CDC to link outbreaks of suspected viral gastroenteritis together and assist in the development of control measures.

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 Coronavirus Patient Under Investigation (MERS-CoV PUI) 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 had been slowed because of the long time required for data entry and coding once the forms were received. In 2001, CDC introduced electronic reporting of foodborne outbreak data through the Electronic Foodborne Outbreak Reporting System (EFORS). EFORS is a web-based reporting system that collects the same information as the paper forms, and can be used by local, county, or State organizations to enter, edit and analyze data and to transmit data electronically to other State or federal offices. All reports beginning with 2001 data are entered into EFORS, however, beginning in 2009, this system was phased out in lieu of the National Outbreak Reporting System (NORS). The current Form 52.13 (eFORS) permits the reporting of foodborne-associated illnesses; however, NORS will allow the continual reporting of foodborne-associated illnesses, in addition to the following modes of transmission: person-to-person, animal contact, and environmental contamination other than food/water.

The National Enterovirus Surveillance System (NESS) uses an MS Excel spreadsheet to list each detection report. The report is completed on a monthly 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.

For 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.

The Adenovirus Typing report form uses a MS Excel spreadsheet which will be completed by respondents on a monthly basis and submitted to the coordinator 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

CDC staff is in constant communication with the State and Territorial Health Officers, as well as with staff of State and local health departments. Through this communication, and their reliance on this data, it has become evident that no other nationwide collection of disease-specific surveillance systems exist that monitors these diseases. Other information on the diseases included in this package is available only for limited geographic areas or collected in one-time studies. Literature searches and communication with other health professionals have revealed that the other information is not a suitable replacement for a national surveillance system. The information collected under this surveillance system is of a continuing nature and facilitates a uniform collection of data from all states and territories of the country.

5. Impact on Small Businesses and Other Small Entities

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

6. Consequences of Collecting Information Less Frequently

Control of diseases is dependent on rapid identification of changes in disease transmission. The frequency requested for submission of forms in this package is dependent on the particular epidemiology of the disease in question and is addressed individually for each form. Without prompt notification to CDC of disease incidence, generally on a weekly basis, epidemics and outbreaks might go undetected and a large number of cases result from failure to implement control and prevention measures.

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.

The Centers for Disease Control and Prevention 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, variant influenza A H3N2 virus, and influenza A (H7N9) virus, necessitate annual virologic and epidemiologic surveillance.

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. 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 reports of enterovirus detections in the US via the National Enterovirus Surveillance System 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 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.

A passive surveillance mechanism to collect adenovirus typing data on a monthly basis from laboratories in the US is being developed to enhance 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.

Due to the uncertainty regarding MERS-CoV and its threat to human health, there is a need for real-time monitoring for its emergence in the US. 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.

There are no legal obstacles to reduce the burden.

7. Special Circumstances Relating to Guidelines of 5 CFR 1320.5

This collection of information is consistent with 5 CFR 1320.5 except for one aspect. Surveillance reports are requested on a periodic basis to permit rapid response to public health problems and prompt initiation of prevention and control measures. As stated in A.6., delays in reporting could result in serious public health consequences.

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

A. A 60-day Federal Register Notice was published in the *Federal Register* on Tuesday 02/25/2014, Vol 79, No. 37, pp. 10527 - 10528 (Attachment C [60-day Federal Register Notice (FRN)). No comments were received.

B. The Council of State and Territorial Epidemiologists (CSTE) is annually consulted regarding the availability of data and frequency of collection, and the revisions of any forms. The Executive Director of CSTE is: Jeff Engel, MD.

9. Explanation of Any Payment or Gift to Respondents

There are no payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

IRB
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.

Privacy Act
No patient identifiers are received at CDC for the majority of the forms in this package.

For the following forms, personal identifiers are collected by state or local public health officials and maintained at the state or local health department before submission to CDC: Human Infection with Novel Influenza A Virus Case Report Form; Human Infection with Novel Influenza A Virus with Suspected Avian Source; Human Infection with Novel Influenza A Virus Severe Outcomes; Novel Influenza A Virus Infection Contact Tracing Form; Novel Influenza A Virus Case Status Summary; Novel Influenza A Virus Case Screening Form; Influenza-Associated Pediatric Mortality Case Report Form; Antiviral Resistant Influenza Infection Case Report Form

This submission has been reviewed by NCIRD and determined that the Privacy Act does not apply.

