contact: Marlana Thieler at 410–786–6274.)

William N. Parham, III,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10712 and CMS–10266]

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 May 18, 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.

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:* Existing Collection in use without an OMB control number; *Title of Information Collection:* Religious Nonmedical Health Care Institutions (RNHCIs) Conditions of Participation; *Use:* The purpose of this package is to request approval for this existing collection in use without an OMB Control Number for Religious Nonmedical Health Care Institutions (RNHCIs) Conditions of Participation (CoPs). RNHCIs are facilities that provide non-medical nursing items and services to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs.

The information collections (ICs) for RNHCIs enable CMS to ensure these facilities comply with health and safety requirements under Title 42 Code of Regulations (CFR) Section 403, Subpart G. The specific ICs associated with burdens are as follows: IC–1: §§ 403.724(a)(2) & (a)(3)—Sign, Date & Notarize election statement; IC–2: § 403.724(a)(4)—Copy & Submit Election Statement to CMS; IC–3: § 403.730(a)—Provide Patients Notice of Rights; IC–4: § 403.736(a)—Provide Discharge Plan.

The previous iteration of this package included an estimated annual burden of 1,943 hours and an annual cost of $79,998. For this iteration, the total annual hourly burden is revised to 824 hours, with an annual burden cost of $38,113. There is no collection instrument. *Form Number:* CMS–10712 (OMB control number: 0938–NEW); *Frequency:* Quarterly; *Affected Public:* Private Sector—Not-for-profit institutions; *Number of Respondents:* 56; *Total Annual Responses:* 2,476; *Total Annual Hours:* 824. (For policy questions regarding this collection contact Claudia Molinar at (410) 786–8445.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Conditions of Participation for Transplant Programs; *Use:* The purpose of this package is to request approval from the Office of Management and Budget (OMB) to reinstate, with change, the information collection request for OMB Control No. 0938–1069, which expired on November 30, 2022. The information collection request described herein is associated with the Conditions of Participation (CoPs) for Transplant Programs, specified at Title 42 Code for Regulations (CFR) Sections §§ 482.68 to 482.104.

A certified Transplant Program is an approved Medicare provider type that is located within an approved Medicare Hospital provider type. Approved Medicare dialysis facilities also work in conjunction with Transplant Programs, as they support patients before and possibly after kidney transplants. Transplant Programs may receive payment for heart, heart-lung, intestine, kidney, liver, lung, and pancreas transplants if, and only if, they are in compliance with the Conditions of Participation (CoPs) specified in 42 CFR 482.68 to 482.104.

The previous iteration was approved on November 29, 2019, with an estimated annual burden of 2,593 hours and an annual cost of $181,130. For this re-instatement, the total annual hourly burden is revised to 3,340, with an annual burden cost of $352,462. The 29% increase in burden hours (from 2,593 to 3,340) is primarily due to the addition of one missing IC, (IC–3), minor corrections to burden estimates, and updating labor wage data to more recently available data. *Form Number:* CMS–10266 (OMB control number: 0938–1069); *Frequency:* Yearly; *Affected Public:* Private sector Business or other

for-profits and Not-for-profit institutions; *Number of Respondents:* 476; *Total Annual Responses:* 476; *Total Annual Hours:* 3,340. (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. 2026–07401 Filed 4–15–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–3446]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of rare pediatric disease priority review vouchers as well as the approval of products redeeming vouchers. FDA has determined that AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted), BLA supplement approved June 7, 2024, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Myrna Hanna, Center for Biologics Evaluation and Research, Food and Drug Administration, *industry.biologics@fda.hhs.gov,* 240–402–7911.

SUPPLEMENTARY INFORMATION: FDA is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted) meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about AREXVY (Respiratory Syncytial Virus Vaccine, Adjuvanted), go to the Center for Biologics Evaluation and Research Approved Products website at *https://www.fda.gov/vaccines-blood-biologics/center-biologics-evaluation-and-research-cber-product-approval-information.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–07368 Filed 4–15–26; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–3400]

Agency Information Collection Activities; Proposed Collection; Comment Request; Orphan Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. 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 of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with orphan drug requirements.

DATES: Either electronic or written comments on the collection of information must be submitted by June 15, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 15, 2026. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–1929 for ''Orphan Drug Designation.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your