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 Office of Scientific Integrity, Office of the  
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**DEPARTMENT OF HEALTH AND  
 HUMAN SERVICES**

**Centers for Disease Control and  
 Prevention**

[30Day-16-0824]

**Agency Forms Undergoing Paperwork  
 Reduction Act Review**

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to *omb@cdc.gov*. Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

**Proposed Project**

BioSense (OMB Control No. 0920-0824, Expiration 11/30/2015)—Revision—Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

The BioSense Program was created by congressional mandate as part of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and was launched by the CDC in 2003. The original BioSense Program (BioSense 1.0) was intended to serve as a national level public health syndromic surveillance system for early detection and rapid assessment of potential bioterrorism-related illness and injury. In 2009, CDC began planning and developing the computing cloud-based BioSense 2.0 Platform. This cloud-based system would offer secure storage space for data and data sharing capacity for each state and local health department. Since August 2012, when CDC submitted a request to OMB for approval of a revision to the BioSense information collection request, HHS published new guidance on Meaningful Use of Electronic Health Records for syndromic surveillance. During this

time, CDC also initiated its new CDC Surveillance Strategy. These actions provided new guidance for improvements to the BioSense Program, which resulted in new requirements for data submission to the BioSense Platform and new requests specified below.

CDC requests a three-year Revision approval for BioSense. This Revision includes new requests for approval to: (1) Change the title of the information collection request from BioSense to the National Syndromic Surveillance Program (NSSP); (2) receive data from additional state, local, and territorial health departments; (3) receive from state, local, and territorial health departments syndromic surveillance data submitted to those health departments from urgent care, ambulatory care and hospital inpatient settings (in addition to data from hospital emergency departments, included in the previously approved information collection request); and (4) receive from state, local, and territorial health departments additional syndromic surveillance data elements.

The total estimated number of burden hours has decreased since the previously approved information collection request because we inadvertently included estimates for the Department of Defense, Department of Veterans Affairs, and the two organizations that provide pharmacy data. We only included estimates for state, local, and territorial public health jurisdictions and the private sector laboratory company that provides laboratory data free of charge to CDC in this information collection request. There is no burden for the private sector laboratory company for recruitment, registration, and healthcare data collection. The private sector laboratory company chose their sharing permissions when they registered to use the system. The estimated annual burden is 39 hours.

**ESTIMATED ANNUALIZED BURDEN HOURS**

| Type of respondents                                     | Form name   | Number of respondents | Number of responses per respondent | Average burden per response (in hrs.) |
|---|---|-----------------------|------------------------------------|---------------------------------------|
| State, Local and Territorial Public Health Departments  | Recruitment Information Collection  | 20                    | 1                                  | 1                                     |
| State, Local and Territorial Public Health Departments  | Registration Information Collection   | 200                   | 1                                  | 5/60                                  |
| State, Local, and Territorial Public Health Departments | Healthcare Information Collection: Administrator Data Sharing Agreements/Permissions. | 20                    | 1                                  | 5/60                                  |

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[30Day-15-0960]

#### Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

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To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to [omb@cdc.gov](mailto:omb@cdc.gov). Written

comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

#### Proposed Project

Epidemiologic Study of Health Effects Associated With Low Pressure Events in Drinking Water Distribution Systems (OMB Control No. 0920-0960, expiration 3/31/2016)—Extension—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

#### Background and Brief Description

In the United States (U.S.), drinking water distribution systems are designed to deliver safe, pressurized drinking water to our homes, hospitals, schools and businesses. However, the water distribution infrastructure is 50-100 years old in much of the U.S. and an estimated 240,000 water main breaks occur each year. Failures in the distribution system such as water main breaks, cross-connections, back-flow, and pressure fluctuations can result in potential intrusion of microbes and other contaminants that can cause health effects, including acute gastrointestinal and respiratory illness.

Approximately 200 million cases of acute gastrointestinal illness occur in the U.S. each year, but we lack reliable data to assess how many of these cases are associated with drinking water. Further, data are even more limited on the human health risks associated with exposure to drinking water during and after the occurrence of low pressure events (such as water main breaks) in drinking water distribution systems. A study conducted in Norway from 2003-2004 found that people exposed to low pressure events in the water distribution system had a higher risk for gastrointestinal illness. A similar study is needed in the United States.

The purpose of this data collection is to conduct an epidemiologic study in the U.S. to assess whether individuals exposed to low pressure events in the water distribution system are at an increased risk for acute gastrointestinal or respiratory illness. This study would

be, to our knowledge, the first U.S. study to systematically examine the association between low pressure events and acute gastrointestinal and respiratory illnesses. Study findings will inform the Environmental Protection Agency (EPA), CDC, and other drinking water stakeholders of the potential health risks associated with low pressure events in drinking water distribution systems and whether additional measures (e.g., new standards, additional research, or policy development) are needed to reduce the risk for health effects associated with low pressure events in the drinking water distribution system.

We will conduct a cohort study among households that receive water from six water utilities across the U.S. The water systems will be geographically diverse and will include both chlorinated and chloraminated systems. These water utilities will provide information about low pressure events that occur during the study period using a standardized form (approximately 11 events per utility). Utilities will provide address listings of households in areas exposed to the low pressure event and comparable households in an unexposed area to CDC staff, who will randomly select participants and send them an introductory letter and questionnaire. Consenting household respondents will be asked about symptoms and duration of any recent gastrointestinal or respiratory illness, tap water consumption, and other exposures including international travel, daycare attendance or employment, animal contacts, and recreational water exposures. Study participants may choose between two methods of survey response: A mail-in paper survey and a Web-based survey.

Participation in this study will be voluntary. No financial compensation will be provided to study participants. The study duration is anticipated to last 30 months. An estimated 6,750 individuals will be contacted and we anticipate 4,050 utility customers (18 years of age or older) will consent to participate in this study. The total estimated annualized hours associated with this study is expected to be 548.

There are no costs to respondents other than their time.