

BioSense

Supporting Statement Section A OMB Control Number 0920-0824

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BioSense Supporting Statement

A. Justification

- The goal of the BioSense Program, which has evolved into the National Syndromic Surveillance Program (NSSP), is to support the sharing and use of high-quality syndromic surveillance data for situational awareness and to identify, monitor, investigate, and respond to hazardous events and disease outbreaks at local, regional and national levels.
- Data are used to support public health event detection, characterization and collaborative response across jurisdiction boundaries.
- CDC, state and local public health departments, the Department of Defense (DoD), the Veterans Administration (VA), and other collaborators participating in NSSP voluntarily submit healthcare data to the BioSense Platform through automated electronic health information exchange.
- The respondent population consists of all state, local, and territorial public health departments in the United States. Currently, there are 66 (41 state and 25 local) public health departments and one national-level private sector clinical laboratory participating.
- Data sharing and analytic tools and services are made available on the Platform to enable CDC and its federal, state and local NSSP participants to share information and conduct data analysis, visualization, querying, anomaly detection and other syndromic surveillance activities. Collaborative projects are conducted to improve the methods and utility of syndromic surveillance.
- CDC will make de-identified national-level aggregate data available to the public in published reports and on the CDC internet.
- [Please clarify in this bullet if participating/non-participating state/local health departments will have access to this data. Will de-identified data be publicly available to any stakeholder per OMB M13-13, or just to Federal agencies?]

1. Circumstances Making the Collection of Information Necessary

CDC requests a three year approval for a Revision for BioSense, OMB Control No. 0920-0824, Expiration Date 11/30/2015. Key changes in this Revision include the following requests:

- To change the title of this Information Collection Request (ICR) from BioSense to the National Syndromic Surveillance Program (NSSP);
- To receive data from additional state, local, and territorial health departments (Attachment 3 lists the current participating state and local health departments);
- To receive from state, local, and territorial health departments syndromic surveillance data submitted to those health departments from urgent care, ambulatory care and inpatient settings (in addition to data from hospital emergency departments, included in the previously approved ICR);
- To receive from state, local, and territorial health departments additional syndromic surveillance data elements;

- To use the non-substantive change request method in the future to request approval to receive additional syndromic surveillance data elements from state, local and territorial health departments when they are recommended by International Society for Disease Surveillance a that includes the Department of Health and Human Services “Meaningful Use” initiative described in the Background section in this ICR. Changes in burden to the ICR introduced by non-substantive changes are intended to be minor, and will thus not exceed 20% of the approved burden hours. If non-substantive change requests are employed to amend the types of syndromic surveillance data elements received from state and local health departments, the agency will submit a non-substantive change request memo to OMB describing the new data elements, the necessity for inclusion, and how the data will be used.

Background

Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which requires specific information collection activities related to bioterrorism preparedness and response. This congressional mandate outlines the need for protecting the overall public’s health through an integrated system for electronic surveillance. The Department of Health and Human Services (HHS) outlined strategies aimed at achieving this goal via the Public Health IT Initiative leading to creation of the BioSense Program. Authorities for this activity are from the Public Health Service Act (42 U.S.C. 241, 247b and 247d-4), as amended by the Pandemic and All-Hazards Preparedness Act (PAHPA), Public Law No. 109-417, and the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) Public Law No. 113-5 (**Attachment 1**).

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. This was to be done by collecting and analyzing, in near real time, health care data submitted to CDC from a variety of sources by means of automated electronic health record messaging systems. BioSense 1.0 became operational in December 2003 within the CDC Emergency Operations Center (EOC). BioSense 1.0 initially received health care data from the Departments of Defense (DoD) and Veteran’s Affairs (VA). Data sources were eventually expanded to include pharmacy, laboratory and over-the-counter drug sales data from national vendors and infectious disease data from sentinel sites. The scope of the surveillance was also expanded to include detecting and monitoring a broader set of syndromes of public health importance (e.g., injuries, certain chronic diseases, and infectious diseases such as influenza). CDC gave 49 state health departments access to the system. CDC also sought to integrate syndromic surveillance services and results with broader biosurveillance

initiatives underway across the federal government. To accomplish this, CDC data analysts interacted closely with the EOC, the HHS Secretary's Operations Center, the Department of Homeland Security National Biosurveillance Integration Center, and other federal partners.