Privacy Impact Assessment Information

A. State participation in the surveillance collection is voluntary.

B. Individual consent for human case reports will be obtained by the health care professional or state epidemiologist responding to the illness report in question.

Other forms included in this package do not bear personal identifiable information.

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.

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 Outbreaks, however, personally identifiable information related to Foodborne Outbreak surveillance is not submitted to CDC. Non-

identifiable data relating to Foodborne Outbreaks is submitted to CDC via a secure system called EFORS (Electronic Foodborne Outbreak Reporting System).

In the influenza surveillance system, no personal identifiers are reported to CDC.

The National Enterovirus surveillance system collects age, gender and state of residence, and notes any fatal outcomes. These data are not identifiable and are not given any identifier that could be traced back to the patient. The data is submitted electronically using the secure web-based platform or entered into the excel spreadsheet and emailed to the coordinator.

NREVSS data are collected through a secure website within the CDC. No identifiers 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 Adenovirus Typing will include age, gender, state of residence, and optional information on broad clinical outcomes. These data are not identifiable and are not given any identifier that could be traced back to the patient. The data will be entered into the excel spreadsheet report and faxed or emailed to the coordinator.

For Middle East Respiratory Syndrome Coronavirus Patient Under Investigation Surveillance, no personal identifiers are reported to CDC.

11. Justification for 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, influenza surveillance, respiratory and enterovirus surveillance, including the new Adenovirus Typing and MERS-CoV forms, 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 for all forms is 31,921 hours in Table 1. Burden estimates are based on previous experience with these instruments.

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)	35	52	10/60	303
U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment	87	1	10/60	15
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 (Electronic, Year Round), PHLIP_HL7 messaging Data Elements	49	52	5/60	212
-Influenza virus (electronic, year round) (PHIN-MS)	3	52	5/60	13
Total				31,921

B. The proposed estimated annual cost to respondents is $740,567.20. This represents a reduction of $384,424.00 from the previous annual cost. Assuming an hourly respondent average labor wage of $23.20 based on data from the Bureau of Labor Statistics web site (see http://www.bls.gov/opub/ted/2002/sept/wk3/art03.htm) for state workers. The total annual burden for this request is 31921 and is presented in Table 2.

Table 2 – Estimated Annualized Burden Costs

Form	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in Hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Foodborne Disease Transmission_Person to Person_Animal Contact CDC 52.13	54	32	20/60	576	$23.20	$13,363.20
WHO Collaborating Center for Influenza Influenza virus Surveillance (Internet; year round) (CDC 55.31)	35	52	10/60	303	$23.20	$7029.60
U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment	87	1	10/60	15	$23.20	$348.00
US Outpatient Influenza-like Illness Surveillance Network (ILINet) Weekly (CDC 55.20)	1800	52	10/60	15600	$23.20	$361,920.00
US Outpatient Influenza-Like Illness Surveillance Network (ILINet), Daily ILINet Reports of Influenza-like Illness (ILI)	75	365	10/60	4563	$23.20	$105,861.60
Influenza-Associated Pediatric Mortality_ Case Report Form	57	2	30/60	57	$23.20	$1322.40
Human Infection with Novel Influenza A Virus Case Report Form	57	6	30/60	171	$23.20	$3967.20
Human Infection with Novel Influenza A Virus with Suspected Avian Source	57	1	30/60	29	$23.20	672.80
Human Infection with Novel Influenza A Virus Severe Outcomes	57	1	1.5/60	86	$23.20	1995.20
Novel Influenza A Virus Infection Contact Tracing Form	57	1	30/60	29	$23.20	$672.80
Novel Influenza A Virus Case Status	57	1	15/60	14	$23.20	$324.80

