To prepare the proposed expansion area for development, some existing utilities and PCA infrastructure will need to be accommodated in a new way, either within the LPOE via easements or moved off site to the west or south on PCA-owned land. Project changes have triggered the reconfiguration of some of the existing PCA operations on PCA lands and will require relocation of some infrastructure associated with PCA, the MD&W Railway, and OfficeMax. Relocation of utilities and infrastructure may be conducted by either GSA or PCA, depending on final acquisition negotiations. Actions taken by PCA are considered as connected actions to the Proposed Action.

Alternative 1 also considers the implementation of renewable energy technologies within the expanded and modernized LPOE. These technologies were not considered in the 2011 Final EIS but have since been proposed for inclusion in future site plans. Renewable technologies that may be incorporated into the facility design include solar and geothermal technologies, depending on the final design.

GSA is currently undergoing formal consultation with the State Historic Preservation Officer (SHPO) and consulting parties to follow coordination procedures as required under Section 106 of the National Historic Preservation Act. GSA intends on implementing and complying with all mitigation measures resulting from section 106 consultation as detailed in the ROD.

**William Renner,**

*Director, Facilities Management and Services Programs Division, Great Lakes Region 5, U.S. General Services Administration.*

[FR Doc. 2024–12700 Filed 6–10–24; 8:45 am]

**BILLING CODE 6820–CF–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

**[Document Identifiers: CMS–381 and CMS–R–38]**

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

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by July 11, 2024.

**ADDRESSES:** Written 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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786–4669.

**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. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Identification of Extension Units of Medicare Approved Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP) Providers and Supporting Regulations; *Use:* Form CMS–381 was developed to ensure that each OPT/OSP extension location at which OPT/OSP providers furnish services, must be reported by the providers to the State Survey Agencies (SAs). Form CMS–381 is completed when: (1) new OPT/OSP providers enter the Medicare program; (2) when existing OPT/OPS providers delete or add a service, or close or add an extension location; or, (3) when existing OPT/OSP providers are recertified by the State Survey Agency every 6 years.

In 2022, CMS transitioned some of the certification processes to the Center for Program Integrity (CPI) and the Medicare Administrative Contractor (MAC). Prior to the transition, the CMS Survey Operations Group was involved in the processing of the extension location requests. As a result of the new processing instructions, CMS is now reconciling the Form CMS–381 with updates to the instructions. Additionally, CMS has revised the Form CMS–381 to incorporate the initial enrollment of OPT/OSPs which was previously completed on the Form CMS–1856 (0938–0065). CMS has combined the forms into one form in order to further align with the transitioned processes and streamline the requests from the provider community. This change will decrease the burden on both the provider community as well as CMS. Furthermore, this change will also allow for OPTs who wish to initially enroll in the Medicare program to submit an extension location request with the initial enrollment. The State Survey Agency or Accrediting Organization (for those OPTs requesting deemed status) will survey the extension location during the initial survey to verify compliance with the Medicare conditions. *Form Number:* CMS–381 (OMB control number: 0938–0273); *Frequency:* Occasionally; *Affected Public:* Private Sector; Business or other for-profit and not-for-profit institutions;

*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