''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph Kotsybar, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 3623A, Silver Spring, MD 20993–0002, 240–402–1062, *PSG-Questions@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products'' that explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific guidances and provide a meaningful opportunity for the public to consider and comment on those guidances. This notice announces the availability of a new draft product-specific guidance on generic estradiol vaginal inserts and a revised draft product-specific guidance on generic estradiol vaginal tablets.

FDA initially approved new drug application (NDA) 208564 IMVEXXY (estradiol) in May 2018. We are now issuing a draft guidance for industry on, among other things, BE recommendations for generic estradiol vaginal inserts that use IMVEXXY as the reference listed drug (RLD) (''Draft Guidance on Estradiol'' (vaginal inserts)). FDA initially approved NDA 020908 VAGIFEM (estradiol) in March 1999. We are also now issuing a revised draft guidance for industry on, among other things, BE recommendations for generic estradiol vaginal tablets that use VAGIFEM as the RLD (''Draft Guidance on Estradiol'' (vaginal tablets)).

In December 2018 and May 2020, TherapeuticsMD, Inc. submitted citizen petitions requesting, among other things, that FDA not approve any ANDA referencing IMVEXXY (estradiol vaginal inserts) unless certain criteria are met and that FDA issue a product-specific guidance for generic estradiol vaginal inserts that recommends studies consistent with those requested in the petitions and includes certain BE recommendations for generic estradiol vaginal inserts that are consistent with the then-current version of ''Draft Guidance on Estradiol'' (vaginal tablets) (Docket No. FDA–2018–P–4714 and Docket No. FDA–2020–P–1334, available at *https://www.regulations.gov*). FDA is separately responding to TherapeuticsMD, Inc.'s citizen petitions.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidances, when finalized, will represent the current thinking of FDA on ''Draft Guidance on Estradiol'' (vaginal inserts; vaginal tablets). They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

As we develop any final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While these guidances contain no collection of information, they do refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for investigational new drugs have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 for applications for FDA approval to market a new drug and in 21 CFR part 320 for bioavailability and bioequivalence requirements have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22249 Filed 12–5–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3477–PN]

Medicare and Medicaid Programs; Continued Approval of the American Association for Accreditation of Ambulatory Surgery Facilities' Rural Health Clinic Accreditation Program

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

ACTION: Notice with request for comment.

SUMMARY: This notice acknowledges the receipt of an application from the American Association for Accreditation of Ambulatory Surgery Facilities (DBA ''QUAD A'') for continued recognition

as a national accrediting organization (AO) for rural health clinics that wish to participate in the Medicare or Medicaid programs. The statute requires that, within 60 days of receipt of an organization's complete application, the Secretary, through the Centers for Medicare & Medicaid Services (CMS), publishes a notice that identifies the AO making the request, describes the nature of the request, and provides at least a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by January 7, 2026.

ADDRESSES: In commenting, refer to file code CMS–3477–PN. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3477–PN, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3477–PN, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Caecilia Andrews (410) 786–2190.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a rural health clinic (RHC) provided certain requirements are met. Sections 1861(aa) and 1905(*l*)(1) of the Social Security Act (the Act), establish distinct criteria for facilities seeking designation as an RHC. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the general provisions for survey and certification of facilities are at 42 CFR part 488, subpart A. The regulations at 42 CFR part 491, subpart A specify the conditions that an RHC must meet to participate in the Medicare program, and 42 CFR 405, subpart X sets forth the scope of covered services and the conditions for Medicare payment for RHCs.

Generally, to enter into an agreement with Medicare, an RHC must first be certified by a State survey agency as complying with the conditions or requirements set forth in 42 CFR part 491. Thereafter, the RHC is subject to regular surveys by a State survey agency to determine whether it continues to meet these requirements.

However, there is an alternative to surveys by State agencies. Section 1865(a)(1)(A) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national AO that all applicable Medicare conditions are met or exceeded, we must deem that provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

Our regulations concerning the approval of accrediting organizations are set forth at 42 CFR 488.5 (Application and re-application procedures for national accrediting organizations).

The QUAD A is requesting continued CMS-approval for its RHC program. QUAD A's current term of approval expires March 23, 2026.

II. Approval of Deeming Organization

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our review and approval of a national accrediting organization's application consider, among other factors, the applying accrediting organization's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities found not in compliance with the conditions or requirements; and ability to provide us with the necessary data for validation.