Summary						
Novel Influenza A Virus Case Screening Form	57	1	15/60	14	$23.20	$324.80
122 CMRS - City Health Officers or Vital Statistics Registrars Daily Mortality Report	58	365	12/60	4,234	$23.20	$98,228.80
122 CMRS - City Health Officers or Vital Statistics Registrars Weekly Mortality Report	122	52	12/60	1,269	$23.20	$29,440.80
Aggregate Hospitalization & Death Reporting Activity Weekly Report Form	56	52	10/60	485	$23.20	$11,252
Antiviral Resistant Influenza Infection Case Report Form	57	3	30/60	86	$23.20	1995.20
National Respiratory & Enteric Virus Surveillance System (NREVSS) (CDC 55.83 Laboratory Assessment, 55.83 A, B, D) (electronic)	300	52	15/60	3900	$23.20	$90,480.00
National Enterovirus Surveillance Report (CDC 55.9) (electronic)	25	12	15/60	75	$23.20	$1,740.00
Adenovirus Typing Report Form	25	12	15/60	75	$23.20	$1740.00
Middle East Respiratory Syndrome Coronavirus (MERS) Patient Under Investigation (PUI) Form	57	3	25/60	71	$23.20	1647.20
Form for Submitting Specimens From Suspected Norovirus Outbreaks	20	5	15/60	25	$23.20	$580.00
Waterborne Disease Transmission CDC 52.12	57	1	20/60	19	$23.20	$440.80
Influenza Virus (Electronic, Year Round), PHLIP_HL7 messaging Data Elements	49	52	5/60	212	$23.20	$4918.40
Influenza virus(electronic year round) (PHIN-MS)	3	52	5/60	13	$23.20	$301.60
Total						$740,567.20

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers

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. The cost of conducting the study to the government is estimated based on the expenses incurred in the following categories: salary, computer resources, printing, mailing, and miscellaneous, such as (telephone calls and stationary supplies). The estimated annual cost to the government is $51,000.

15. Explanation for Program Changes or Adjustments

This is a request for a revision. Revisions are as follows:

Foodborne Disease Transmission_Person to Person_Animal Contact CDC 52.13_Attachment D
Name Modification from Foodborne Outbreaks 52.13 to Foodborne Disease Transmission_Person to Person_Animal Contact CDC 52.13.

Waterborne Disease Transmission CDC 52.12_Attachment Z
Name Modification from Waterborne Diseases Outbreak 52.12 to Waterborne Disease Transmission CDC 52.12.

Influenza Virus Surveillance (CDC 55.31); covers the following:
WHO Collaborating Center for Influenza_Influenza Virus Surveillance (Internet; year round) (CDC 55.31), Attachment E
Influenza Virus (Electronic, Year Round), PHLIP_HL7 messaging Data Elements, Attachment AA
Influenza Virus (Electronic, Year Round) (PHIN-MS), Attachment BB

Form CDC 55.31 is used to collect summary influenza virus data from World Health Organization (WHO) collaborating laboratories in the United States that report the data over the Internet. For laboratories that utilize the electronic method of reporting data, there is no reporting form due to an existing connection between the laboratory and a CDC server.

State, county, city, or university laboratories that collaborate with the U.S. WHO Influenza Surveillance Program report the number of respiratory specimens submitted for influenza diagnosis and the number positive for influenza. All laboratories report these data weekly throughout the year. These reports are used to assess and report the distribution of influenza virus strains throughout the United States.

Weekly data are transmitted to CDC throughout the year. 35 laboratories transmit data via the Internet. 3 laboratories transmit data electronically using the Public Health Information Network – Messaging System (PHIN-MS) and 49 laboratories transmit data using the Public Health Laboratory Interoperability Project (PHLIP). Transmission of data via PHIN-MS and PHLIP improves the timeliness and quality of the data. The 52 laboratories using PHIN-MS and PHLIP have elected to develop an interface between their laboratory computer and PHIN-MS and PHLIP to transmit their data, thus removing Influenza Virus (fax, Oct- May) and Influenza Virus (fax, year round).

Changes to the form 55.31 include:

- Influenza Virus (fax, Oct – May), Influenza Virus (fax, year round), Influenza Virus (Internet, Oct – May) have been removed from 0920-0004 as all virologic surveillance data is now submitted electronically year-round.
- There is an increase in the number of respondents using (Attachment AA, Influenza Virus (Electronic, Year Round), PHLIP_HL7 messaging) PHLIP Data Elements electronic methods thus increasing the total burden hours for this particular transmission.
- There is a decrease in the number of respondents using PHIN Electronic method (Attachment BB), thus decreasing the total burden.

U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment (Form CDC 55.31A), Attachment F

At the beginning of each influenza season, a survey is sent to each participating U.S. WHO laboratory to obtain information used in the analysis and interpretation of data obtained from year-to-year.

*Changes to the form 55.31A include**:***

- Name Modification: The name of the survey has been modified from "Influenza Annual Survey" to "U.S. WHO Collaborating Laboratories Influenza Testing Methods Assessment" to better account for the data being collected by the survey.
- A reduction in the average burden in response from 15/60 to 10/60.
- An addition to the number of respondents (i.e. an additional laboratory has been added to the list of participating laboratories).
- All overall reduction in the total burden hours from 22 to 15.

