Number of Respondents: 506; *Total Annual Responses:* 506; *Total Annual Hours:* 253. (For policy questions regarding this collection contact Caecilia Andrews at 410–786–2190.)

2. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Conditions for Certification for Rural Health Clinics and Conditions for Coverage for Federally Qualified Health Centers in 42 CFR 491; *Use:* The Conditions for Medicare Certification (CfCs) for Rural Health Clinics (RHCs) are based on criteria prescribed in law and designed to ensure that each RHC has properly trained staff to provide appropriate care and to assure a safe physical environment for patients. The information collection requirements described herein are needed to implement the Medicare and Medicaid CfCs for a total of 5,349 RHCs. These requirements are similar in intent to standards developed by industry organizations such as the Joint Commission on Accreditation of Hospitals, and the National League of Nursing/American Public Association, and merely reflect accepted standards of management and care to which rural health clinics must adhere.

Federally Qualified Health Centers (FQHCs) are also subject to Conditions for Certification to participate in the Medicare and Medicaid programs. These health and safety standards are the foundation for improving quality and protecting the health and safety of Medicare and Medicaid beneficiaries. The information collection requirements described herein affect approximately 11,252 FQHCs. The current information collection requirements at 42 CFR 491.9(b) and 491.11 are applicable to both RHCs and FQHCs. *Form Number:* CMS–R–38 (OMB control number: 0938–0334); *Frequency:* Recordkeeping and Reporting—Annually; *Affected Public:* Business or other for-profits; *Number of Respondents:* 17,663; *Total Annual Responses:* 17,663; *Total Annual Hours:* 104,245. (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–12774 Filed 6–10–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2332]

Emerging Drug Safety Technology Meetings; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) within the Food and Drug Administration (FDA or we) is announcing a meeting program, the Emerging Drug Safety Technology Meeting (EDSTM) program. These meetings will be administered by staff in the newly established CDER Emerging Drug Safety Technology Program (EDSTP). EDSTMs provide applicants with an approved application and/or other relevant parties supporting industry's pharmacovigilance (PV) activities (*e.g.,* academia, contract research organizations (CROs), pharmacovigilance vendors, software developers) who meet the eligibility and selection criteria for participation with an opportunity to meet with CDER staff to discuss their research, development, and use of Artificial Intelligence (AI) and other emerging technologies in PV. The goals of the meeting program in its initial phase are to facilitate mutual learning and discussion of the pharmaceutical industry's application of these technologies to PV, including efforts to validate and verify relevant models. While the EDSTP is specifically focused on the use of AI in PV for postmarket activities, it is part of CDER's multifaceted approach to enhance mutual learning of where and how specific innovations, such as AI, can best be used across the drug product life cycle.

DATES: Applicants and other relevant parties may submit meeting requests under the program beginning June 11, 2024.

ADDRESSES: For additional information about the EDSTM program, please refer to FDA's web page at *https://www.fda.gov/drugs/science-and-research-drugs/cder-emerging-drug-safety-technology-program-edstp.*

FOR FURTHER INFORMATION CONTACT: Ricardo Hernandez, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993–0002, 240–402–9526, or email *AIMLforDrugDevelopment@fda.hhs.gov* with the subject line ''EDSTM—General Inquiry''.

SUPPLEMENTARY INFORMATION:

I. Background

The pharmaceutical industry is expanding its use of AI and other emerging technology across the drug product life cycle. FDA is interested in accelerating its understanding of the research, development, and use of AI and other emerging technology in the area of pharmacovigilance, including their performance characteristics. The EDSTM is a means by which applicants and other relevant parties who meet the eligibility and selection criteria for participation, can meet with CDER to share information about their use of AI and other emerging technology, and its potential application in PV, including efforts to validate and verify relevant models.

The goal of the EDSTM is to facilitate mutual learning and discussion on the opportunities and challenges with using such technologies in PV. If selected for a meeting, application holders and/or other relevant parties will meet with CDER staff to discuss their research, development, and/or use of AI and other emerging technologies in PV. FDA plans to leverage these learnings to help inform potential regulatory and policy approaches, within the use of emerging technology in PV. The EDSTM program is not an avenue to seek regulatory advice on compliance with pharmacovigilance regulations. Rather, we expect that the information gained during this program will help CDER consider providing regulatory advice on specific technologies to facilitate their adoption when appropriate. The discussions and background information submitted through the EDSTMs are nonbinding on both FDA and EDSTM requesters.

