20852, 301–796–8867, *PRAStaff@ fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork

Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet

at *https://www.reginfo.gov/public/do/ PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control No.	Date approval expires
Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002	0910–0520	9/30/2026
Voluntary Qualified Importer Program	0910–0840	9/30/2026
Radioactive Drug Research Committees	0910–0053	9/30/2026
Animal Drug and Animal Generic Drug User Fee Submissions	0910–0540	9/30/2026
Food Labeling Requirements	0910–0381	9/30/2026
Investigational New Drug Application Requirements	0910–0014	9/30/2026

Dated: October 13, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–23002 Filed 10–17–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Strategic Preparedness and Response

Request for Information (RFI): HHS Initiative To Enhance National All Hazards Hospital Situational Awareness

AGENCY: Administration for Strategic Preparedness and Response (ASPR), HHS.

ACTION: Notice of request for information.

SUMMARY: The Administration for Strategic Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), and the Office of the National Coordinator for Health Information Technology (ONC) are seeking broad public input from entities across the health care readiness community on a national, all-hazards standardized set of essential elements of information (EEIs) and vendor-neutral data collection mechanisms for hospital data that drive action for emergency preparedness and response. This input will inform efforts to provide recommendations for a standardized lens into the readiness of, stress on, and resources available in hospitals before, during, and after emergencies

DATES: To be assured consideration, comments on the RFI must be received on or before December 18, 2023. HHS

will not reply individually to responders but will consider all comments submitted by the deadline.

ADDRESSES: Please submit all responses via email to *AllHazards@hhs.gov* within 60 days of publication of this notice as a Word document attachment or in the body of an email. Include ''All Hazards Hospital Situational Awareness RFI'' in the subject line of the email.

FOR FURTHER INFORMATION CONTACT: For additional information, direct questions to Sayeedha Uddin at (202) 699–1874 or *Sayeedha.Uddin@hhs.gov.*

When submitting comments or requesting information, please include ''All Hazards Hospital Situational Awareness RFI'' in the subject line of the email.

When submitting comments or requesting information, please include ''All Hazards Hospital Situational Awareness RFI'' in the subject line of the email.

SUPPLEMENTARY INFORMATION: Respondents may provide information for one or more of the questions or topic areas listed below, as desired.

Outside of the federal COVID–19 hospital data collection, what essential elements of information does your entity report or collect (or plan to report/collect in the future) related to health care capacity, facility status, stress, supplies, staffing, infrastructure, and/or other information that is needed to inform hospital emergency preparedness and response?

What information do you collect internally, including key areas your leadership monitors for preparedness and response purposes?

What information do you report to other entities, and to whom? Specifically, consider regular reporting that is required by regulatory agencies,

notifiable disease reporting, payors, as well as time-limited or voluntary reporting efforts to trade groups and professional associations.

On what cadence does your entity collect and report these essential elements of information?

How is information used for driving action in areas such as patient placement, patient movement, load balancing, equipment/supply procurement, or other preparedness and response areas? If you are a reporting entity (ex. hospital), do you know how your data is being used to create value for your community?

What electronic systems are used to collect the essential elements of information (*e.g.,* electronic health record systems (EHRs), hospital operations systems, etc.)? Who are the primary vendors/developers?

What is your expectation for federal government situational awareness of hospital status, capacity, stress, etc. before, during, and after a crisis?

Please share any potentially relevant clinical and/or situational awareness measures, efforts, and/or definitions that might be helpful to inform this effort (ex. National Emergency Department Overcrowding Scale (NEDOCS) scores, International Organization for Standards (ISO) Health informatics— Interoperability of public health emergency preparedness and response information systems, the Situational Awareness Network for Emergencies (SANER) Project, etc.).

We are interested in promising practices in specific areas:

Decreasing burden is a core goal of this initiative. Please share any promising practices related to data automation and/or other ways to reduce burden of data collection and reporting.

We recognize data often are sourced from multiple systems. Please share any promising practices in aggregating and assessing data from multiple source systems in a cohesive and standard way.

During response incidents, immediate patient care needs, power outages, and competing priorities can be significant challenges in maintaining shared situational awareness. Please share any promising practices for continued reporting during incidents.

We recognize that some healthcare partners have more advanced data and situational awareness programs while others may have minimal resources. Please share any promising practices for effectively leveraging minimal resources.

Please share any ongoing or anticipated challenges with reporting or collecting data related to hospital capacity, facility status, hospital stress, supply inventory, or other information that is needed to inform hospital emergency preparedness and response.

