Information Collection on Cause-Specific Absenteeism in Schools Request for OMB Approval of a New Information Collection

Statement A

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Information Collection on Cause-Specific Absenteeism in Schools

Request for OMB Approval of a New Information Collection (OMB Control # 0920-XXXX)

A. Justification

1. Circumstances Making the Collection of Information Necessary

This is a request for approval of a new three year information collection. The Centers for Disease Control and Prevention (CDC), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Global Migration and Quarantine (DGMQ), requests approval of a new information collection on Cause-Specific Absenteeism in Schools. The project is implemented under the cooperative agreement between the University of Wisconsin-Madison and CDC. This information collection will be conducted for a period of three years in kindergarten to 12th grade (K-12) schools of Oregon school district, Wisconsin. The cooperative agreement covers project activities over the three school years: 2013-2014, 2014-2015 and 2015-2016. Data collection will be conducted by the University of Wisconsin-Madison research team with technical assistance in study design, data analysis, and preparation of manuscripts resulting from this study from the CDC staff.

This information collection aims to improve our understanding of the role of influenza-like illness (ILI)-specific absenteeism in schools in predicting community-wide influenza transmission. Insights gained from this information collection will be used to strengthen the evidence-base of CDC's Pre-Pandemic Guidance prior to next pandemic.

Section 361 of the Public Health Service (PHS) Act (42 USC 264) (Attachment A1) authorizes the Secretary of Health and Human Services (HHS) to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from one state or possession into any other state or possession. These regulations are codified in 42 Code of Federal Regulations (CFR) Part 70 (Attachment A2). CDC is authorized to collect these data under the Public Health Service Act (42 USC 241), Section 301 (Attachment A3). The information collection for which approval is sought is in accordance with DGMQ's mission to prevent the introduction, transmission, or spread of communicable diseases within the United States.

Influenza pandemics are inherently unpredictable, caused by newly emerged viruses that differ in geographical and biological origin, transmissibility, drug sensitivity, and capacity for causing severe illness (1). When a pandemic first emerges, the most effective countermeasure— a vaccine against the new pandemic virus—may not be available for 4 to 6 months, and may not be produced in sufficient quantities to immunize all risk groups (including school-aged children) for 6 to 8 months (2). Moreover, antiviral medications, which can ameliorate symptoms if provided within 24-48 hours of onset, may not be effective against a new pandemic strain or may quickly become ineffective due to the emergence of drug resistance.

A comprehensive community strategy for mitigating the effects of a pandemic must, therefore, address not only medical countermeasures (3-6) but also school related mitigation measures — one of our first lines of defense at the earliest stages of a pandemic. To be effective, these measures must be strategically targeted and tailored to the pandemic severity. Because most school-related measures do

not require medical resources or specialized equipment, they are available to public health officials in all state and local communities.

The 2007 *Community Strategy for Pandemic Influenza Mitigation in the US* was developed with a severe pandemic in mind, amid fears that the virulent avian influenza A (H5N1) virus—which reemerged in Southeast Asia in 2003 and spread to Africa, the Middle East, and Europe—might evolve into a highly dangerous human pandemic strain (7). A new H5N1 virus was thought most likely to emerge overseas, providing some lead-time to prepare for a U.S. response that might make use of a stockpiled pre-pandemic H5N1 vaccine. Instead, the next pandemic virus turned out to be a human H1N1 strain (a quadruple reassortant with genes from influenza viruses of humans, birds, European swine, and Asian swine) that apparently emerged in Mexico and was first identified as a new strain in the United States on April 19, 2009, when cases were reported in two children in adjacent California counties. On April 23, CDC confirmed that the influenza cases in Mexico and California were caused by the same H1N1 strain.

Implementation of school-related measures was especially important during the earliest stage of the H1N1 pandemic, because a pandemic vaccine was not available until October (6 months later), and sufficient stocks to immunize all school-age children were not available until December. However, retrospective review of the U.S. government response to the pandemic identified limited information on the effectiveness, acceptability, and feasibility of school measures, especially for prolonged school closures, to slow the spread of the pandemic virus. Guidance updates will require an evidence-based rationale for the use of school-related measures.

