BILLING CODE: 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-19-0824; Docket No. CDC-2019-0024]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled the National Syndromic Surveillance Program (NSSP). The NSSP promotes and advances development of a syndromic surveillance system for the timely exchange of syndromic data.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2019-0024 by any of the following methods:

- Federal eRulemaking Portal: Regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to Regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Leroy A. Richardson, Information Collection Review Office, Centers for Disease

Control and Prevention, 1600 Clifton Road, N.E., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. 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 submissions of responses.
5. Assess information collection costs.

Proposed Project

National Syndromic Surveillance Program – Revision – Center for Surveillance, Epidemiology and Laboratory Services (CSELS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Syndromic surveillance uses syndromic data and statistical tools to detect, monitor, and characterize unusual activity for further public health investigation or response. Syndromic data include electronic extracts of electronic health records (EHRs) from patient encounter data from emergency departments, urgent

care, ambulatory care, and inpatient healthcare settings, as well as pharmacy and laboratory data. Though these data are being captured for different purposes, they are monitored in near real-time as potential indicators of an event, a disease, or an outbreak of public health significance. On the national level, these data are used to improve nationwide situational awareness and enhance responsiveness to hazardous events and disease outbreaks to protect America's health, safety, and security.

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 BioSense Program has since been expanded into the National Syndromic Surveillance Program (NSSP) which promotes and advances development of a syndromic surveillance system for the timely exchange of syndromic data.

CDC requests a three-year approval for a Revision for NSSP (OMB Control No. 0920-0824, Expiration Date 5/31/2019). This Revision includes a new request for approval to receive onboarding data from state, local and territorial public health departments about healthcare facilities in their jurisdiction.

NSSP features the BioSense Platform and a collaborative Community of Practice. The BioSense Platform is a secure integrated electronic health information system that CDC

provides, primarily for use by state, local and territorial public health departments. It includes standardized analytic tools and processes that enable users to rapidly collect, evaluate, share, and store syndromic surveillance data. NSSP promotes a Community of Practice in which participants collaborate to advance the science and practice of syndromic surveillance. Health departments use the BioSense Platform to receive healthcare data from facilities in their jurisdiction, conduct syndromic surveillance, and share the data with other jurisdictions and CDC.

The BioSense Platform provides the ability to analyze healthcare encounter data from EHRs, as well as laboratory data. All EHR and laboratory data reside outside of CDC in a cloud-enabled, web-based platform that has Authorization to Operate from CDC. The BioSense Platform sits in the secure, private Government Cloud which is simply used as a storage and processing mechanism, as opposed to on-site servers at CDC. This environment provides users with easily managed on-demand access to a shared pool of configurable computing resources such as networks, servers, software, tools, storage, and services, with limited need for additional IT support. Each site (i.e., state or local public health department) controls its data within the cloud and is provided with free secure data storage space with tools for posting, receiving, controlling and analyzing their

data; an easy-to-use data display dashboard; and a shared environment where users can collaborate and advance public health surveillance practice. Each site is responsible for creating its own data use agreements with the facilities that are sending the data, retains ownership of any data it contributes to its exclusive secure space, and can share data with CDC or users from other sites.

NSSP has three different types of information collection:

(1) Collection of onboarding data about healthcare facilities needed for state, local, and territorial public health departments to submit EHR data to the BioSense Platform;

(2) Collection of registration data needed to allow users access to the BioSense Platform tools and services; and

(3) Collection of data sharing permissions so that state and local health departments can share data with other state and local health departments and CDC.

Healthcare data shared with CDC can include: EHR data received by state and local public health departments from facilities, including hospital emergency departments and inpatient settings, urgent care, and ambulatory care; laboratory tests ordered and their results from LabCorp, a national private sector laboratory company; and EHR data from the Department of Defense (DoD) and the Department of Health and Human Services

(HHS) National Disaster Medical System (NDMS) Disaster Medical Assistance Teams (DMATs).

Respondents include state, local, and territorial public health departments. There are no costs to respondents other than their time to participate. The only burden incurred by the health departments are for submitting onboarding data about facilities to CDC, submitting registration data about users to CDC, and setting up data sharing permissions with CDC. The estimated annual burden is 195 hours.

Estimated 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	Onboarding	10	100	10/60	167
State, Local, and Territorial Public Health Departments	Registration	10	15	10/60	25
State, Local, and Territorial Public Health Departments	Data Sharing Permissions	10	1	15/60	3
Total					195

Jeffrey M. Zirger,

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