BioSense - Recruitment of Data Sources

Supporting Statement

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A. JUSTIFICATION

A.1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) requests a three year approval for an existing information collection that has been in use without an OMB control number. Due to a number of questions, issues and discussions about the need for OMB approval of the BioSense Program, the request for authorization of the information collections for the Program's recruitment of data sources and access to the BioSense Application has not been submitted in a timely manner. However, it is noted that during the discussions and decision-making process, OMB recognized the value of the BioSense Program and stated that BioSense should continue its current work while the Program's scope of activities were evaluated and a final determination rendered. This authorization request responds to the determination.

Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which requires specific activities related to bioterrorism preparedness and response. This congressional mandate outlines the need for improving the overall public's health through electronic surveillance. The Department of Health and Human Services outlined strategies aimed at achieving this goal via the Public Health IT Initiative thereby creating the BioSense program. The Public Health Service Act (42 U.S.C. 241, 247b and 247d-4) and the Pandemic and All-Hazards Preparedness Act (PAHPA), Public Law No. 109-417 authorizing this activity are included as **Attachment 1**.

BioSense is a national, human health surveillance system designed to improve the nation's capabilities for disease detection, monitoring, and health situational awareness. This work is enhanced by providing public health real-time access to existing information from healthcare organizations, state syndromic surveillance systems, national laboratory corporations, and others for just in time public health decision-making; this information is made available to users in the BioSense Application. The Application provides charts, graphs, and maps through a secure Web-based interface which can be accessed by CDC and authorized users from state and local public health departments and healthcare organizations.

In order to meet the congressional mandate outlined above, the BioSense program must have access to electronic health information. This is done by recruiting data sources--healthcare organizations, state syndromic surveillance systems, etc. -- and arranging for the automated transfer of existing electronic data from these sources to CDC. The collection of new data is not requested or performed. The recruitment of additional data sources increases situational awareness over time and coverage of geographic areas and jurisdictions.

This is a request for a three-year authorization for purposes of: (1) collecting information needed to add up to 20 new sources of data for BioSense per year; and (2) collecting information to provide access to the BioSense Application to approximately 800 users per year. Both information collection instruments are identical to those in use prior to this request.

Overview of Data Collection System

Procedures for recruitment of new data sources include personal and telephone discussions and site visits to collect information on the facilities, the types of computer systems used, and the types and volume of data available. The collection of this information is performed by BioSense personnel and contractors from Science Applications International Corporation (SAIC) using a series of questionnaires in an Excel spreadsheet. This information collection process takes about 4 hours, sometimes spread over a number of interviews. The information will be collected only once from each respondent. The information is maintained by the SAIC contractors and retained as long as the data source remains active with BioSense. **Attachment 3**

Access to the BioSense Application is obtained using an automated data collection form which is completed on the Internet via the CDC Secure Data Network in which a prospective user identifies what activities are requested. Federal rules mandate that permission be renewed each year, and therefore annual collection of the information is necessary. **Attachment 4**

Items of Information to be Collected

For recruitment of data sources, information on facilities, types of computer systems used, and the types and volume of data available is collected. While the name and address of the prospective data source being recruited and the name of the individual(s) responding on behalf of the organization is collected, the information is for contact purposes only, i.e., to facilitate information collection. No other information in identifiable form is collected.

Information collected when requesting access to the BioSense Application does not include personal identifiers. Potential users only identify the activities (such as the BioSense Application) they are requesting permission to access.

As stated in section A.1., both the recruitment and access information collection instruments are identical to those used prior to this three-year authorization request.

Identification of Websites(s) and Website Content Directed at Children Under 13 Years of Age

Not applicable.

A.2. Purpose and Use of the Information Collection

In order to meet the congressional mandate outlined in section A.1., which requires specific activities related to bioterrorism preparedness and response, BioSense must have real-time access to electronic health data. Rapid automated receipt and availability of health data is essential for recognizing and managing large-scale outbreaks, disasters, and other public health emergencies. The Nation's health situational awareness improves as additional data sources are recruited, providing more health data and better geographic coverage that can be accessed via the BioSense Application.

Recruitment of data sources is ongoing as potential sources are identified. Current information sources include 8 state or local health departments, 22 healthcare/hospital groups (which collectively transmit data from 460 hospitals), the Department of Veterans Affairs (which transmits data from 820 facilities), the Department of Defense (which transmits data from 320 facilities), two national laboratory corporations, and one pharmacy claims system (which transmits data from >30,000 pharmacies). Information from these sources is displayed in the BioSense Application.