Due to the congregation of children at schools and their susceptibility to many infectious diseases, children are frequently the main introducers of influenza to their families (8-10), and schools serve as amplification points for influenza transmission (11). Therefore, the collection of ILI-specific absenteeism could provide information needed to detect influenza outbreaks in schools and protect school-aged children from infectious diseases, which subsequently may enable a reduction in the impact of outbreaks on the wider community. This information could in turn inform the timely implementation of appropriate school-related control and prevention measures.

Experiences from 2009 H1N1 influenza pandemic when persons 18 years of age and younger were the most susceptible group further highlight the need for additional research on ILI-related absenteeism that may prompt school-related mitigation measures. Such measures may be the only means to slow down the spread of emerging respiratory infections for which vaccines and pharmaceutical prophylaxis are not yet available. This information collection will focus on ILI but may also be applicable to outbreaks caused by other serious acute respiratory infections, with similar modes of transmission as influenza.

1.1. Privacy Impact Assessment Information

Overview of Data Collection System

This information collection will be implemented in collaboration with the University of Wisconsin and will target students attending kindergarten to 12th grade (K-12) schools (Attachment C1 Protocol, Attachment C2 School District Approval Letter). The University of Wisconsin will implement the project in Oregon School District, Wisconsin at the following six schools: Oregon High School, Oregon Middle School, Rome Corners Intermediate, Netherwood Knoll Elementary, Prairie View Elementary, and Brooklyn Elementary. Information will be collected on the number, duration, and specific cause of school absences and obtained through telephone and in-person interviews.

Students and parents/guardians in the school district will be informed about the opportunity to participate in the study at school events, through promotional materials (flyers, postcards, posters) distributed around the community, and also using an existing call-in absentee messaging system. In the absentee phone line, the existing message will be modified to include an invitation to participate in the study.

When a student is absent from school and has symptoms such as a sore throat, fever, or other respiratory symptoms, his/her parent or guardian, or an adult student (age 18 or older) him/herself, can call the study telephone number directly to learn more about participation in this study. The phone will connect to an enrolling surveillance assistant. The enrolling surveillance assistant will describe the program and will screen for inclusion and exclusion criteria using the Screening form (Attachment C3 – Screening form). If the student meets eligibility criteria and is willing to proceed, arrangements will be made for a face-to-face household visit for obtaining informed consent and assent (Attachment C4 –Consent/Assent Form), data and specimen collection. During the household visit, trained surveillance assistant will use the Acute Respiratory Infection and Influenza Surveillance Form (Attachment C5 - Acute Respiratory Infection and Influenza Surveillance Form) to collect information about student's illness. Additionally, during the home visit, research team will obtain nasopharyngeal or oropharyngeal swabs for RT-PCR.

Appropriate statistical models will be used to assess the utility of these data to predict community-wide influenza transmission according to established local, state, and national influenza surveillance systems.

Items of Information to be Collected

This information collection will target children, with some screening information and consent gathered from parents/guardians as well as age-appropriate verbal assent gathered from students, followed by surveillance information. Additionally, aggregate data on ILI-specific absenteeism will be gathered from the school district and data on immunization will be shared by the Wisconsin Immunization Registry.

Information that will be gathered from students (through parents/guardians for students younger than 18) (Attachments C3-Screening Form and C5 Acute Respiratory Infection and Influenza Surveillance Form):

- Demographic information
- Reports of exposure to other persons with ILI symptoms within 1-3 days
- Information on recent travel
- Information on symptoms (measured temperature, presence of symptoms compatible with ILI) and treatment

Information that is being collected by the Oregon school district using existing absentee monitoring system from each participating school and will be used by the research team:

- Number of students absent due to all causes, by grade for each day of the school year.
- Number of students absent due to ILI by grade for each day of the school year

Information that will be gathered from Wisconsin Immunization Registry

 Vaccine history of participating students. This will be done by an approved study research assistant using the look-up function. In order to obtain information on respiratory pathogens circulating at times when absences are low, University of Wisconsin will also seek to collect reports of illnesses among students who remain in school.

