Assessment of the STLT Health Department Data Submission Processes into BioSense 2.0

OSTLTS Generic Information Collection Request
OMB No. 0920-0879

Supporting Statement – Section A

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Section A – Justification

1. Circumstances Making the Collection of Information Necessary

Background

This information collection is being conducted by the CDC's Office for State, Tribal, Local and Territorial Support (OSTLTS) using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. The respondent universe for this data collection aligns with that of the OSC. Data will be collected from officials in state, tribal, local, and territorial (STLT) health departments acting in their official capacities.

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 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 Security and Bioterrorism Preparedness Act of 2002 **(Attachment A)**, Pandemic and All-Hazards Preparedness Act (PAHPA) of 2006, Public Law No. 109-417 **(Attachment B)**, and Pandemic and All Hazards Preparedness Reauthorization Act of 2013 **(Attachment C)** authorizing this activity are included with this application.

BioSense is a national-level, electronic, human health surveillance system designed to improve the nation's capabilities for disease detection, monitoring, and health situation awareness through timely access to existing healthcare encounter information from emergency departments for just-in-time public health decision-making.

The BioSense program currently has an OMB-approved information collection (OMB Control Number 0920-0824), the purpose of which differs substantively from this request and is three-fold: 1) to gather information needed for recruiting STLT health departments for BioSense 2.0; 2) to gather information to allow access to appropriate users of the new system; and 3) to collect already existing healthcare encounter data. That OMB information collection did not authorize the collection of BioSense 2.0 assessment data. It only collected information on the utility of syndromic surveillance data within select health departments and for select diseases or conditions. This specific information collection's purpose is to allow examination of the internal processes associated with data transmission into the BioSense 2.0 system.

The first version of BioSense envisioned a national picture of syndromic surveillance through the direct collection of healthcare data, transmitted from facilities to an internal CDC server database. However, even with these feeds, the program was only ever able to achieve approximately 10% coverage of the United States' population, and state and local public health departments were bypassed in this model.

Over time, the BioSense 1.0 model proved unsustainable and unpopular with the STLT jurisdiction stakeholders, who had little insight into the CDC server database. In 2010, the BioSense Program began transitioning from the original BioSense 1.0 to the new BioSense 2.0. The system has been redesigned by CDC to meet the needs expressed by STLT health departments that BioSense 1.0 could not meet and uses cloud computing technology in accordance with the White House Federal Cloud Computing Strategy **(Attachment D)**.

Initially intended to serve as a tool for early detection and rapid assessment of potential bioterrorism-related illness, the BioSense Program has since expanded its role to detecting changes over time in predefined syndromes and sub-syndromes of public health importance (ex., injury, chronic disease, and influenza) and providing timely, all-hazard, national public health situational awareness throughout the course of public health emergencies (ex., 2009 H1N1).

BioSense 2.0 was launched in 2012, and subsequently, the program's priority was to increase STLT health departments' participation in the new system. Use of the cloud allows emergency department data from participating health departments to be sent in varying formats, providing more flexibility in how the data is transmitted. As recently as 2011, only eight jurisdictions had "joined" BioSense 2.0 (i.e., agreeing to provide their data feeds to the system). As a result of the redesign, 49 STLT health departments have signed a Data Use Agreement (DUA) as of August 23, 2013 **(Attachments E and F)**. At present, the BioSense program's primary focus is enabling the STLT health departments with a Data Use Agreement (DUA) to transmit their emergency department data into the new system.

This assessment aligns with recommendations from multiple Government Accountability Office (GAO) reports that specify that CDC ensure that the BioSense 2.0 meets the needs of STLT health agencies **(Attachments G and H)**. RTI International, a CDC contractor, will conduct the information collection which encompasses focus groups with STLT health officials involved in the onboarding process, including epidemiologists and the information technology staff.