U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet); covers the following:
US Outpatient Influenza-like Illness Surveillance Network (ILINet) Weekly, (CDC 55.20), Attachment G
US Outpatient Influenza-like Illness Surveillance Network (ILINet), Daily ILINet Reports of Influenza-like Illness (ILI), Attachment I
US Outpatient Influenza-like Illness Surveillance Network (ILINet) Workfolder,(CDC 55.20E), Attachment H

CDC 55.20, CDC 55.20E, and the daily ILI 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. Data collected on CDC 55.20 is for a 7-day period that starts on Sunday and ends the following Saturday. CDC 55.20E is used by the participating healthcare provider to track their weekly ILI reports for an entire influenza season and is used for data verification purposes. Data collected on the daily ILI reporting form is for a single day.

Form CDC 55.20 is a single form used to collect summary influenza-like illness data from participating healthcare providers. Providers have the option of faxing this data via a toll-free fax number or reporting data over the Internet. The web interface is identical to the fax form. The workfolder (CDC 55.20E) is used by the provider to track their own data submitted throughout the season.

Because state health department morbidity estimates are imprecise and generally untimely, a system was developed in 1982 to collect influenza-like illness data directly from practicing family physicians who voluntarily participated without remuneration. Prior to 1997, CDC and state health departments' maintained separate influenza sentinel provider surveillance systems. In 1997, CDC collaborated with state health departments to reduce duplication of efforts and allow resources to be focused on expanding the number of providers reporting in order to improve the geographic representation and completeness of the data. Over the years, the system

has continued to evolve and expand. For the 2013-14 season, approximately 1,800 health care providers in all 50 states regularly reported to CDC.

Participating providers report the following data each week of the year: influenza-like illnesses by age group (0-4 years, 5-24 years, 25-49 years, 50-64 years, and >64 years) and the total number of patients seen for any reason. These data are shared by CDC and state health departments. Year-round influenza surveillance data typically provides a baseline level of influenza activity during the summer months and are essential components of seasonal and pandemic influenza surveillance and are used to detect other unusual occurrences of influenza-like illness.

The primary method of reporting is Internet (95%) using form 55.20E as a work folder. A few providers still prefer to transmit their data via facsimile (5%) (CDC55.20). The facsimile form is part of the work folder.
In 2009, enhanced surveillance efforts were recommended by CDC in response to the emergence of the influenza A (H1N1)pdm09 virus in the United States. The CDC pandemic surveillance plan calls for increasing the frequency of surveillance reporting from weekly to daily in sites where that is feasible. Daily influenza-like illness reporting will result in more timely data collection and accelerate the implementation of public health responses. The US Outpatient Influenza-like Illness Surveillance Network (ILINet), Daily ILINet Reports of Influenza-like Illness (ILI) is a single fax form used to collect daily summary influenza-like illness data from participating healthcare providers. Providers have the option of faxing this daily ILI data in via a toll-free fax number or reporting data over the Internet. The web interface is identical to the fax form. Daily ILINet reporting will only be implemented in the event of public health emergency.

Changes to the forms:

- Name Modification; From Daily Influenza-like Illness Year Round to US Outpatient Influenza-like Illness Surveillance Network (ILINet), Daily ILINet Reports of Influenza-like Illness (ILI)
- Name Modification; From Weekly Influenza-like Illness year round 55.20 to US Outpatient Influenza-like Illness Surveillance Network (ILINet) Weekly, (CDC 55.20)
- Weekly Influenza-like Illness (Oct – May) has been removed.
- Daily Influenza-like Illness (Oct – May) has been removed.
- The annualized total burden hours for US Outpatient Influenza-like Illness Surveillance Network (ILINet) Weekly, (CDC 55.20) increased due to the fact that for the 2013-14 season, approximately 1,800 health care providers in all 50 states regularly reported to CDC.
- The annualized total burden hours for US Outpatient Influenza-like Illness Surveillance Network (ILINet), Daily ILINet Reports of Influenza-like Illness (ILI) decreased due to the change in the average burden per response from 15/60 to 10/60.