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 from each state and local health department. A key additional feature was its data sharing capacity. This would enable state and local health departments, CDC, the VA, DoD, and other users to share de-identified data, analytic tools, and services on the Platform. The data sharing capability allowed state and local health departments to choose to share within their health department, with other health departments, with CDC, or with any combination of these choices. These multi-tiered interactions and knowledge exchanges within the Platform's common operational environment would strengthen regional and national situational awareness based on improved access to local, state, and federal surveillance data. On October 13, 2009, CDC received a three-year approval (OMB Control Number 0920-0824) for an existing information collection that has been in use without an OMB control number to collect data for recruitment of data sources and access to the BioSense Application. CDC subsequently received a three-year approval on November 5, 2012 for a revision to 0920-0824 to collect: (1) information needed for recruitment of participating jurisdictions to BioSense 2.0 each year; (2) the one-time collection of information to provide access to the BioSense 2.0 Application to all appropriate users in participating jurisdictions and organizations, and (3) the collection of already existing healthcare encounter data.

The Association of State and Territorial Health Officials (ASTHO) was funded through a cooperative agreement with CDC to support BioSense 2.0. The agreement includes ASTHO providing the cloud-based computing infrastructure for the Platform through a contract with Amazon Web Services. In addition, ASTHO developed data use agreements with state and local health departments. This meant CDC no longer developed agreements with hospitals to directly submit their data to CDC. Instead, state and local public health departments developed such agreements with hospitals. In this way, hospital emergency department data were submitted to each public health jurisdiction's secure data storage space on the BioSense Platform either by means of health information exchanges within the jurisdictions or directly by the hospitals. Jurisdictions then shared specific types of their data with CDC, the VA, DoD, other state and local health department representatives, and other users.

Since August 2012, when CDC submitted a request to OMB for approval of a revision to the BioSense ICR, HHS published new guidance on Meaningful Use of Electronic Health Records for syndromic surveillance (<http://www.cdc.gov/ehrmeaningfuluse/>). During this time, CDC also initiated its new CDC Surveillance Strategy. These actions provided new guidance for improvements to the BioSense Program

(<http://www.cdc.gov/ophss/docs/cdc-surveillance-strategy-final.pdf>), which resulted in new requirements for data submission to the BioSense Platform as described below.

As part of the HHS Meaningful Use of electronic health record information initiative, in September 2012, syndromic surveillance became an objective for hospitals and health professionals to reach in order to receive incentives from the Centers for Medicare and Medicaid Services (CMS). These incentives are authorized by the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009.

The HITECH Act promotes the meaningful use of health information as a way to improve the health of the U.S. population. The Act specifically promotes the use of electronic health records as a means for public health surveillance. To receive certain meaningful use incentives, hospitals and health professionals are required to successfully submit data from their electronic health records to public health departments for use in syndromic surveillance. To support the meaningful use of syndromic surveillance desired by HHS, CDC collaborated with a number of partners to lead a consensus-driven process to identify core data elements needed for syndromic surveillance from hospital emergency departments and urgent care centers. This list of data elements was published in the “Final Recommendation: Core Processes and EHR Requirements for Public Health Syndromic Surveillance” in January 2011. (https://www.syndromic.org/storage/ISDSRecommendation_FINAL.pdf)

Another workgroup was formed and identified data elements for inpatient, and ambulatory care. This list of data elements was published in the “Electronic Syndromic Surveillance Using Hospital Inpatient and Ambulatory Clinical Care Electronic Health Record Data” in November 2012. (http://www.syndromic.org/storage/ISDS_2012-MUse-Recommendations.pdf) (