The information collection will allow examination of the "onboarding" process, defined as the technical process that enables data transmission from a given STLT jurisdiction into BioSense 2.0, and the costs associated with this process. In order to begin the onboarding process, STLT jurisdictions must first sign a DUA to participate in BioSense 2.0 **(Attachment F)**. After the DUA has been signed, a contractor working for CDC on BioSense 2.0 will contact the STLT jurisdiction point of contact designated in their DUA, and explain the variety of technical options available to them for data message type and transmission type. Once those options are selected, the contractor will perform necessary steps to set up the chosen transmission type, run a test message, and then work out any bugs. Once all issues are mitigated, the transmission will go into production, and onboarding has been "completed" for that feed. STLT jurisdictions can have multiple feeds depending on the existing technical and business process infrastructure of the health department. BioSense 2.0 accepts many different types of infrastructure models, so the system flexes to work with the STLT jurisdiction. Diagrams of the data flow for both versions of BioSense 1.0 and 2.0 are included as **Attachment I**. The knowledge gained will be used to refine processes for those STLT health departments that have yet to submit their emergency department data into BioSense 2.0. In addition, this information collection will document the actual costs of onboarding and provide insight for where costs may be contained. The report audience is STLT health departments, CDC, the BioSense Governance Council[i], and other federal and regional stakeholders.

The data required for the assessment do not exist in any form that would make information collection unnecessary. The redesign of BioSense is a first of its kind endeavor due to the technology involved (i.e. cloud computing environment, electronic health record data submission, federal, state, and local shared utility, etc.), therefore there is no precedent for the collection of this type of information. Since prior onboarding in BioSense 1.0 only included emergency department facilities and CDC, this assessment of BioSense 2.0 is addressing a completely different onboarding process and associated set of stakeholders. Experience with preparing for and the actual submission of emergency department data by a STLT health department into BioSense 2.0 is required. No surrogate data exist that can approximate that experience. Only those questions minimally sufficient to complete the assessment will be included in the information collection. Participation by STLT health departments in this information collection request is voluntary.

This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241).

Privacy Impact Assessment

Overview of the Data Collection System

At this point in BioSense 2.0 system's lifecycle, it is of utmost importance to understand the STLT health departments' experiences as they work with health information technology staff to submit data feeds into the new system, especially since the system is based on cloud computing technology which is new for many STLT health departments. At this stage of development of BioSense 2.0, we must rely on currently participating jurisdictions to give us feedback on the experiences they have had on onboarding and the associated costs through focus groups. As such, two data collection instruments related to this are proposed **(Attachments J and K)**:

1. **Onboarding Process:** To identify the common and systematic barriers and challenges encountered during the onboarding process and develop a set of solutions and best practices to address them through technical assistance activities and resources. This instrument will explore each phase of the process (e.g., introduction to the system and process in general, the technical meeting to understand the jurisdiction's requirements, implementation of the technology, maintenance of data feeds in the new system, etc.).

2. **Cost Analysis:** To develop BioSense 2.0 cost estimates, including identifying key factors affecting the costs incurred during and after the onboarding process, and to review the related benefits. Emphasis will be placed on accurately estimating the costs of participation in the BioSense 2.0 community—labor, capital, and services spending—including adoption costs and ongoing costs Although the focus will be on costs, benefits will also be studied such as estimating the difference in the costs to comply with Meaningful Use Stage 2 with and without BioSense 2.0. Other perceived benefits of BioSense 2.0 will be assessed qualitatively.

Items of Information to be Collected

Questions fall into the following domains: onboarding, use and utility, technical implementation, syndromic surveillance, and resources. The interviewers will first describe the purpose of the focus groups which is to achieve the following: 1) gain better understanding of the onboarding experience; 2) use the information to improve the onboarding experience; and 3) share what is learned with the BioSense community and CDC. The terms for the interview will be defined. Questions will be asked on experience with syndromic surveillance, experience with BioSense 2.0, adoption and ongoing costs of syndromic surveillance, and adoption and ongoing costs of BioSense 2.0. Case study participants will be advised that results will be aggregated for the final analysis.