Please share any non-financial resources that would be useful to improve your reporting capability.

Title: Request for Information on All-Hazards Hospital Data.

Abstract: The Administration for Strategic Preparedness and Response (ASPR), Centers for Disease Control and Prevention (CDC), Centers for Medicare & Medicaid Services (CMS), and the Office of the National Coordinator for Health Information Technology (ONC) are co-leading an effort to define the vendor-agnostic technical and policy infrastructure, standards, and capabilities necessary to support all-hazard data reporting by all hospitals nationally including rehabilitation, psychiatric, and long-term care acute care hospitals as well as those providing acute medical care. This effort will gather information to provide recommendations for a standardized lens into the readiness of, stress on, and resources available in hospitals before, during, and after emergencies (including all-hazard incidents such as public health emergencies, hurricanes, mass casualty incidents, infectious disease outbreaks, etc.) for needs across the country. While this effort is led by federal partners, it is intended to also support local response efforts. For example, standardized essential elements of information (EEIs) may help to facilitate coordination across jurisdictions when load balancing or medical operations coordination centers are needed. The effort will leverage past efforts and collaborate with ongoing initiatives across the healthcare situational awareness sphere, such as the National Biodefense Strategy.

Importantly, this is a nationwide effort for which partner input across the healthcare readiness community is essential. The healthcare community rose to increased demands during the COVID–19 public health emergency, reinforcing their commitment to always providing the highest quality level of safe care to patients. ASPR, CDC, CMS, and ONC are committed to working together with partners to help shape the path forward towards efficient information sharing, minimizing burden and increasing transparency on how information is used to drive action. Partners such as jurisdictions, hospital associations, hospitals, healthcare coalitions, medical operations coordination centers, transfer centers, nurses, emergency medical services, health information technology, and more will help to inform the project. ASPR, CDC, CMS, and ONC will be co-hosting a series of listening sessions in addition to seeking comments through this RFI.

To date there has been a limited unified, all-hazards understanding of national level hospital-facility status, capacity, resources, and capabilities. An all-hazards approach addresses capabilities-based preparedness to prevent, protect against, respond to, and recover from terrorist attacks, major disasters, and other emergencies. Existing efforts have included the COVID–19 hospital data collection, ad-hoc surveys performed after incidents such as hurricanes, targeted surveillance systems for specific communicable diseases and/or specific types of care (ex. Emergency Department (ED) visits), and individual efforts within jurisdictions. While each existing effort has been important, data collection efforts are patchwork, crisis-driven, and not standardized with respect to how EEIs are defined and operationalized. As a result, the nation continues to lack a comprehensive, standardized view of the state of the healthcare system that can be shared across partners at all levels to inform coordinated action.

In addition to informing nationwide EEIs, input provided will also be used for related initiatives such as the National Healthcare Safety Network (NHSN) hospital bed capacity data pilot project, the Health Level 7 (HL7) Helios Fast Healthcare Interoperability Resources (FHIR) Accelerator, the Medical Countermeasures and Data Information Technology Ecosystem, and CDC data modernization efforts. Nationwide EEIs identified through this effort will directly inform updates to the USCDI+ for Public Health, Situational Awareness, and Emergency Response dataset, where additional input will be

solicited on how to represent concepts for data exchange purposes. The effort also aligns with programs across the ASPR Health Care Readiness Portfolio and the CDC Public Health Emergency Program.

Sherrette A. Funn,
Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.
[FR Doc. 2023–22931 Filed 10–17–23; 8:45 am]
BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Project: SAMHSA Generic Clearance for the Collection of Qualitative Research and Assessment

SAMHSA is requesting approval from the Office of Management and Budget (OMB) for their Generic clearance for purposes of conducting qualitative research. SAMHSA conducts qualitative research to gain a better understanding of emerging substance use and mental health policy issues, improve the development and quality of instruments, and to ensure SAMHSA leadership, centers and offices have recent data and information to inform program and policy decision-making. SAMHSA is requesting approval for at least four types of qualitative research: (a) interviews, (b) focus groups, (c) questionnaires, and (d) other qualitative methods.

SAMHSA is the agency within the U.S. Department of Health and Human Services (HHS) that leads public health efforts to advance the behavioral health of the nation and to improve the lives of individuals living with mental and substance use disorders, and their families. It's mission is to lead public health and service delivery efforts that promote mental health, prevent substance misuse, and provide treatments and supports to foster recovery while ensuring equitable access and better outcomes. SAMHSA pursues this mission by providing grant