<u>Influenza-Associated Pediatric Mortality (case report form),</u> Attachment J

In 2004, the Council of State and Territorial Epidemiologists (CSTE) adopted a position statement making influenza-associated deaths in children (persons less than 18 years) a nationally notifiable condition. The Influenza-associated Pediatric Mortality case report form, a

standardized case questionnaire which contains detailed questions on relevant clinical and epidemiologic features of influenza, was developed by CSTE and CDC. State or territorial influenza surveillance epidemiologists report these data over the Internet on the Secure Data Network (SDN) or Secure Access Management Services (SAMS). Each week, limited data on laboratory-confirmed influenza-associated deaths in children is transmitted from the CDC/Influenza Division to the Nationally Notifiable Disease Surveillance System (NNDSS). Data obtained from this form has led to the modification of influenza vaccine recommendations.

Privacy Impact Assessment: Personal identifiers are collected by state or local public health officials; this information is removed from the form and maintained at the state or local health department before submission to CDC.

Changes to Influenza-associated Pediatric Mortality case report form include:

- Name modification from Influenza Associated Pediatric Death Case Report Form to Influenza-associated Pediatric *Mortality* case report form.
- A question was added to the case report form capture the patient's usual country of residence
- Options for unknown sex, ethnicity, and race were removed to be consistent with OMB federal guidelines
- Question 14C regarding the submission of *Staphylococcus aureus* isolates being sent to CDC was removed from the form because specimens are no longer being tested at CDC
- Questions regarding influenza vaccine history were updated to include the new vaccines that are available beginning in the 2013-14 influenza season
- The total burden hours increased from the previous approval from 29 to 57 due to an increase from one response per respondent to 2 responses per respondent due to the rise in the number of influenza-associated pediatric deaths since 2009.

<u>Human Infection with Novel Influenza A Virus; covers the following forms:</u>
Human Infection with Novel Influenza A Virus Case Report Form, Attachment K
Human Infection with Novel Influenza A Virus with Suspected Avian Source, Attachment L
Human Infection with Novel Influenza A Virus Severe Outcomes, Attachment M
Novel Influenza A Virus Infection Contact Tracing Form, Attachment N
Novel Influenza A Virus Case Status Summary, Attachment O
Novel Influenza A Virus Case Screening Form, Attachment P

In 2007, the Council of State and Territorial Epidemiologists (CSTE) adopted a position statement making human infection with a novel influenza A virus a nationally notifiable condition. Novel influenza A virus infections include all human infections with influenza A viruses that are different from currently circulating human influenza H1 and H3 viruses. These viruses include those that are subtyped as nonhuman in origin and those that are unsubtypable with standard methods and reagents. Human infections with novel influenza A viruses that can be transmitted from person to person may signal the beginning of an influenza pandemic. Rapid detection and reporting of human infections with novel influenza A viruses – viruses against which there is little to no preexisting immunity – will facilitate prompt detection and characterization of Influenza A viruses with pandemic potential and accelerate the implementation of effective public health responses.

From 2005 to early 2012, only 36 cases of variant (v) influenza virus infection were reported to the Centers for Disease Control and Prevention (CDC). From July–December 2012, however, 309 cases of H3N2v were reported in 11 states, representing the largest outbreak of human infections with a variant influenza virus since the 2009 H1N1 pandemic. In 2013, 19 cases of H3N2v were reported in 5 states. A majority of cases had self-limited illness, but hospitalizations were more prevalent among those with young age and the presence of underlying medical conditions. Most cases reported prolonged and direct exposure to swine at an agricultural fair, suggesting that was the primary risk factor for illness. These outbreaks highlight the assertion that every case of variant influenza virus infection has epidemic potential and must be investigated thoroughly and rapidly.

Changes to the forms include:

Human Infection with Novel Influenza A Virus Case Report Form; Attachment K

- Name modification from Novel Human Influenza A Virus Infection Case Report Form to Human Infection with Novel Influenza A Virus Case Report Form
- Addition of one question (q4) regarding patient's country of usual residence.
- No change in total burden

Human Infection with Novel Influenza A Virus with Suspected Avian Source; Attachment L

- New Form; The Human Infection with Novel Influenza A Virus with Suspected Avian Source form will collect information from novel influenza A cases where an avian species is suspected as the source of their infection. It will assist in the understanding of the basic epidemiology of new variant influenza viral infections and the implementation of effective public health responses, thereby preventing additional morbidity and mortality.

Human Infection with Novel Influenza A Virus Severe Outcomes; Attachment M

- New Form; The Human Infection with Novel Influenza A Virus Severe Outcomes form will be used on patients that became severely ill (i.e. hospitalized or died) after an infection with a novel influenza A virus.
- It will aid in the understanding of the basic epidemiology of new variant influenza viral infections and the implementation of effective public health responses, thereby preventing additional morbidity and mortality.

