requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Improving the Quality and Representativeness of the Treatment Center Program Data—Data Modifications to the Current Survey Instrument Format To Minimize Misclassification**

*OMB Control Number 0910–NEW*

FDA has a need for valid, high-quality surveillance data on misuse of pharmaceutical products and use of other substances in the United States. FDA is funding the evaluation and improvement of the data validity and reliability of the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) Substance Abuse Treatment Center Programs Combined (TCPC) survey. The RADARS TCPC is comprised of two unique programs, the Opioid Treatment Program and the Survey of Key Informants' Patients Program. These two programs use the same core paper data collection form and complement each other by providing information from patients entering both private and public opioid addiction treatment programs. Patients enrolling in the study complete a self-administered anonymous questionnaire, within the first week of admission. The objective of these programs is to provide timely prevalence estimates of abuse of legal and illegal opioids and other substances, within the past month, among patients enrolling in treatment primarily for opioid use disorders. Surveillance data collected by these programs are used by FDA as well as researchers, industry, and other public health stakeholders to inform policy and regulatory decisions. FDA will be providing public health expertise on the survey validity and reliability questions before implementation to ensure that they generate quality data. FDA will also be providing its expert input on the results, analysis, and interpretation, as well as how the survey may be improved in light of the results.

This FDA-funded information collection will include three survey arms, two arms focused on survey validity (is the survey measuring what it is intended to measure) and the third arm focused on survey reliability (do the questions consistently produce the same results when asked at different time points and in a different format). For both survey validity arms—a digital survey only and digital survey plus interview arm—volunteer participants will be asked to pause after answering each survey question to answer a series of content validation questions concerning comprehension and quality of survey items. Items assessed will include survey instructions, active pharmaceutical ingredient and product content, reason for use, and route of administration. For the survey reliability arm, TCPC paper survey participants at selected sites will be invited to voluntarily participate in a second, digital survey, and the results of the two survey formats will be compared. The data collected through the three arms of this information collection will be analyzed to validate the content of a modified TCPC survey and to then determine the reliability among a proxy population for the target population. Results from the three arms will inform the format, structure, and wording of the modified digital TCPC survey, prior to its launch.

The annual participant burden hours requested are based on the number of collections FDA expects the contractor to conduct over the requested time frame for this clearance. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Type of respondent/interview | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Content Validity—Digital Survey Arm | 175 | 1 | 175 | 0.25 (15 minutes) | 44 |
| Content Validity—Digital Survey and Cognitive Interview Arm. | 25 | 1 | 25 | 1.5 (90 minutes) | 38 |
| Reliability Survey Arm—Digital Survey | 250 | 1 | 250 | 0.33 (20 minutes) | 83 |
| Total | 450 | | 450 | | 165 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: October 13, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–22966 Filed 10–17–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2023–N–0465; FDA–2023–N–1529; FDA–2010–N–0583; FDA–2020–N–0145; FDA–2023–N–0918; FDA–2014–N–1721]**

### Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD

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.