Electronic health messaging guides were developed by CDC in consultation with representatives from many national and state public health organizations, standards development organizations, and vendors of electronic health record systems to provide technical guidance for syndromic surveillance message implementation. Representatives consulted included those from the Joint Public Health Informatics Taskforce (JPHIT), Public Health Data Standards Consortium (PHDSC), and the American Health Information Management Association (AHIMA). ISDS collected and compiled additional information from the syndromic surveillance community as a whole. . The most recent PHIN Guide for Syndromic surveillance, Version 2.0 (April 2015) covers emergency

department, urgent care, inpatient care, and ambulatory care (http://www.cdc.gov/nssp/documents/guides/syndrsurvmsgguide2_messagingguide_phn.pdf).

Based on the HHS Meaningful Use Initiative, this ICR includes a new request that the BioSense Platform be authorized to receive syndromic surveillance data from state and local health departments that are submitted to the health departments from urgent care, ambulatory care and inpatient settings. Previously, CDC received permission from OMB through the prior ICR clearance to only receive data from state and local health departments that were submitted by hospital emergency departments.

In addition, this ICR includes a new request for approval for CDC to receive additional data elements (indicated in bold in Attachment 5, Nssp Table of Healthcare Data Elements) from state and local health departments as identified in the ISDS workgroup recommendations described above. The health departments submitting these additional data elements will receive them from hospital emergency departments and inpatient settings as well as from ambulatory care and urgent care settings.

This ICR also includes a request for approval to use the non-substantive change request method in the future to request approval to receive additional syndromic surveillance data elements from state, local and territorial health departments if the list of data elements identified in the HHS Meaningful Use Initiative is expanded.

The document describing the CDC Surveillance Strategy (<http://www.cdc.gov/ophs/docs/cdc-surveillance-strategy-final.pdf>) was released in February 2014, and the BioSense Enhancement Initiative (BEI), was launched simultaneously. The BEI is building on successes of the past and making a number of improvements. These improvements include expanding the number of state and local health departments participating in the program; enhancing data sharing and data quality control capabilities; and improving tools for data analysis, visualization, and querying. In addition, CDC will enhance its support for the syndromic surveillance community of practice. Key members of the community include state and local health departments, CDC, DoD, the VA, and other organizations. As the CDC Surveillance Strategy was implemented, BioSense evolved into Nssp to better recognize the public health purpose of the program (syndromic surveillance) and to distinguish the program name from the web-based BioSense Platform.

Accordingly, on the basis of CDC Surveillance Strategy and the BioSense Enhancement Initiative, this ICR includes a request to change its title from BioSense to the National Syndromic Surveillance Program and a request to receive data from additional state, local, and territorial health departments.

2. Purpose and Use of the Information Collection

NSSP has three different types of information collection:

(1) data needed for recruitment of state, local, and territorial public health departments in order for them to submit healthcare data to the BioSense Platform (submitting recruitment data is approved in the previous ICR)

(2) data from users to allow them access to the BioSense Platform tools and services (submitting registration data is approved in the previous ICR)

(3) healthcare data received from:

a. state and local health departments, including electronic health record (EHR) data they obtain from

1. hospital emergency departments (approved in the previous ICR)

2. inpatient settings, urgent care, and ambulatory care (not previously approved)

b. a national private sector laboratory company, including laboratory tests ordered and their results (approved in the previous ICR)

Recruitment Data

CDC collaborates with ASTHO, the National Association of County and City Health Officials (NACCHO), the Council of State and Territorial Epidemiologists (CSTE), and ISDS to inform state and local public health departments about the opportunity to participate in NSSP. These efforts involve only outreach and information sharing; no survey or questionnaire is used. State and local public health departments approach CDC via a general email account and request an Information Sharing and Data Use Agreement with ASTHO in order to submit data to the BioSense Platform. First and last names, email addresses, organizational affiliations, and telephone numbers of individuals responding on behalf of their public health jurisdictions are collected for contact purposes only. The BioSense Platform is not used to collect or store this information. Once this agreement with ASTHO is signed, CDC provides contractor support (ICF International) to establish the ability of the health departments and their data sources, e.g., hospitals, to submit data to the BioSense Platform.