2. Purpose and Use of the Information Collection

The purpose of this new information collection is to evaluate the role of ILI-specific absenteeism in schools in predicting community-wide influenza transmission. Insights gained from this information collection will strengthen the evidence-base for CDC's Pre-Pandemic Guidance on the school-related mitigation measures during an influenza pandemic.

When a pandemic first emerges, CDC will assess the situation and develop mitigation guidance for state and local authorities, aiming to provide the best technical advice, based on the best available data on clinical severity and viral transmissibility. Implementation will depend on local conditions, including (but not limited to) patterns of local disease spread (e.g., outbreaks in schools) and hospital and medical resources. School-related measures implemented early and in a coordinated and targeted approach are likely to have the greatest impact on slowing influenza transmission during a pandemic.

Though the findings will not be generalizable beyond the settings or populations from which the information is collected, state and local authorities will be able use the mitigation guidance (and the updated evidence-base following this information collection) to facilitate decision-making and to inform their communities and mobilize them to take action.

2.1 Privacy Impact Assessments

- 1. The proposed information collection will not involve the sharing of respondent's personal identification or place of residence with persons outside of the project coordinating organizations. Information collected will include personal identifying information and is covered by Privacy Act System Notice 09-20-0160 (Records of Subjects in Health Promotion and Education Studies). Persons covered by the system notice include adults and children, including health and education agency administrators, school health personnel, teachers, parents, and students who participate in studies and surveys designed to obtain data on their knowledge, attitudes, and reported behavior related to a variety of health problems and/or other potentially preventable conditions of public health significance; also included are control group participants.
- 2. The proposed collection will not impact the respondents' privacy. Parental consent and student assent will be obtained prior to reviewing vaccine history of participating students in the Wisconsin Immunization Registry. Verification of the immunization history will be done by an approved study research assistant using the look-up function. All collected information will remain secure. Collected information will be entered into appropriate data management systems, and all personal identifying information will be deleted following information verification and cleaning. Final datasets will be maintained by the University of Wisconsin. DGMQ will only have access to coded data (all links to individual identifiers will be maintained by the University of Wisconsin). Analysis and resulting publications will not include any personal identifying information regarding participants.

3. Use of Improved Information Technology and Burden Reduction

Information collection will be obtained through telephone contact and in-person interviews and does not involve the use of information technology. Information collection tools for the proposed project are included in the attachments and have been reviewed and approved by the University of Wisconsin as well as by DGMQ. The number of questions posed has been held to the minimum required in order to elicit the necessary information. Particular emphasis will be placed on compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

4. Efforts to Identify Duplication and Use of Similar Information

Using school absenteeism data to predict influenza outbreaks has been suggested in previously done studies (12-14). Although several studies (15-17) have demonstrated usefulness of absentee data for detection of infection disease outbreaks, these studies were conducted in developing countries and findings are not fully applicable to the United States. It was also demonstrated that non-disease specific absenteeism data alone are of little use for school-based influenza surveillance (18). On the other hand, influenza-specific absenteeism data from schools were better able to predict a community outbreak of influenza than all-cause absenteeism. There is an evident lack of data on ILI-specific absenteeism as a predictor of the community-wide influenza outbreaks. As such, it is not expected that any of the information collected under this package is duplicative or is already in the possession of the federal government or other organizations that study or promote school-related mitigation measures. The proposed project will allow DGMQ to obtain important information from school settings in order to strengthen the evidence base for CDC's Pre-Pandemic Guidance. DGMQ will make all reasonable effort to ensure that the information collection does not overlap with other projects on infectious disease control measures in school settings.