Part 1 (onboarding) only contains 53 questions for STLT health officials to address. Officials are asked questions related to the following areas: 1) the initial contact between the jurisdiction and the onboarding team; 2) the overview call with their onboarding coordinator; 3) technical meetings that followed the orientation call; 4) technical implementation activities; 5) testing phase of onboarding; and 6) maintenance. Information for the onboarding case study will be collected from a health department's Chief Epidemiologists and onboarding teams. Focus groups will include additional verified state health department staff. Emphasis will be placed on examining the technical, data sharing, data quality, and training issues that facilitate or impede onboarding efforts. Information collection will occur during a half day site visit to each STLT health department or during a telephone interview if a site visit cannot be arranged within the timeframe for the data collection.

Part 2 (cost) only contains 26 questions related to following areas: 1) the jurisdiction's experience with syndromic surveillance; 2) budget and resources for their syndromic surveillance efforts; 3) BioSense 2.0 specific labor and capital; and 4) their overall experience with BioSense 2.0. Information for the cost case study will be collected from STLT Chief Epidemiologists and onboarding team members. Emphasis will be placed on accurately estimating the costs of participation in the BioSense 2.0 community—labor, capital, and services spending—including adoption costs and ongoing costs. Data collection will include a short Excel spreadsheet with information that the STLT health official will be asked to confirm as a part of the half day site visit to conduct focus groups with key informants.

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

The data collection system does not involve the use of a web-based survey.

2. Purpose and Use of the Information Collection

The information collection will support a process and cost assessment that will be used to assess progress towards and refine processes for on-boarding public health jurisdictions to BioSense 2.0, and improve participation in BioSense overall. BioSense has been redesigned to meet needs expressed by STLT health departments. The process and cost assessment aligns with recommendations from multiple GAO reports that specify that CDC ensure that the BioSense 2.0 meets the needs of STLT health departments **(Attachments G and H)**.

The purpose of Part 1 (onboarding) is to identify the common and systematic barriers and challenges encountered during the BioSense 2.0 onboarding process and develop a

set of solutions and best practices to address them through technical assistance activities and resources. The goals are to 1) provide input on the technical assistance needs and areas for improvement; 2) provide input into technical assistance planning and material development; 3) develop best practices/ standard operating procedures for onboarding barriers/challenges; and 4) help other STLT health departments prepare for BioSense 2.0 onboarding. The results will present a set of specific recommendations from STLT health departments currently using BioSense 2.0 that CDC will act upon to enhance the onboarding experience for STLT health departments. The assessment will document best practices and standard operating procedures to support technical assistance. In addition, the findings of the onboarding case study will be used to develop technical assistance materials (e.g. tip sheets, webinars, readiness tools) and resources.

The purpose of Part 2 (cost) is to document the costs of onboarding for STLT health departments. The costs for jurisdictions will be analyzed, including identifying key factors affecting the costs incurred during and after onboarding. The key goals of this cost case study are to: 1.) develop costs estimates which will be used to ensure that BioSense 2.0 is meeting the cost utility goals set for the system by STLT health departments; 2.) facilitate jurisdictions' BioSense 2.0 adoption planning; and 3.) assess the feasibility of systematically collecting cost data from jurisdictions in the future. The assessment will present quantitative estimates of the adoption costs and ongoing costs and qualitative assessments of the perceived benefits for each jurisdiction. It will also provide a recommendation of whether data on the costs of participation in BioSense 2.0 should and can be collected, calculated, and reported moving forward.

The assessment will be used to refine the participation and onboarding processes for future STLT health departments, document the actual costs of onboarding, and provide insight for where costs may be contained for future onboarding efforts. The report audience is STLT health departments, CDC, the BioSense Governance Council, and federal and regional stakeholders.

Privacy Impact Assessment

During the scheduling of the data collection visits, RTI international will potentially have information about the names of the individuals participating at the STLT health department in order to facilitate the visit agenda. These emails and agendas associated with the logistics of the data collection will be stored on a secure, password protected shared drive accessible only to RTI International project staff.