EDSTMs may be requested by applicants with at least one approved application regulated by CDER, including new drug applications, abbreviated new drug applications, or biologics license applications, and/or by other relevant parties supporting industry's PV activities (*e.g.,* academia, CROs/PV vendors, software developers) who develop, leverage, or intend to leverage AI or other emerging technology that can be used to satisfy the postmarketing reporting requirements in 21 CFR 314.80, 314.98, and 600.80. Eligible parties, such as an applicant or an applicant's PV vendor, may request meetings separately or in partnership. Requests may be submitted on a rolling basis and will be reviewed quarterly each calendar year. Please refer to the EDSTM program web page for details on submission deadlines for quarterly review. CDER will select up to

nine participants whose submissions meet the eligibility and selection criteria in a 12-month period for the initial phase of the EDSTM.

FDA has a longstanding commitment to ensure medicines marketed in the United States are safe through continued surveillance and research following approval. In the postmarket setting, regulated industry is obligated to review all adverse drug experience information received or otherwise obtained and submit timely reports to FDA. Both industry and regulatory authorities face challenges with timely and efficient collection, processing, and evaluation of single and aggregate patient safety data compounded by ever-increasing case volumes. Advances in emerging technology have the potential to address some of these challenges by creating more efficiencies within a PV system. For example, early adopters of AI are leveraging these emerging technologies to automate fundamental tasks (*e.g.,* adverse event intake, data entry, and processing) with the intention to drive down associated administrative burden and costs. These technologies can also make safety surveillance more efficient and effective by capturing, aggregating, and analyzing larger and more diverse data sets.

FDA recognizes industry's interest in dialogue around AI capabilities that advance PV. Knowledge and awareness of emerging technology tools, such as AI, and how they are used to advance PV will help inform CDER's regulatory approaches and policies. FDA expects that increased communication with industry and/or other relevant parties during EDSTMs will accelerate FDA's understanding of how AI enabled tools are being used for PV, their associated risks and benefits, and barriers to implementation.

FDA has established an EDSTP website that includes EDSTM eligibility and selection criteria, instructions for submission of a meeting request, meeting request and package content descriptions, and submission timelines. The program's website address is *https://www.fda.gov/drugs/science-and-research-drugs/cder-emerging-drug-safety-technology-program-edstp.*

II. Paperwork Reduction Act of 1995

Collections of information from fewer than 10 respondents within any 12-month period are not subject to the Paperwork Reduction Act of 1995 (PRA) (5 CFR 1320.3(c)(4)). For the initial phase of this program, FDA will request information from no more than nine sponsors. Initial requests from sponsors interested in participation in the program are not ''information'' in accordance with 5 CFR 1320.3(h)(1). Therefore, clearance by the Office of Management and Budget under the PRA is not required.

Dated: June 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–12770 Filed 6–10–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: 0937–0191–60D]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. The ICR is for extending the use of the approved information collection assigned OMB control number 0937–0191, which expires on June 30, 2024. Prior to submitting the ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before August 12, 2024.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 264–0041 and *PRA@HHS.GOV.*

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0937–0191–60D and project title for reference, to Sherrette A. Funn, email: *Sherrette.Funn@hhs.gov, PRA@HHS.GOV* or call (202) 264–0041 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Application Packets for Real Property for Public Health Purposes

Type of Collection: Reinstatement, with no change.

OMB No.: 0937–0191.

Abstract: The Office of Assistant Secretary for Administration, Program Support Center, Federal Real Property Assistance Program is requesting OMB approval on a previously approved information collection, 0937–0191. 40 U.S.C. 550 (the ''Act''), as amended, provides authority to the Secretary of Health and Human Services to convey or lease surplus real property to States and their political subdivisions and instrumentalities, to tax-supported institutions, and to nonprofit institutions which (except for institutions which lease property to assist the homeless) have been held exempt from taxation under section 501(c)(3) of the 1954 Internal Revenue Code, and 501(c)(19) for veterans organizations, for public health and homeless assistance purposes. Transfers are made to transferees at little or no cost.

Type of respondent: Responses are dependent on when Federal surplus real property is made available and is desired by a respondent/applicant for acquisition. Likely respondents include State, local, or Tribal units of government or instrumentalities thereof, and not-for-profit organizations.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Applications for surplus Federal real property		10	1	200	2,000
Total		10	1	200	2,000