Section 1865(a)(3)(A) of the Act further requires that we publish, within 60 days of receipt of an organization's complete application, a notice identifying the national accrediting body making the request, describing the nature of the request, and providing at least a 30-day public comment period. Due to the Federal lapse in appropriated funding, certain parts of CMS operations were temporarily halted on September 30, 3025. Therefore, this notice was impacted and did not publish on or before October 24, 2025 (60 days of the receipt of the complete application). We have 210 days from the receipt of a complete application to publish notice of approval or denial of the application.

The purpose of this proposed notice is to inform the public of QUAD A's request for continued CMS-approval for its RHC accreditation program. This notice also solicits public comments on whether QUAD A's requirements meet or exceed the Medicare conditions for certification (CfCs) for RHCs.

III. Evaluation of Deeming Authority Request

QUAD A submitted all the necessary materials to enable us to make a determination concerning its request for continued approval of its RHC accreditation program. This application was determined to be complete on August 25, 2025. Under section 1865(a)(2) of the Act and our regulations at § 488.5, our review and evaluation of QUAD A may include:

- The equivalency of QUAD A's standards for RHCs as compared with CMS' RHC CfCs.
- QUAD A's survey process to determine the following:

++ QUAD A's capacity to adequately fund the required surveys.

++ The comparability of QUAD A's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited RHCs.

++ QUAD A's processes and procedures for monitoring RHCs found out of compliance with QUAD A's program requirements. These monitoring procedures are used only when QUAD A identifies noncompliance. If noncompliance is

identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at 42 CFR 488.9(c).

++ QUAD A's capacity to report deficiencies to the surveyed RHCs and respond to the RHC's plan of correction in a timely manner.

++ QUAD A's capacity to provide us with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ The adequacy of QUAD A's staff and other resources, and its financial viability.

++ QUAD A's policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced.

++ QUAD A's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ QUAD A's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

The Administrator of CMS, Mehmet Oz, having reviewed and approved this document, authorizes Trenesha Fultz-Mimms, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Trenesha Fultz-Mimms,

Federal Register Liaison, Center for Medicare & Medicaid Services.

[FR Doc. 2025–22219 Filed 12–5–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0937–0198–30D]

Agency Information Collection Request. 30-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, submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on the ICR must be received on or before January 7, 2026.

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.

FOR FURTHER INFORMATION CONTACT: Sheila Garrity, Director, Office of Research Integrity, *ORI_Public_Comments@hhs.gov*. When submitting comments or requesting information, please include the document identifier 0937–0198–30D and project title for reference.

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.

Title of the Collection: Public Health Service Policies on Research Misconduct (42 CFR part 93) .

Type of Collection: Revision.

OMB No. 0937–0198.

Abstract: The Office of Research Integrity (ORI) is seeking a revision of its collection instruments to reflect updates in the Public Health Service Policies on Research Misconduct (42 CFR part 93) published on September 17, 2024. The purpose of the Institutional Assurance and Annual Report on Possible Research Misconduct form PHS–6349 is to provide data on the amount of research misconduct activity (*e.g.,* allegations of research misconduct and assessments, inquiries, and/or investigations of such allegations) occurring at institutions conducting PHS-supported research. These data enable the ORI to monitor institutional compliance with the PHS regulation. Form PHS–6349 has undergone minor revisions, but its function is unchanged. The purpose of the Assurance of Compliance by Sub-Award Recipients form PHS–6315 establishes an assurance of compliance for a sub-awardee institution. Form PHS–6315 is being discontinued. In its place, ORI developed a new form, the Research Integrity Assurance Establishment form PHS–7091. This form allows all institutions subject to 42 CFR part 93 to establish an assurance with ORI, regardless of sub-awardee status. Additionally, ORI developed a second new form, the Institutional Record Transmittal form PHS–7092, which accounts for the varied types of information collection that can occur during the course of institutional research misconduct proceedings. ORI continues to utilize the Small Institution Statement to assist small institutions as part of the assurance process, which has been updated to reflect new regulatory language. This statement is an addendum that can be included with form PHS–6349 and PHS–7091, where applicable.

Need and Proposed Use: The information is needed to fulfill section 493 of the Public Health Service Act (42 U.S.C. 289b), which requires assurances from institutions that apply for financial assistance under the Public Health Service Act for any project or program that involves the conduct of biomedical or behavioral research. In addition, the information is also required to fulfill the assurance and annual reporting requirements of 42 CFR part 93. ORI uses the information to monitor institutional compliance with the regulation. Lastly, the information may be used to respond to congressional requests for information to prevent misuse of Federal funds and to protect the public interest.

In accordance with 5 CFR Part § 1320.8(d), 60-day notice was published on September 30, 2025, in the **Federal Register** Volume 90, Number 187, Pages 46901–46902 to solicit public comment on the revision of form PHS–6349, the new collection instruments (the Institutional Record Transmittal