Registration Data

Through the one-time completion of a registration form on the BioSense Platform, state and local health department professionals become users with access to the Platform. Data elements collected on this form include first and last names, email addresses, title, affiliation, organization, security questions and passwords (**Attachment 4**). First and last names, email addresses, and passwords are excluded from the Paperwork Reduction Act (PRA) requirements per section 4 (Uses of the “like items” regulatory exclusion for social media and other Web-based technologies, a. User Accounts) of OMB/OIRA guidance dated September 5, 2014 (Web-based Interactive Technologies: Data Search Tools, Calculators, and the Paperwork Reduction Act). These data elements are used only to facilitate user approval and setting user data access privileges for the system. They are retained only for as long as the user chooses to keep an account. No other information in identifiable form is collected for this activity. This information is used primarily for granting access to the Web application and for setting user permissions. Additionally, this information in aggregate form might be used to establish application use statistics, such as the number of total users of the Platform or number of users of the Platform by state.

Healthcare Data

The primary sources of healthcare data submitted to NSSP’s BioSense Platform are state and local health departments. They receive data from inpatient and emergency departments, urgent care, and ambulatory care clinics. Healthcare data from these health departments are submitted to the jurisdictions’ secure data spaces on the BioSense Platform in one of 3 ways: 1) the health departments submit data from their jurisdiction-based electronic syndromic surveillance systems, 2) the health departments arrange to have health information exchanges or other data aggregators in their jurisdictions submit data, or 3) hospitals and clinics submit data. All data submission is through automated electronic systems, so once the systems are set up, no additional work on the part of the data submitters is required except for system maintenance.

New sources of data received from state, local and territorial health departments include data from urgent care, ambulatory care and inpatient settings. These sources of data were not included in the previous ICR which only included data from hospital emergency departments.

The healthcare data elements from the state and local health departments are described in **Attachment 5**. New data elements that were not in the previous ICR and that are based on the ISDS workgroup recommendations as noted above, are highlighted in bold.

All of the healthcare data reside outside of CDC in a computing-cloud enabled, Web-based platform that has Authorization to Operate from CDC and has been through CDC’s Certification & Accreditation (C&A) process (**Attachment 6**). The BioSense Platform sits in secure, Government Cloud servers operated by Amazon Web Services.

State and local health departments submit healthcare data to the BioSense Platform only after they have made arrangements to receive it from hospitals and clinics in their jurisdictions. Data submissions to CDC are made by means of an automated system. **The expansion of syndromic surveillance data elements noted in Attachment 5 and the inclusion of data from inpatient, urgent care and ambulatory care settings as provided for under the HHS Meaningful Use initiative require no additional activity by health department data administrators in order to share these new data with CDC.**

All jurisdictions are required to choose the data sharing permissions for each of their users by accessing a Web-based submenu of the BioSense Platform (**Attachment 7**). This submenu allows them to choose with whom to share data and at what level of aggregation. In addition to choosing data sharing preferences on this submenu, each health department is responsible for creating its own data use agreements with their data providers, retains ownership of all data it contributes to its exclusive secure space, and is not required to share its data with any other BioSense Platform user.

The BioSense Platform provides participating state and local health departments, CDC and other federal agencies with easily managed on-demand access to a shared pool of configurable computing resources. These include networks, servers, software, tools, storage, and services. These only need limited additional IT support. Each health department and federal agency controls its data within the cloud. It is provided with secure data storage space with tools for posting, receiving, controlling and analyzing its data. Also provided is an easy-to-use data display dashboard and a shared environment where users can collaborate and advance public health surveillance practice. Data residing within the shared space are aggregated into pre-defined syndromes and sub-syndromes. Time series are created that can be viewed on the Web application dashboard by approved users.