For purposes of gathering and organizing the interview responses, participants will be referenced by a number, e.g. "participant 1, 2, and 3, etc." during the focus groups . There will be no personally identifiable information collected.

The focus groups will be recorded. Recordings will be destroyed after qualitative analysis of information contained therein and the final report has been completed. A consent form will be used which indicates the STLT health department's agreement to participate in the information collection.Information will be presented in the aggregate, although direct quotes may be used to emphasize specific points.

RTI International will maintain electronic documents on a secure, password protected shared drive accessible only to project staff. Collected information will not be shared with any parties outside of the assessment team, including with CDC.

3. Use of Improved Information Technology and Burden Reduction

All information will be shared with respondents in advance. Due to the number and nature of questions in the data collection tool, it will reduce the time needed if completed via a 90 minute key informant focus group. This method was chosen to reduce the overall burden on respondents. The data collection tool was designed to collect the minimum information necessary for the purposes of this project (i.e., limited to 26 to 39 survey questions per individual STLT health official. Conducting a web-based survey is not an option because a pre-identified set of responses for this area is not available. These focus groups will be a mechanism to arrive at such a set if future data collections are conducted. Additionally, responses will be context-specific for each jurisdiction, therefore a comprehensive set of responses is not feasible.

4. Efforts to Identify Duplication and Use of Similar Information

The BioSense redesign is the first of its kind endeavor due to the technology involved, therefore there is no precedent for the collection of this type of information. The data required for this assessment do not exist in any form that could make information collection unnecessary. Due to the differences between onboarding and participation process in BioSense 1.0 and 2.0, there has never been an assessment of this process with this set of stakeholders. BioSense 2.0 onboarding experience is required and no surrogate data exist that could approximate that experience. Only those questions minimally sufficient to complete the assessment will be included in the information collection.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this data collection.

6. Consequences of Collecting the Information Less Frequently

- If these assessments are not completed then CDC will be unable to identify possible common and systematic barriers and challenges encountered during the BioSense 2.0 onboarding process, and to participation in the new system in general.
- The inability to identify possible common and systematic barriers and challenges would impede the development of a set of solutions and best practices to address them through technical assistance activities and resources.
- Inability to collect this information will limit CDC's ability to optimize the efficiency and quality of the onboarding process, and to identify where costs may be contained for future onboarding efforts.

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

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5 and will be voluntary.

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

This data collection is being conducted using the Generic Information Collection mechanism of the OSTLTS Survey Center (OSC) – OMB No. 0920-0879. A 60-day Federal Register Notice was published in the Federal Register on October 22, 2010, Vol. 75, No. 204; pp. 65353-54. Two comments were received from the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO).

CDC partners with professional STLT organizations, such as the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) along with the National Center for Health Statistics (NCHS) to ensure that the collection requests under individual ICs are not in conflict with collections they have or will have in the field within the same timeframe.

9. Explanation of Any Payment or Gift to Respondents

CDC will not provide payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

The Privacy Act does not apply to this data collection. Employees of STLT health departments will be speaking from their official roles and will not be asked, nor

will they provide, personally identifiable information. This data collection is not research involving human subjects.

11. Justification for Sensitive Questions

No information will be collected that are of personal or sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

The estimate for burden hours is based on the pilot test of the data collection instrument by eight STLT health officials at the Kansas Department of Health and Environment (KDHE). During pretesting, the average time to complete the survey including time for reviewing instructions, gathering needed information and completing the survey, was approximately 90 minutes.

Seven BioSense participant STLT health departments are anticipated to participate, with no more than eight individual health officials from each STLT health department representing the Chief Epidemiologist and the department's IT Onboarding team perspectives. Comprehensively, a maximum of 56 STLT health officials are expected to participate.

Based on these results, the estimated time for all respondents to complete the survey is 85 hours. Estimates for the average hourly wage for respondents are based on the Department of Labor (DOL) National Compensation Survey estimate for management occupations – medical and health services managers in state government for the Chief Epidemiologist Team (http://www.bls.gov/ncs/ocs/sp/nctb1349.pdf). The wage rates for the Onboarding Team are from the computer and information system management position.

