Approved: July 19, 2022.

Emory Rounds,

Director, Office of Government Ethics.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-22-0824]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "National Syndromic Surveillance Program (NSSP)" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on May 6, 2022, to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected:
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and

instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/ do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Syndromic Surveillance Program (NSSP)(OMB Control No. 0920– 0824, Exp. 7/31/2022)—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 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.

CDČ requests a three-year approval for a Revision for NSSP (OMB Control No. 0920–0824, Exp. 7/31/2022). This Revision includes a request for approval to continue to receive onboarding data from state, local and territorial public health departments about healthcare facilities in their jurisdiction; registration data needed to allow users access to the BioSense Platform tools and services; and data sharing permissions so that state, local and territorial health departments can share data with other state, local and territorial health departments and CDC.

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 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 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, local, and territorial health departments can share data with other state, local, and territorial 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; mortality data from state and local vital statistics offices; laboratory tests ordered and their results from 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. 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 671 hours. There are no costs to respondents other than their time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
State, Local, and Territorial Public Health Departments	Registration	20	100	10/60
State, Local, and Territorial Public Health Departments		20	100	10/60
State, Local, and Territorial Public Health Departments		20	1	15/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-22-22CL]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Populationbased Surveillance of Outcomes, Needs, and Well-being of Children and Adolescents with Congenital Heart Defects to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations' notice on February 14, 2022 to obtain comments from the public and affected agencies. CDC received five comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary

for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Enhance the quality, utility, and clarity of the information to be collected;
- (d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and
- (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/ do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Population-based Surveillance of Outcomes, Needs, and Well-being of Children and Adolescents with Congenital Heart Defects—New— National Center on Birth Defects and Developmental Disabilities (NCBDDD), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Congenital heart defects (CHD) are the most common type of structural birth defects, affecting approximately one in 110 live-born children. Due to advances in survival, there are approximately one million children with CHD in the United States. With vast declines in mortality from pediatric heart disease over the past 30 years, it is vital to evaluate health, social, educational, and quality of life outcomes beyond infancy and early childhood. However, existing U.S. population-based data are lacking on these outcomes among those born with CHD and the changes that may occur with time and age. U.S. data is needed to provide insight into the public health questions that remain for this population and to develop services and allocate resources to improve longterm health and well-being.

For this project, we will use data from U.S. birth defect surveillance systems, or population-based studies derived from them, to identify a population-based sample of children and adolescents two to 17 years of age born with CHD. Parents and caregivers of these individuals will serve as respondents for the CHSTRONG-KIDS survey. The CHSTRONG-KIDS survey will be administered at three sites. One site will be Atlanta, Georgia, where CDC