CDC and health professionals from state and local health departments, the VA and DoD use NSSP data to support the detection and characterization of public health events of potential concern, such as disease outbreaks or hazardous conditions. NSSP platform users use data analysis, visualization and querying tools to monitor the occurrence (e.g., number and proportion of hospital emergency department visits) of a selected set of syndromes (e.g., flu-like symptoms and opioid poisoning). For health event detection, statistical algorithms (e.g., Poisson regression) are used to alert users that there are increases in emergency department visits for a given syndrome during a certain period of time in a certain geographic area. The alerts may or may not indicate that a significant health event is occurring. Alerts are not used to draw conclusions about the actual occurrence of adverse events in that geographic area. Instead, public health officials use the alerts along with other

information available in the syndromic surveillance system and other sources to determine if a public health investigation should be undertaken. Monitoring is continued after alerts have occurred in order maintain an understanding of the potential event of concern (situational awareness). No conclusions are drawn about possible events in locations not covered by the system.

Additional use of the NSSP data involves improving techniques for data quality assessment and problem resolution, analytic data processes to support syndromic surveillance needs, and statistical algorithms for anomaly detection. As these various data analytic processes are improved and tested, they will be implemented into standardized methods for using NSSP data for outbreak event detection, characterization, and situation awareness at all levels of public health. By using these techniques and methods, CDC data analysts, in collaboration with partners, will monitor and report syndromic surveillance results. These reports will be provided to the CDC Emergency Operations Center, the VA and DoD, and state and local health departments. They also will be used to provide technical assistance to state and local health departments and CDC programs in best-practices use of NSSP data for event- or disease-specific public health investigations. CDC, in collaboration with partners, will develop and publish technical papers on the analytical processes and techniques that support syndromic surveillance efforts. In accordance with data use agreements with state and/or local health departments, CDC programs may publish event- or disease-specific reports that use NSSP data. CDC will make de-identified national-level aggregate data available to the public in published reports and on the CDC internet.

3. Use of Improved Information Technology and Burden Reduction

Recruitment Information Collection

Recruitment data are collected through email. State and local health departments spend minimal time and resources to participate in NSSP.

Registration Information Collection

An automated data collection form (**Attachment 4**) is used to provide access to the Web application and other tools and services on the BioSense Platform. This use of information technology reduces burden on prospective BioSense users and facilitates the most rapid processing of requests.

Healthcare Information Collection

To reduce burden, 100 percent of the data collection from state and local health departments, health information exchanges, or hospitals, clinics or providers in those jurisdictions and the national laboratory

company is conducted electronically. Data in various formats are sent to CDC using various electronic transport mechanisms. The data are automatically processed and made available to the end user for analysis. To participate in the shared space, a person who serves as the Administrator of the BioSense Platform at the public health jurisdiction must choose the sharing permissions for each of their users for the BioSense Platform (Attachment 7). Once a jurisdiction chooses to share, they access a submenu of the Platform. The submenu allows them to choose with whom to share data and at what level of aggregation. After this initial selection, the jurisdictions' data are accessible to whom they shared the data with. Each Administrator is responsible for maintaining the sharing permissions of their users including adding and removing users as necessary and modifying their sharing permissions as appropriate. This use of improved information technology reduces burden on BioSense Platform users sharing data with CDC.

4. Efforts to Identify Duplication and Use of Similar Information

Recruitment Information Collection

State and local health departments respond to communication outreach materials and can solicit information themselves on how to join. If they do choose to join, the NSSP technical team works to accommodate their specifications for data submission. There is no information other than contact information collected during this process; therefore, information must be collected directly from those interested in participating in NSSP (i.e., state and local health departments) and would not be available from another source.

Registration Information Collection

Regarding provision of access to the BioSense Platform that includes the Web application and other tools and services, the information must be collected directly from those applying for access and would not be available from another source.