The BioSense Application may be viewed by federal, state, and local public health personnel; by officials of the VA and DoD; and personnel at hospitals or hospital systems providing data. The Application is accessed by logging onto the CDC Secure Data Network (SDN). The SDN allows access to a number of different services (e.g., Epi-X) in addition to BioSense. The Application provides statistical algorithms and time series charts to enable the user to identify increased numbers or rates of patient visits that may indicate an outbreak, patient visit line lists to assist in data collection for investigations, maps to visualize the geographic areas involved, and charts to assist in monitoring long-term trends in disease activity and increase understanding of disease patterns in the area.

Privacy Impact Assessment Information

The information collected in the recruitment of a data source is needed to determine the technical requirements for linking a data source into the BioSense program, this information is extremely specific to and varies from location to location. It is due to these levels of specificity and variance that it is only by performing the proposed information collection can the BioSense program obtain the information necessary for the set up of a new linkage. Therefore, information is collected once from each prospective data source (i.e., healthcare organization, etc.) to identify the types of computer systems used and the types and volume of information available. **See Attachment 3.** The information collection is performed by BioSense personnel and contractors via direct and telephone discussions and the use of a questionnaire. Recruitment of new data sources will be ongoing throughout the requested three year authorization. We estimate that up to 20 new data sources will be recruited per year.

The proposed information collections will have little or no effect on the respondents' privacy. While the name and address of the prospective data source, (i.e., healthcare organization, etc.) and the name of the individual(s) responding on behalf of the organization is collected, the information is for contact purposes only, i.e., to facilitate information collection. No other information in identifiable form is collected. Information collected when requesting access to the BioSense Application does not include personal identifiers. Potential users only identify the activities (such as the BioSense Application) they are requesting permission to access.

A.3. Use of Improved Information Technology and Burden Reduction

For obtaining information on new data sources, Excel sheets are the optimal method of implementing collection of these data. **(Attachment 3)** They are quick and easy for respondents to use and facilitate collation of the data by CDC. Because of the small number of

respondents per year, it would not be helpful or cost-effective to use web-based approaches or specialized survey software for this data collection.

For providing access to the BioSense Application, automated data collection forms **(Attachment 4)** are used. This use of improved information technology reduces burden on prospective BioSense users and facilitates the most rapid processing of requests.

A.4. Efforts to Identify Duplication and Use of Similar Information

Regarding the collection of information about new data sources, a limited number of surveys have been performed specifically to determine the number of state and local health departments, and private sector entities operating automated surveillance systems. These surveys have had a poor response rate and little information attained on the types of computer systems used, and the types and volume of information available.

The information that is needed to satisfy the technical requirements to link a data source into the BioSense program is extremely specific to and varies from location to location. It is due to these levels of specificity and variance that it is only by performing the proposed information collection can the BioSense program, obtain the information necessary for set up of new linkages.

Regarding provision of access to the BioSense Application, the information must be collected directly from those applying for access and would not be available from another source.

A.5. Impact on Small Businesses or Other Small Entities

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

A.6. Consequences of Collecting the Information Less Frequently

Regarding recruitment of new data sources, information will be collected only once from each respondent.

Regarding provision of access to the BioSense Application, federal rules mandate that permission be renewed each year, and therefore annual collection of the information is necessary.

There are no legal obstacles to reducing the burden.

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

This request fully complies with the regulation 5 CFR 1320.5.

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

A. The agency's 60-day notice of proposed data reporting was printed in the *Federal Register* on **October 16, 2008 (Volume 73, Number 201, Pages 61423-61424)**. See **Attachment 2**. No public comments were received in response to the notice.

B. During 2007-2008, a series of three BioSense Roundtables were held. At each one-day meeting, representatives from federal, state, and local public health and hospital personnel discussed biosurveillance needs and the role of BioSense as a national biosurveillance system. Participants provided recommendations on programmatic issues, challenges, and opportunities with a goal of informing and advancing the BioSense program. Through these Roundtables, collaboration and an open source environment was enforced as the foundation of the future state of the program. The names and contact information for participants in the Roundtables is in **Attachment 5**. No major data collection problems exist that could not be resolved through these consultations.

CDC also regularly engages users through periodic teleconferences ("Real-time, Real-talk), national and jurisdiction-specific webinars, and at national academic meetings such as the Public Health Information Network (PHIN) conference and the International Society for Disease Surveillance (ISDS) meeting.

A.9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents who provide information for enrolling new data sources or who apply for access to the BioSense Application.

A.10. Assurance of Confidentiality Provided to Respondents

The information collections have been reviewed and it has been determined that the Privacy Act is not applicable. No sensitive or personal identifying information will be collected.

A.11. Justification for Sensitive Questions

There are no questions of a sensitive nature asked in the collection of information for the recruitment of data sources, which is to determine the types of computer systems used and the types and volume of data available.