Novel Influenza A Virus Infection Contact Tracing Form; Attachment N

- Combination of 2 previous form into a New Form; The Novel and Pandemic Influenza A Virus Infection Contact Trace Back Form and Novel and Pandemic Influenza A Virus Infection Trace Forward Form have been consolidated into one new form, Novel Influenza A Virus Infection Contact Tracing Form.
- Novel Influenza A Virus Infection Contact Tracing Form resulting in a decrease on the burden on respondents. Final burden hours are 29 instead of the combined 58 for both forms.
- This form is used to identify and follow contacts of persons with suspected or confirmed novel influenza A virus infection and determine the source of infection.

Novel Influenza A Virus Case Status Summary; Attachment O

- Name Modification; The Novel and Pandemic Influenza A Virus Case Status Summary form is now Novel Influenza A Virus Case Status Summary and is used by state health

departments to report aggregate numbers of suspected, probable, or confirmed cases of novel and pandemic influenza A virus infection to CDC.
- No Change in the Total Burden

Novel Influenza A Virus Case Screening Form; Attachment P
- Name Modification; was previously named The Novel and Pandemic Influenza A Virus Infection Case Investigation Form. It may be used by local or state health departments for cases under investigation for possible human infection with novel influenza A viruses.
- There is a reduction in burden hours from 29 to 14 due to a decrease in the average burden per response from 30/60 to 15/60.

Each form contains detailed questions on relevant clinical and epidemiologic features of influenza and was developed by CSTE and CDC. Each week, limited data on human infections with novel influenza A viruses is transmitted from the CDC/Influenza Division to the Nationally Notifiable Disease Surveillance System (NNDSS).

<u>122 Cities Mortality Reporting System Weekly Mortality Report (CDC 43.5) covers the following forms:</u>
122 CMRS - City Health Officers or Vital Statistics Registrars, Daily Mortality Report, Attachment Q
122 CMRS - City Health Officers or Vital Statistics Registrars Weekly Mortality Report, Attachment R

The weekly mortality report is completed by city health officers or vital statistics registrars from 122 major cities and metropolitan areas, using CDC 43.5. All reporters submit their weekly mortality report via the Internet using form CDC 43.5.

It is a report in which total deaths by age categories are cross-classified by number of deaths assigned to pneumonia and influenza. In preparing the report, the number of total deaths for all causes is entered for each age category: less than 28 days of age, 28 days to 1 year, and for succeeding age groupings; then the number of pneumonia and the number of influenza deaths are entered for each age category. Thus, the total number of deaths shown for any age category includes the number of deaths assigned to pneumonia and/or influenza. The weekly mortality report from 122 U.S. cities covers a period of 7 days. The beginning and ending dates of the reporting week are established by the city or county health officer or vital statistics registrar, preferably dates which correspond with the usual work week. Their reporting period should be constant from week to week. The report should be received in Atlanta as soon as possible after the close of each weekly reporting period, and no later than noon on the following Tuesday. If a city's weekly mortality report is not received in Atlanta by Tuesday noon, a staff member from the Influenza Division (ID) in NCIRD telephones that city's reporter and collects the necessary data, as available. The data collected by Tuesday noon are published electronically on Thursday in the *Morbidity and Mortality Weekly Report (MMWR)* with a publication date of Friday.

Each week, the vital statistics offices of 122 cities report the total number of death certificates received and the number of those for which pneumonia or influenza was listed as the underlying

or contributing cause of death by age group. The percentage of all deaths due to pneumonia and influenza (P&I) are compared with a seasonal baseline and epidemic threshold value calculated for each week. The seasonal baseline of P&I deaths is calculated using a periodic regression model that incorporates a robust regression procedure applied to data from the previous five years. An increase of 1.645 standard deviations above the seasonal baseline of P&I deaths is considered the "epidemic threshold," i.e., the point at which the observed proportion of deaths attributed to pneumonia or influenza was significantly higher than would be expected at that time of the year in the absence of substantial influenza-related mortality.

Weekly reporting of mortality data by health officers and vital registrars in 122 U.S. cities and metropolitan areas is used with data reported from collaborating laboratory and epidemiologic surveillance to identify national and regional influenza outbreaks.