5. Impact on Small Businesses or Other Small Entities

Small entities, including small governments (i.e. county and local public health and school officials), will be included in the proposed information collection. A small government is defined as a government jurisdiction of a city, county, town, township, school district, or special district with a population of less than 50,000. Questions will be held to the absolute minimum required for the intended use when participants could include officials representing small government offices (e.g., obtaining aggregate information on student absences for defined period of time).

6. Consequences of Collecting the Information Less Frequently

CDC is requesting that respondents record and report any instance of absence from school. The proposed information collection is required to strengthen the evidence-base for mitigation measures in school settings. The lack of additional information on ILI-specific absenteeism will negatively impact the federal government's capacity to provide data driven guidance during the next pandemic. There are no legal obstacles to reducing burden. Burden to individuals has been minimized and only necessary fields are included in the collection instruments.

Due to the congregation of children at schools and their susceptibility to many infectious diseases, school-based infectious disease outbreaks frequently precede disease transmission in the wider

community. Therefore, the collection of cause-specific absenteeism could provide important information needed to protect school-aged children from influenza and the impact of outbreaks on the wider community. Timing of influenza season is usually shorter than the academic year (on average, it lasts from October-end of March, peaking in January), and intensity of influenza activity varies across the season. Therefore, it is important to collect information for the study consistently during the academic year in order to maintain the validity of the study results. Findings from this information collection will be used to validate existing pandemic mitigation strategies, refine current strategies if needed, and strengthen the evidence-base for decision making on implementation of school-related measures during a pandemic.

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

One information collection activity in Madison, Wisconsin will be conducted under the auspices of this request. Individual respondents may be asked to respond to investigators more than once following subsequent ILI-related absence of the same student if at least 30 days have passed since his/her previous ILI-related absence. All materials related to this information collection are included in this package as specified in regulation 5 CFR 1320.5.

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

8a. A 60-day Federal Register notice was published in the Federal Register on May 14, 2014 (Vol. 79, No. 93, PP 27617-27618)(Attachment B). One non-substantive comment was received, and CDC's standard response was sent.

8b. Consultation

The following agencies and organizations outside of CDC have been consulted on the need for data collection with the audiences, and for the purposes, described in this information collection:

• In consultation with University of Wisconsin-Madison on the need for and process of data collection with the audiences described in this package:

Jonathan Temte, MD, PhD, Principal Investigator

Phone: 608-577-5846

E-mail: Jon.Temte@fammed.wisc.edu

• In consultation with University of Michigan the need for additional school-related mitigation measure research was identified in 2013.

Allison Aeillo, PhD, Epidemiologist

Phone: 734-615-9213 E-mail: aielloa@umich.edu

• In consultation with University of Utah the need for appropriate statistical methods for mitigation measure research was identified in 2013.

Molly Leecaster, PhD, Statistician

Phone: 801-585-6924

E-mail: Molly.Leecaster@utah.edu

 In consultation with University of Pittsburgh the need for additional school-related research was identified in 2013.

Charles Vukotich, MS, Senior Program Manager

Phone: 412-383-2882 E-mail: charlesv@pitt.edu

9. Explanation of Any Payment or Gift to Respondents

DGMQ will not directly offer cash incentives to the participants targeted in this information collection. However, the University of Wisconsin organizations will provide small, tangible tokens of appreciation for participants' time. All participating students (or parents of younger students) will receive \$20 gift card after the home visit is completed.

The Need for Incentives

Incorporating modest incentives to aid in recruitment for information collection is standard practice among commercial market researchers. For a number of reasons, this practice is also appropriate for the information collection covered by this package.

The most important aspect of an incentive plan may be its potential for reducing response bias, underreporting bias, and similar sources of error. Findings from the National Survey of Family Growth (a study in which childbearing and family planning patterns are collected from young women) demonstrated that incentives not only had positive effects on response rates, but they also increased the accuracy of reporting (19). This population will be included in our study population as part of our proposed school absentee monitoring system projects. Incentives are often necessary for testing in order to ensure that those who are willing to participate are as representative as possible of the wider public. Failure to provide a basic incentive may bias samples in the direction of well-educated individuals who are unlikely to be representative of the entire target population.