Healthcare Information Collection

Though there are public health jurisdiction-level syndromic surveillance systems established in some areas of the country (e.g., statewide syndromic surveillance systems in North Carolina – NC DETECT (Disease Event Tracking and Epidemiologic Collection Tool), Ohio – EpiCenter, and New Hampshire – AHEDD (Automated Hospital Emergency Department Data), without the BioSense Platform, there would be no syndromic surveillance system that could combine non-federal hospital, VA, DoD, pharmacy and laboratory data to provide public health situation awareness at the regional and national level. This was the case when Congress mandated an integrated system(s) of surveillance networks in 2002, and it is still the case for NSSP today.

5. Impact on Small Businesses or Other Small Entities

This collection of recruitment, registration and healthcare information does not involve small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

Recruitment and registration for access to the BioSense Platform requires only a one-time collection of information. There are no recurring burdens on the user for these activities. There are no legal obstacles to reducing the burden.

Regarding healthcare information collection, public health jurisdictions are encouraged to contribute data to the shared space on a voluntary basis. As the system developed to answer Congress' mandate for a national, human health surveillance system designed to improve the nation's capabilities for disease detection, monitoring, and health situational awareness, and to provide public health near real-time access to existing information from healthcare encounters for just-in-time public health decision-making, NSSP requires daily feeds from its data sources.

To participate in the shared space, public health jurisdictions must choose their sharing permissions on the Web application for each of their users (**Attachment 7**). Jurisdictions have the right at any time to revise the level of sharing permissions regarding the data in their secure space. Choosing and maintaining data sharing permissions is not a one-time collection of information. After the Administrator chooses the initial data sharing permissions for each user, the Administrator has the ability to add, remove or change the data sharing permissions for each user. Removing the ability of the Administrator to manage their users' sharing permissions would interfere with data sharing.

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

Regarding recruitment and registration information collection, this request fully complies with the regulation 5 CFR 1320.5.

Healthcare data are received by CDC on at least a daily basis, because CDC must have access to electronic health information at this frequency in order to meet the congressional mandate outlined in A.1. Notably, however, the

collection of data requires only a one-time initial set-up by the sender; afterward, data are sent in an automatic, electronic transmission that involves no effort on the part of the sender. Other than this exception, the request fully complies with the regulation 5 CFR 1320.5.

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 February 25, 2015, vol. 80, No. 37, pp. 10096–10098 (**Attachment 2**). There were no public comments.

B.

In planning and developing NSSP, the BioSense Platform and collection and use of syndromic surveillance data, CDC has engaged with individuals and organizations outside of the agency in a variety of ways. The primary group with which CDC consults is an expert group of individuals from public health associations, including ASTHO and CSTE; federal agencies, including the VA and DoD; state and local public health departments; and healthcare. The names, affiliations, and contact information for that group are in **Attachment 7**. That group, including CDC, meets monthly to discuss issues related to availability, quality, security, sharing, use, and reporting of data. As a source of information on data elements for syndromic surveillance, CDC makes use of ISDS recommendations to the healthcare and public health communities through the meaningful use initiative on use of EHRs for syndromic surveillance (<http://www.syndromic.org/resources/meaningful-use/meaningful-use-resources>). CDC collaborates with ISDS to improve electronic data exchange specifications for syndromic surveillance data from EHRs. CDC also participates in monthly conference calls with the community of practice in addition to consulting with stakeholders at annual meetings of ISDS and CSTE.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift is provided to respondents who provide information during the recruitment of state and local public health departments, the registration of users for access to the BioSense Platform, or the provision of healthcare encounter, laboratory or pharmacy data to NSSP.

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

As concluded by the CDC Chief Privacy Officer in Office of the Chief Information Security Officer (OCISO), the Privacy Act applies; the Privacy Impact Assessment (PIA) is dated October 9, 2015 (**Attachment 9**). The System of Records Notice (SORN) is 09-20-0136, Epidemiologic Studies and Surveillance of Disease Problems. The data collected are in electronic format and are secured on a cloud-enabled, Web-based platform that is in compliance with the Federal Information Security Management Act (FISMA). The BioSense Platform has been through the C&A process performed by CDC security personnel (**Attachment 6**). All information collected for NSSP is treated in a secure manner and will not be disclosed, unless otherwise compelled by law.