In 2009, enhanced surveillance efforts were recommended by CDC in response to the emergence of the influenza A (H1N1)pdm09 virus in the United States. The CDC pandemic surveillance plan calls for increasing the frequency of surveillance reporting from weekly to daily in sites where that is feasible. Daily mortality reporting will result in more timely data collection and accelerate the implementation of public health responses. The daily mortality report is a form used to collect the total deaths by age categories that are cross-classified by number of deaths assigned to pneumonia and influenza from participating city health officers or vital statistics registrars. Participants report data over the Internet. Daily mortality reporting will only be implemented in the event of public health emergency.

Changes to the form 43.5 include:

- CMRS – City Health Officers or Vital Statistics Registrars (daily) has been renamed to 122 CMRS - City Health Officers or Vital Statistics Registrars Daily Mortality Report;
- CMRS – City Health Officers or Vital Statistics Registrars (weekly) has been renamed to 122 CMRS - City Health Officers or Vital Statistics Registrars Weekly Mortality Report;
- There has been no change to burden hours in either form

<u>Aggregate Hospitalization & Death Reporting Activity Weekly Report Form, Attachment S</u>

The Aggregate Hospitalization and Death Reporting Activity (AHDRA) Weekly Report Form is a single form used to collect summary data from the New York City, state, and territorial health departments regarding influenza-associated hospitalizations and deaths. State or territorial influenza surveillance epidemiologists report these data over the Internet on the Secure Data Network (SDN).

In 2009, to supplement data from established influenza surveillance systems, improve surveillance timeliness, and expand geographic coverage to meet specific needs of the influenza A (H1N1)pdm09 pandemic response, the Centers for Disease Control and Prevention (CDC) and the Council for State and Territorial Epidemiologists (CSTE) established AHDRA. AHDRA provides timely and representative notification of severe outcomes associated with influenza infection by providing CDC with the ability to: (i) track severe disease within states and territories in order to better capture the focal nature of the pandemic, (ii) track disease trends over brief periods of time in order to facilitate rapid public health responses to changes in

influenza epidemiology, and (iii) accommodate variation in local resources by providing a simple, flexible method that allowed reliable reporting by all states and territories without overwhelming health departments during the course of the pandemic response.

Reporting jurisdictions are permitted to submit using a laboratory-confirmed or syndromic definition and are instructed to report aggregate counts for both outcomes on a weekly basis throughout the influenza season (October through mid-May of the following year). These data are shared by CDC and state health departments. The method of reporting is via a web-based data entry screen. Only aggregate data are reported and no patient identifiers are received by CDC. AHDRA reporting will only be implemented in the event of a public health emergency.

Changes to the form include:

- No revisions

Antiviral Resistant Influenza Infection Case Report Form, NEW Attachment T

Antiviral drugs are the second line of defense against influenza viruses. Currently, only two drugs are licensed for use and active against circulating viruses, oseltamivir and zanamivir; oral oseltamivir is used for almost all infections in the US. There are limited treatment options for an infection with an oseltamivir-resistant viruses, experimental drug use would be required; thus widespread circulation of resistant viruses is a public health emergency requiring special guidance and testing. After a resistant virus is identified by the laboratory, it is necessary to obtain key information from the infected patient to determine whether the resistant virus was circulating in the community or whether the resistant virus developed during treatment. This information is critical to antiviral recommendations and guidance.

National Enterovirus Surveillance System (Form CDC 55.9), Attachment V

Changes to form CDC 55.9 include:

- Addition of new enterovirus type categories to include newly discovered enteroviruses.
- Addition of new specimen type categories to accurately reflect current laboratory practices.
- Addition of a field, "Outcome," to indicate whether the patient is living or deceased.
- Addition of fields, "Nucleic Acid Extracted," to accurately describe specimen type according to current laboratory practices.

National Respiratory and Enteric Virus Surveillance System (NREVSS) covers the following forms;

National Respiratory & Enteric Virus Surveillance System (NREVSS) Laboratory Assessment (CDC 55.83) (electronic), Attachment U
NREVSS Laboratory Assessment (CDC 55.83A) (electronic), Attachment U1
NREVSS Virus Isolation (Culture) Worksheet (CDC 55.83B) (electronic), Attachment U2
NREVSS Polymerase Chain Reaction (PCR) Worksheet (CDC 55.83D) (electronic), Attachment U3

To reflect ongoing technical developments and increasingly routine use of assays and multiplex PCR panels for detection of respiratory virus, in 2007, rhinovirus, human metapneumovirus, and enteric enteroviruses were added to the forms for data collection. In 2013, the electron microscopy data collection form was replaced with the Annual Assessments of Laboratory Practices among participating laboratories and represents 55.83C. In this revision, human coronaviruses is added to form D for PCR testing since appropriate assays for these viruses have recently become more commercially available. In addition, CDC is relabeling the "rhinovirus" column to "rhinovirus/enterovirus" since PCR assays typically do not reliably differentiate between these closely related viruses. There is an increase in the total burden hours from 75 to 3900.