In the National Adult Literacy Survey by Berlin and colleagues (20), a \$20 incentive resulted not only in higher response rates from the sample cohort, but also in lower costs per completed case-report than the comparison group. Importantly, the incentives provided higher response rates from adults with lower-than-average levels of education and basic literacy and numeracy skills.

Empirical evidence suggests that motivation is increased when an incentive is present for research. Without providing minimal levels of monetary compensation, insufficient numbers of participants will likely participate and results will not be useful (20). In addition, there is substantial evidence that monetary incentives increase response rates to surveys. In a meta-analysis of 38 experiments and quasi-experiments, researchers found that nonmonetary gifts were significantly less effective than cash in generating survey responses, and noted that offering pre-paid monetary incentives yielded an average increase of 19.1 percentage points over comparison groups (21).

Level of Incentive Payment

DGMQ will not directly provide remuneration to project participants. However, during the recruitment process, the University of Wisconsin organizations will provide small tokens of appreciation to participants (see above). To account for differences in local culture and socioeconomic factors, project investigators have worked with contractors and the University of Wisconsin to ensure that incentive type and value are appropriate and do not have the effect of coercing individuals to participate.

10. Assurance of Confidentiality Provided to Respondents

The information collection described in this package has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). Individuals will be responding to the information collection completely voluntarily and will be covered by Privacy Act System Notice 09-20-0160, Records of Subjects in Health Promotion and Education Studies. Persons covered by the system notice include adults and children, including health and education agency administrators, school health personnel, teachers, parents, and students who participate in studies and surveys designed to obtain data on their knowledge, attitudes, and reported behavior related to a variety of health problems and/or other potentially preventable conditions of public health significance; also included are control group participants.

DGMQ, contractors, and the University of Wisconsin organizations will follow procedures for securing and maintaining privacy during all stages of information collection. Participants will be recruited directly from project schools and all students who are recruited will have parental consent using Attachment C3 Consent/Assent form. The University of Wisconsin and contractors will collect and analyze the project specific data. DGMQ will provide technical assistance in the design, implementation, and analysis of the project but will not be contact with project participants (and will only have access to coded data). All information provided by participants will be treated in a secure manner and will not be disclosed unless otherwise compelled by law. Participants will be informed prior to participation that their responses will be treated in a secure manner.

IRB Approval

The protocols and tools included in this information collection request have been reviewed and approved by the IRB at the University of Wisconsin with CDC review and deferral to the University. Approval letters from each academic institution and CDC's deferral approval are included in the attachments (Attachments C6 University of Wisconsin - IRB approval and Attachment C7 - CDC IRB deferral notice).

Privacy Impact Assessment Information

- 1. Participants will be advised of the nature of the information collection activity, the length of time it will require, and that participation is purely voluntary. Participants will be assured that no penalties will occur if they wish not to respond to the information collection as a whole or to any specific questions. These procedures conform to ethical practices for collecting data from human subjects.
- 2. The proposed information collection has been reviewed and approved by the IRB at the University of Wisconsin (with CDC deferral to that academic institution's IRB). Prospective participants will receive information on the purpose and sponsorship of the project, their rights as participants, risks and benefits

in participating, and contacts for more information about the project. Prior to the beginning of the information collection, a staff member will address any questions the participants have about the project.

For the project implemented by the University of Wisconsin, project staff will request verbal consent during initial telephone contact with the student's parent/guardian when assessing eligibility. During the in-person home visit, parental/guardian written consent will be obtained for students < 18 years of age. Additionally, during the home visit, verbal assent will be obtained from students aged 4 to 6 years of age, written assent will be obtained from children aged 7 to 14 years, and written consent will be obtained from students 15 years or older.