There are no questions of a sensitive nature asked in the collection of information for access to the BioSense application.

A.12. Estimates of Annualized Burden Hours and Costs

The contractor administering the EXCEL spreadsheet for data source recruitment has provided an estimate of four hours per respondent. This encompasses the time for reviewing

instructions, gathering the information needed, and completing and reviewing the collection of information. Private sector respondents for this information include healthcare organizations such as hospitals and hospital systems, national laboratory corporations and a pharmacy claims system.

CDC personnel who have applied for access to the BioSense Application provided an estimate of 5 minutes. Private sector users are primarily epidemiologists from healthcare organizations.

A.12-A. Estimates of Annualized Burden Hours

Type of Respondents	**Number of Respondents**	**Number of Responses per Respondent**	**Average Burden Per Response (in hours)**	**Total Burden (in hours)**
Recruitment of prospective data source entities				
State & Local Governments	14	1	4	56
Federal Government	1	1	4	4
Private Sector (healthcare organizations, national laboratory corporations, and a pharmacy claims system)	5	1	4	20
Total				**80**
Access to BioSense Application				
State & Local Governments	560	1	5/60	47
Federal Government	40	1	5/60	3
Private Sector (healthcare organizations)	200	1	5/60	17
Total				**67**
Overall Total				**147**

A.12-B. Estimates of Annualized Cost Burden

Type of Respondents	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Hourly Wage Rate	Respondent Cost
Recruitment of prospective data source entities					
State & Local Government	14	1	4	$35.82	$2,005.92
Federal Government	1	1	4	$35.82	$143.28
Private Sector	5	1	4	$35.82	$716.40
Total					**$2,865.60**
Access to BioSense Application					
State & Local Government	560	1	5/60	$30.90	$1,442.00
Federal Government	40	1	5/60	$30.90	$103.00
Private Sector	200	1	5/60	$30.90	$515.00
Total					**$2,060.00**

According to the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2008 National Occupational Employment and Wage Estimates, the mean hourly wage for Computer and Mathematical Science Occupations is $35.82. This rate is used as the hourly wage rate for respondents to the recruitment survey of prospective data sources because it represents the category of occupations most likely held by the respondents

For requesting access to the BioSense Application, the hourly wage rate is taken from the Life, Physical, and Social Science Occupations listed under the U.S. Department of Labor Employment and Wage Estimates because it best represents the occupations of the Application's current and potential users. The mean hourly wage is $30.90.

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

There are no costs to respondents other than their time.

A.14. Annualized Cost to the Federal Government

Item	Cost to Federal Government
Recruitment of prospective data source entities	
Contracts	$3277.00
Project Officer (GS-14, .05 FTE)	$4,213.00
Access to BioSense Application	
Contracts	$2731.00
Project Officer (GS-13, .02 FTE)	$2,454.00
Total	**$12,675.00**

The estimated total cost to the federal government for collecting information on data sources and granting access to the BioSense Application to prospective users is $12,675.00. An 18% overhead has been added to the costs. This 18% increase is an estimate based on the average costs related to organizational management support over the past three fiscal years.

A.15. Explanation for Program Changes or Adjustments

This is a new data collection.

A.16. Plans for Tabulation and Publication and Project Time Schedule

The information collection for the recruitment of data sources will be ongoing throughout the requested three year authorization. There is no specific timeline for recruitment; only as potential data sources are identified. As well, information collection for accessing the BioSense Application will be ongoing throughout the three year approval period and initiated by the prospective user; therefore, a timeline is not applicable to this activity.

Information collected for the recruitment of data sources and provision of access to the BioSense Application are not tabulated or reported.

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

It would be inappropriate to display an OMB expiration date on the information collection instrument used to request access to the BioSense Application. The information collection site is a submenu accessed by logging onto the CDC Secure Data Network (SDN). The submenu consists of a drop down list of a number of different services. In addition to the BioSense Application, an individual may request permission to access other services (e.g., Epi-X); the site is not exclusive to BioSense. **See Attachment 4.**

A.18. Exceptions to Certification for Paperwork Reduction Act (PRA) Submissions 5CFR 1320.3(h) (1) – (10)

There are no exceptions to the certification.

B. Collections of Information Employing Statistical Methods

Information for data source recruitment or for access to the BioSense Application is used to perform services and is not summarized statistically. Therefore these data reporting processes do not involve statistical methods.

List of Attachments

Attachment 1: Authorizing Legislation

Attachment 2: 60 Day *Federal Register* Notice

Attachment 3: BioSense Enablement Preparation Workbook MDS

Attachment 4: Request Access to the BioSense Application

Attachment 5: BioSense Roundtable Participants