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

Institutional review board (IRB) review and approval is not necessary for NSSP, because its surveillance activities are conducted solely to provide national public health situation awareness and are considered public health practice, not research (**Attachment 10**).

There are no questions of a sensitive nature asked in the collection of information for recruitment of jurisdictions that express interest in participating in NSSP, user access to the BioSense Platform or transmission of EHR data.

12. Estimates of Annualized Burden Hours and Costs

Recruitment Information Collection

CDC staff participating in recruitment estimate 1 hour per respondent. This encompasses the unstructured conversation between the contractor, ICF International, and the respondent where the contractor discusses the respondent's various options to connect to the BioSense Platform. Respondents include state, local, and territorial public health departments. The recruitment process and this estimate have not changed since the previously approved ICR. Currently, there are 41 state and 25 local public health departments that are participating and have signed the data use agreement with ASTHO. We request the ability to add up to 60 state, local and territorial public health departments over the next 3 years. Based on the history of the program, we don't anticipate that there will be more than 20 state, local, and territorial public health departments that request to participate per year.

Registration Information Collection

CDC personnel who have applied for access to the BioSense Platform (Registration) provided an estimate of 10/60 hours per respondent (**Attachment 4**). This is a one-time data collection. The registration process for state, local, and territorial public health departments has not changed since the previously approved ICR. **The burden estimate increased from 5 minutes to 10 minutes because of the new registration screen (Attachment 4). There are currently 601 and 194 registered state and local public health department users, respectively. We request the ability to register up to 600 state, local, and territorial health department users over the next 3 years. Based on the history of the program, most participating public health departments usually register at least 2 users but this varies. Recently, we have noticed that state health departments are registering multiple users at the state and at the county level. To accommodate this trend, we are requesting to be able to register up to 200 users each year. We would like each health department (up to 20 per year) to be able to register up to 10 users.**

Healthcare Information Collection: Administrator Data Sharing Permissions

State, local, and territorial public health departments using the BioSense Platform have the option to share health care data in the shared space on the BioSense Platform. This activity entails accessing a submenu of the Platform. The submenu allows respondents to choose with whom to share data and at what level of aggregation from a series of drop-down lists. **Based on their experience with NSSP, the current contractor, Deloitte Consulting LLP, estimated 40/60 hours per respondent.**

A.12-A. **Estimates of Annualized Burden Hours**

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden (in hours)
State, Local, and Territorial Public Health Departments	Recruitment Information Collection	20	1	1	20
State, Local, and Territorial Public Health Departments	Registration Information Collection	200	1	10/60	33
State, Local, and Territorial Public Health Departments	Healthcare Information Collection: Administrator Data Sharing Permissions	20	1	40/60	13
Total					66

According to the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment Statistics, May 2014 National Occupational Employment and Wage Estimates (http://www.bls.gov/oes/current/oes_nat.htm), the mean hourly wage for Computer and Mathematical Occupations is \$40.37. This rate is used as the hourly wage rate for respondents to the recruitment of state and local health departments because it represents the category of occupations most likely held by the respondents. For registration and data sharing agreements and permissions, 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 \$33.69.

A.12-B. Estimates of Annualized Cost Burden

Type of Respondents	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Respondent Costs
State, Local, and Territorial Public Health Departments	Recruitment Information Collection	20	1	1	20	\$40.37	\$807.40
Total							\$807.40
State, Local, and Territorial Public Health Departments	Registration Information Collection	200	1	10/60	33	\$33.69	\$1111.77
Total							\$1111.77
State, Local, and Territorial Public Health Departments	Healthcare Information Collection: Administrator Data Sharing Permissions	20	1	40/60	13	\$33.69	\$437.97
Total							\$437.97
Overall Total							\$2357.14

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

There are no costs to respondents other than their time.