- 3. All data will be stored in secured electronic files with the University of Wisconsin and will be accessible only to staff directly involved in the project. All members of the project will be required to sign a statement pledging their personal commitment to guard the security of data. Online information collections will conform completely to federal regulations [the Hawkins-Stafford Amendments of 1988 (P.L. 100-297) and the Computer Security Act of 1987]; all information will be maintained in a password protected secure location. All project personnel having access to individual identifiers will sign non-disclosure agreements. DGMQ will have access to only coded data (all links to individual identifiers will be maintained by the University of Wisconsin organizations).
- 4. No system of records is being created for this information collection. However, information collected as part of this package from students and parents will be covered by Privacy Act System Notice 09-20-0160 Records of Subjects in Health Promotion and Education Studies, Federal Register /Vol. 51, No. 226 /Monday, November 24, 1986/ PP 42484-42485.

11. Justification for Sensitive Questions

Mitigation measure research typically does not involve questions of a sensitive nature. However, questions about the reasons for absences could be considered sensitive by some participants. A portion of participants could also consider questions about race, ethnicity, or other demographic characteristics to be sensitive. Where relevant to the information collection, race and ethnicity data will be collected consistent with HHS policy and standard OMB classifications.

Additionally, some participants may feel uncomfortable answering particular questions about their individual experiences, level of disease awareness, and/or adopted preventative behaviors (or lack thereof) associated with various diseases (e.g. influenza vaccination). Such questions, when asked, are necessary for the purposes of this information collection. To minimize psychological distress, the moderator or information collection instructions will inform participants that they do not have to respond to any questions they do not want to answer and that they may stop participating at any time. In addition, a subject matter expert from the University of Wisconsin will be available to answer questions from participants following the information collection activity.

12. Estimates of Annualized Burden Hours and Costs

This information collection will be implemented in collaboration with the University of Wisconsin and will target students attending K-12 schools in Madison, Wisconsin. Information will be collected on student absences for enhanced cause-specific school absentee monitoring as previously described.

We outline the estimated burden hours for the proposed project in Table 12A. The burden table provides estimated annualized burden hours and costs across the different project locations.

A maximum of 500 students will be enrolled annually in the project. We estimate that each student will have on average four absent episodes per year, and use the Screening Form and Acute Respiratory Infection and Influenza Surveillance Form – one for each of these episodes (an episode is defined as an ILI-related absence of at least one day). A student can be included in the study again, following his/her subsequent absence if 30 days have passed since their last enrollment. University of Wisconsin staff estimates that it will take less than 5 minutes to respond to the initial screening call (Screening Form), less than 15 minutes to complete the in-person interview (Acute Respiratory Infection and Influenza Surveillance Form), and less than 5 minutes to complete the biospecimen collection. These same tools (Screening Form and Acute Respiratory Infection and Influenza Surveillance Form) will be used to identify and follow-up on students who continue to attend school despite being ill. The total burden to participants is estimated at 834 hours annually.

Table 12-A: Estimated Annualized Burden to Participants for example projects

| Type of Respondent | Form Name | No. of Respondents | No. of Responses per Respondent | Average Burden per Response (in hours) | Total Burden Hours |
|--|---|-----------------------|--|---|--------------------------|
| Parents of children/adolescents or adult students (≥18 yo) attending schools | Screening Form | 500 | 4 | 5/60 | 167 |
| Parents of children/adolescents or adult students (≥18 yo) attending schools | Acute Respiratory Infection and Influenza Surveillance Form | 500 | 4 | 15/60 | 500 |
| Biospecimen collection from student | N/A | 500 | 4 | 5/60 | 167 |
| TOTAL | | 500 | | | 834 |

Table A.12-B presents the calculations for cost of respondents' time using the general public's mean hourly wages. Hourly mean wage information is from the U.S. Department of Labor's Bureau of Labor Statistics website, specifically originating from the 2013 National Occupational Employment and Wage Estimates for the United States (http://www.bls.gov/oes/current/oes_nat.htm#00-0000). An average hourly salary of approximately \$22.33 is assumed for all participants, based on the Department of Labor (DOL) National Compensation Survey. The average salary was used rather than attempting to estimate salaries for different audiences due to the scope of this package. With an annual burden of hours of 834 the overall cost of participants' time for the example information collections is estimated to be a maximum of \$18,625 (834 * \$22.33 per hour).