Changes to the Laboratory Assessment form include:

- Rearrangement of question regarding number of specimens collected per week for better flow.
- In addition to inpatient and outpatient, included emergency department as a location where specimens are collected to clarify distinction.
- Added none as an option to types of PCR respiratory virus assays used in labs
- Added questions regarding typing for enterovirus and adenovirus
- Divided question regarding testing practices changes for RSV and Flu during season into two questions to distinguish difference for virus
- Removed question regarding additional comments/suggestion after discerning it to be repetitive during pilot
- Increase in the number of respondents due to the increased number of participating laboratories
- Increase in the burden per response from 10/60 to 15/60 to account for additional virus types

<u>Adenovirus Typing Report Form – NEW, Attachment W</u>

Middle East Respiratory Syndrome Coronavirus Patient Under Investigation Surveillance - NEW
Due to the emergence of a novel coronavirus associated with severe acute respiratory illness and death among individuals in the Middle East, the Middle East Respiratory Coronavirus Patient Under Investigation (MERS-CoV PUI) form was developed. This form gathers basic demographic and clinical information on individuals under investigation for possible MERS-CoV infection.

<u>Form for Submitting Specimens From Suspected Norovirus Outbreaks _Attachment Y</u>

Outbreaks of viral gastroenteritis are usually caused by norovirus or sapovirus which collectively are referred to as caliciviruses.

Noroviruses are estimated to cause 23 million cases (33%) of all cases of gastroenteritis annually. Norovirus disease occurs as sporadic disease or as outbreaks of diarrhea and vomiting, in all age groups.

Noroviruses can be transmitted via contaminated food, contaminated water or directly from person to person. Many outbreaks involve several modes of transmission such as initial foodborne followed by person to person. In many cases the source of infection is unknown. The diverse modes of transmission are reflected in the diverse settings in which outbreaks occur such as restaurants, nursing homes, hospitals and schools. Historically however, diagnosis of noroviruses has been very difficult. Recent development of RT-PCR techniques has revolutionized the detection and characterization of norovirus strains, and testing for norovirus in outbreaks of gastroenteritis is gradually becoming more frequent.

For effective interpretation of the significance of similar sequences, however, some epidemiological information is required. Currently, epidemiological information on norovirus outbreaks that are linked to food contamination is reported to the foodborne branch electronically via EFORS. However, there is no collection of epidemiological data of non-foodborne outbreaks of norovirus.

Data collected will include suspected source, setting, number exposed, and number of cases. This will allow CDC to link outbreaks together and assist in the development of control measures. In the future, this information will be collected through a web-based reporting system which is currently being developed. The information will be accessible to states investigating outbreaks, initially by contact with the viral gastroenteritis section at CDC, and in the future via the Internet.

Changes to the Form for Submitting Specimens from Suspected Norovirus Outbreaks include:

- Name Modification from Suspected Viral Gastroenteritis AKA Calicivirus Surveillance to Form for Submitting Specimens from Suspected Norovirus Outbreaks
- Overall simplification and reformatting of data fields
- Updated CDC contact information including phone, fax numbers, name of lab
- Removed ‘options’ for outbreak information, suspected mode of transmission, setting options
- The outbreak information and illness characteristics fields are arranged in tabular form rather versus open text
- Removed Yes/No options in Specimen Collection and Added ‘Age’ to Specimen Details section
- Reevaluated time to complete the form; increase in the average burden in response from 5/60 to 15/60
- Increase in total burden hours from 8 to 25 due to the change in average burden in response

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). Once laboratory and influenza-like illness data have been cleaned, datasets for each season are also made available via the Influenza website.

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.

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 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 Middle East Respiratory Syndrome Coronavirus Patient Under Investigation Surveillance 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 domestic surveillance activities.

Data on Calicinet (suspected Viral Gastroenteritis) have been published in the Journal of Infectious Diseases in 2006.

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

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

18. Exceptions to Certification for Paperwork Reduction Act Submission

As stated in A.17 above, many of these reports are rarely revised and are in stock at the time of the routine expiration date. Due to this, the public burden statement has not been revised on most of the forms. The most current statement will be added to each form upon OMB approval of the current package and reprinting of the forms.