14. Annualized Cost to the Federal Government

The total cost covered by the maximum 3-year term for OMB clearance will be \$53.2M. The annualized cost of \$17.7M shown below was estimated by including the known contract costs for FY 2015-2017, the projected value of cooperative agreements for the same time period, and projected salaries and benefits.

A.14-A. Estimates of Annualized Cost Burden

Recruitment Information Collection	Cost per year
Contracts/ Cooperative Agreements	\$3.8M
Project Officer (FTE)	\$70,500
Registration Information Collection	
Contracts	\$2.9M
Project Officer (FTE)	\$70,500
Healthcare Information Collection	
Cooperative Agreement	\$8.6M
FTE Salaries and Benefits	\$2.3M
Total Annualized Cost	\$17.7

15. Explanation for Program Changes or Adjustments

There are no changes in the collection of information needed for recruitment of public health departments, to provide access to the BioSense Platform (registration). Registration is a one-time data collection that is only needed for new registrants. All previous registrants do not need to register again.

The request to include data elements from urgent care, ambulatory care and inpatient settings in the data that are sent to CDC by state and local public health jurisdictions participating in NSSP and the request to include

additional syndromic surveillance data elements recommended for the Meaningful Use Initiative will not increase the burden. This is because state and local health jurisdictions choose whether or not they want to send urgent care, ambulatory care and inpatient data (see additional data elements in bold on **Attachment 5**) to CDC if they do in fact receive these data. These data are sent electronically to CDC at the same time that the state and local public health jurisdictions send emergency department data (already approved in the previous ICR) to CDC. CDC does not recruit hospitals, urgent care or ambulatory care entities to participate in NSSP nor does CDC register any individuals from these entities to access NSSP data. As in the previously approved ICR, CDC recruits state, local, and territorial public health jurisdictions to participate in NSSP. It is up to each public health department to recruit hospitals, urgent care or ambulatory care entities in their jurisdictions to submit syndromic surveillance data to that particular public health department or to the BioSense Platform. The participating public health departments that participate in NSSP then send their data to CDC.

As stated earlier, the burden increased because of the new screens for the registration data collection and the additional data collection for data sharing permissions which is no longer a one-time data collection. In addition, we did not include burden estimates for DoD, VA, and the 3 private sector organizations that provide the pharmacy data in this ICR are already registered and their corresponding burden incorporated in the previously approved ICR.

16. Plans for Tabulation and Publication and Project Time Schedule

New jurisdictions have the potential to begin participating in NSSP and user accounts have the potential to be granted throughout the duration of the three-year authorization requested. Currently, there are 66 (41 state and 25 local) public health departments participating and the goal is to have 60 new public health departments participating in NSSP by 2018. Recruitment, outreach, and registration information is not reported or published.

CDC and health professionals from state, local, and territorial health departments, the VA and DoD and the community of practice will use NSSP data in support of public health event detection and characterization at the national, state, and local level. The primary use involves developing techniques for data quality assessment and problem resolution, developing analytic data processes to support syndromic surveillance needs, and developing statistical algorithms for anomaly detection. As these various data analytic processes are developed and tested, they will be implemented into standardized methods for utilizing NSSP data to support outbreak event detection, characterization, and situation awareness at all levels of public health. Utilizing these techniques and methods, CDC data analysts, in collaboration with partners, will perform monitoring and reporting of syndromic surveillance results to the CDC Emergency Operations Center, the VA and DoD, and to state and local health

departments, and provide technical assistance to state and local health departments and CDC programs in the utilization of NSSP data for event- or disease-specific public health investigations. CDC will publish technical papers on the analytical processes and techniques that support syndromic surveillance efforts, and in accordance with Data Use Agreements with the state, local and/or territorial health departments, CDC programs may publish event- or disease-specific reports that utilize NSSP data.

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

There is no data collection instrument used for collecting recruitment information. Regarding registration, and data sharing permissions, the OMB control number and expiration date are displayed on the appropriate data collection screens(Attachments 4 and 7).

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.