The total respondent costs are summarized below in Table A.12-B.

Table A.12-B: Estimated Annualized Cost to Respondents

| Type of Respondents | Form Name | Total Burden Hours | Hourly Wage Rate | Total Respondent Costs |
|---|---|-----------------------|---------------------|------------------------|
| Parents of children/adolesc ents or adult students (≥18 yo) attending schools | Screening Form | 167 | \$22.33 | \$3,730 |
| Parents of children/adolesc ents or adult students (≥18 yo) attending schools | Acute Respiratory Infection and Influenza Surveillance Form | 500 | \$22.33 | \$11,165 |
| Biospecimen collection from student | N/A | 167 | \$22.33 | \$3,730 |
| TOTAL | | 834 | | \$18,625 |

^{*}Public wages from http://www.bls.gov/oes/current/oes nat.htm#00-0000

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There is no cost or burden to respondents other than their time.

14. Annualized Cost to the Government

There is no equipment or overhead cost. The only cost to the federal government would be the salary of CDC staff supporting the information collection activities and associated tasks.

Table A.14-A: Estimated Annualized Cost to the Government per Activity and Total

| Estimated Annualized Cost to the Government per Activity and Total | | |
|--|---------------------------|--|
| Cost Category | Estimated Annualized Cost | |
| Federal employee costs, per information collection | \$36,000 | |
| (15% FTE of two GS-14 step 6 at ~\$120,000/year) | | |

| Contractual costs for an information collection (e.g. facility rental, moderator/interviewer, participant recruitment, translations, transcriptions and final reports) | \$500,000 |
|--|-----------|
| School absentee project = \$500,000/year | |
| Cost per information collection | \$536,000 |
| Total cost for annualized information collections | \$536,000 |

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

In collaboration with the University of Wisconsin, DGMQ anticipates starting data collection in August 2014. DGMQ expects to begin tabulating data at the end of the first school year (in June 2015) and publish the results from this information collection upon completion of the project after June 2016. Results will be presented at professional conferences and in peer-reviewed journals. We do not aim to generalize results obtained from the project covered by this information collection.

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

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

REFERENCES

- 1. Kilbourne ED. Influenza pandemics of the 20th century. *Emerg Infect Dis* 2006;12 (1):9-14.
- 2. Leung GM, Nicoll A. Reflections on pandemic (H1N1) 2009 and the international response. *PLoS Med* 2010; 7(10):1-6.
- 3. Department of Health and Human Services. Guidance on Allocating and Targeting Pandemic Influenza Vaccine. Available at http://www.pandemicflu.gov/vaccine/allocationguidance.pdf. Accessed on August 21, 2013.
- 4. DiMenna LJ, Ertl HCJ. Pandemic Influenza Viruses. In: Compans, RW, Orenstein WA, eds. Vaccines for Pandemic Influenza. Berlin (Germany): Springer; 2009.
- 5. Schwartz B, Ornstein WA. Prioritization of Pandemic Influenza Vaccine: Rationale and Strategy for Decision-Making. In: Compans, RW, Orenstein WA, eds. Vaccines for Pandemic Influenza. Berlin (Germany): Springer; 2009.
- 6. CDC. Antiviral Agents for the Treatment and Chemoprophylaxis of Influenza: Recommendations of the ACIP. *MMWR* 2011; 60:1-24.
- 7. Centers for Disease Control and Prevention. Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States-Early, Targeted, Layered Use of Non-Pharmaceutical Interventions, February 2007. Available from: http://www.flu.gov/planning-preparedness/community/community_mitigation.pdf. Accessed April 4, 2013.
- 8. Viboud C, Boelle PY, Cauchemez S, Lavenu A, Valleron AJ, Flahault A, et al. Risk factors of influenza transmission in households. Br J Gen Pract. 2004 Sep;54(506):684-9.
- 9. Longini IM, Jr., Koopman JS, Monto AS, Fox JP. Estimating household and community transmission parameters for influenza. Am J Epidemiol. 1982 May;115(5):736-51.
- 10. Davis LE, Caldwell GG, Lynch RE, Bailey RE, Chin TD. Hong Kong influenza: the epidemiologic features of a high school family study analyzed and compared with a similar study during the 1957 Asian influenza epidemic. Am J Epidemiol. 1970 Oct;92(4):240-7.
- 11. Dennis L. Chao, M. Elizabeth Halloran, and Ira M. Longini, Jr,2School Opening Dates Predict Pandemic Influenza A(H1N1) Outbreaks in the United States. JID 2010:202 (15 September)
- 12. Besculides M, Heffernan R, Mostashari F, Weiss D. Evaluation of school absenteeism data for early outbreak detection, New York City. BMC Public Health. 2005;5:105. http://dx.doi.org/10.1186/1471-2458-5-105
- 13. Rodriguez D, Zhang G, Leguen F, O'Connell E, Bustamante M. Using public school absentee data to enhance syndromic surveillance in Miami-Dade County, 2007. Advances in Disease Surveillance. 2007;4:188.