Table A-12: Estimated Annualized Burden Hours and Costs to Respondents

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
STLT Epidemiologist	7	1	1.5	11	$57.11	$628.21
STLT BioSense Information Technology Staff	49	1	1.5	74	$40.38	$2,988.12

TOTALS	**56**	**1**		**85**		$3,616.33

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

There will be no direct costs to the respondents other than their time to participate in each survey.

14. Annualized Cost to the Government

There are no equipment or overhead costs. RTI International will support this data collection as part of their regular duties. The only cost to the federal government would be the salary of CDC staff and internal contractor monitoring and supporting the data collection activities.

The data collection tool will be prepared by CDC staff (FTE) and contractors. An FTE manager will review the data collection tool. A senior level FTE will review and approve the activities. The estimated cost to the federal government for the entire data collection period is $70,342.56. Table A-14 describes how this cost estimate was calculated.

Table A-14: Estimated Annualized Cost to the Federal Government

Staff (FTE)	Average Hours per Collection	Average Hourly Rate	Average Cost
Public Health Analyst (GS-14) Lead on review and development of OMB package preparation, data collection, quality control, data analysis, report preparation	6/month, May – January (9 months) = 54 hours	$53.25	$2,875.50
RTI International Contractor OMB package preparation, data collection, data coding and entry, quality control, data analysis, report preparation	40/month, May-January (9 months) = 540 hours	$120	$64,800.00
McKing Consulting - Policy Analyst Support for OMB package preparation, data collection, data coding and entry, quality control, data analysis, report preparation	6/month, May – January (9 months) = 54 hours	$49.39	$2,667.06
Estimated Total Cost of Information Collection			**$70,342.56**

15. Explanation for Program Changes or Adjustments

This is a new data collection.

16. Plans for Tabulation and Publication and Project Time Schedule

The results of the data collection are 1) 2–4-page Onboarding Assessment Briefs, 3) 4–6-page Cost Assessment Brief and 4) A 15–20-page Onboarding and Cost Case Study Report.

Project Time Schedule

Description	**Due Date**
Pilot Site Focus groups	July 2013
Focus group Site Selection	+2 weeks post GenIC approval
Focus group Visits	+1 to +2 months post GenIC approval
Draft Focus group Briefs	+3 to +4 months post GenIC approval
Final Focus group Briefs	+5 months post GenIC approval
Draft Comprehensive Report	+3 months post GenIC approval
Final Comprehensive Report	+4 months post GenIC approval

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

We are requesting no exemption.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification. These activities comply with the requirements in 5 CFR 1320.9.

LIST OF ATTACHMENTS – Section A
Note: Attachments are included as separate files as instructed.

Attachment A: Public Health Security and Bioterrorism Preparedness Act of 2002

Attachment B: Pandemic and All-Hazards Preparedness Act of 2006

Attachment C: Pandemic and All-Hazards Preparedness Reauthorization Act of 2013

Attachment D: White House Federal Cloud Computing Strategy

Attachment E: Data Use Agreement Participation Map

Attachment F: Template BioSense Data Use Agreement

Attachment G: (GAO-05-308) Federal Agencies Face Challenges in Implementing Initiatives to Improve Public Health Infrastructure

Attachment H: (GAO-09-100) More Detailed Plans Needed for the Centers for Disease Control and Prevention's Redesigned BioSense Program

Attachment I: Data Flow Diagram for BioSense 1.0 and BioSense 2.0

Attachment J: Information collection instrument for Part 1

Attachment K: Information collection instrument for Part 2

[i] *The BioSense Governance Council is made up of participant elected state and local health jurisdiction representatives and representatives from involved organizations: CDC, Department of Defense, Department of Veterans Affairs, Association of State and Territorial Health Officials, Council of State and Territorial Epidemiologists, National Association of City and County Health Officials, and the International Society of Disease Surveillance.*