- 14. Rodriguez CV, Rietberg K, Baer A, Kwan-Gett T, Duchin J. Association between school closure and subsequent absenteeism during a seasonal influenza epidemic. Epidemiology. 2009;20:787–92. http://dx.doi.org/10.1097/EDE.0b013e3181b5f3ec
- 15. L. Tan, L. Cheng, W. Yan, J. et al. Using daily syndrome-specific absence data for early detection of school outbreaks: a pilot study in rural China. Public Health. 128 (2014) 792e798.
- 16. Calvin K. Y. Cheng1, Hing Channarith2, Benjamin J. Cowling. Potential Use of School Absenteeism Record for Disease Surveillance in Developing Countries, Case Study in Rural Cambodia. PLoS One. October 2013 | Volume 8 | Issue 10 | e76859.
- 17. Yunzhou Fan, Mei Yang, Hongbo Jiang et al. Estimating the Effectiveness of Early Control Measures through School Absenteeism Surveillance in Observed Outbreaks at Rural Schools in Hubei, China. PLoS One. September 2014, Volume 9, Issue 9, e106856.
- 18. Joseph R. Egger, Anne G. Hoen, John S. Brownstein, David L. Buckeridge, Donald R. Olson, Kevin J. Konty. Usefulness of School Absenteeism Data for Predicting Influenza Outbreaks, United States. Letter to Editor. Emerging Infectious Diseases. Vol. 18, No. 8, August 2012
- 19. Mosher, W., *Design and operation of the 1995 National Survey of Family Growth*. Family Planning Perspectives, 1998. **30**(1).
- 20. Berlin, M., et al. An experiment in monetary incentives, in Proceedings of the American Statistical Association Section on Survey Research Methods. A.S. Association, Editor 1992, American Statistical Association: Alexandria, Virginia. p. 393-398.
- 21. Krueger, R. Focus groups: A practical guide for applied research. 2nd ed1994, ThousandOaks, California: Sage Publications.

ATTACHMENTS

- A1. Section 361 of the Public Health Service Act (42 USC 264).
- A2. 42 Code of Federal Regulations Part 70 Interstate Quarantine
- A3. Section 301 of the Public Health Service Act (42 USC 241)
- B. 60-Day Federal Register Notice
- C1. IRB-approved Study Protocol
- C2. School district approval letter
- C3. Screening Form
- C4. Consent/Assent form
- C5. Acute Respiratory Infection and Influenza Surveillance Form
- C6. Wisconsin IRB approval
- C7. CDC IRB deferral notice