review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Chyana Woodyard, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2025–00385 Filed 1–8–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10069]

Agency Information Collection Activities: Proposed Collection; 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 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates 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 must be received by March 11, 2025.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

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 N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS 10069 Rural Community Hospital Demonstration Program Application

Under the 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 requires Federal agencies to publish a 60-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.

Information Collections

1. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Rural Community Hospital Demonstration Program Application; *Use:* CMS is requesting the information collection request previously approved under OMB control number 0938–0880, the Medicare Waiver Demonstration/Model Application, be reinstated. The approval lapsed due to an administrative oversight.

The Centers for Medicare & Medicaid Services (CMS) has operated the statutory Rural Community Hospital (RCH) Demonstration since 2004. The authorizing statute instructed CMS to test cost-based payment for Medicare inpatient services for rural hospitals with fewer than 51 beds that are not eligible to be Critical Access Hospitals (CAH).

The RCH Demonstration Program was initially authorized by section 410A of the Medicare Modernization Act (MMA) of 2003. Following the initial 5-year authorization, the demonstration has been extended 3 times, each time for an additional 5 years—first, by Sections 3123 and 10313 of the Affordable Care Act; then by section 15003 of the 21st Century Cures Act; and by section 128 of the Consolidated Appropriations Act of 2021. Currently, the demonstration has 20 participants out of a maximum of 30 hospitals, and it is scheduled to end in 2028.

For previous authorizations, CMS has issued a Request for Applications (RFA) to solicit applications for the demonstration program. For the last solicitation, in 2017, CMS received 51 applications for 13 open spaces. CMS is planning on a new RFA to fill the ten spaces that are currently open.

Per the RFA, applications are requested in identical format, regardless of the specific goals and projects of the individual applicants. The standardized application format is not controversial, and it will reduce burden on applicants and reviewers. Responses are strictly voluntary. The standard format will enable CMS to select proposals that meet CMS objectives and show the best potential for success.

The RFA will ask interested hospitals to provide a problem statement, strategies for ongoing financial viability, goals for participation in the demonstration, and plans for collaboration with other providers in the area. Applications will be submitted in the user-friendly format outlined in the Medicare Waiver Demonstration/Model Application.

A panel of evaluators will be assembled and utilize a standardized rubric to score the submitted proposals and identify hospitals with the highest scores. Results will be used to guide the future of the Medicare and Medicaid programs and to inform reform initiatives. *Form Number:* CMS–10069 (OMB control number: 0938–0880); *Frequency:* Once; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 2,400. (For policy questions regarding this collection contact Alexis Lilly at 410–786–3501).

William N. Parham, III,

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

[FR Doc. 2025–00399 Filed 1–8–25; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Amendment of the Statement of Organizations, Functions and Delegation of Authority

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice of amendment.

SUMMARY: The Administration for Children and Families (ACF) is amending the Statement of Organization, Functions and Delegation of Authority (''Statement'') issued in the **Federal Register** on April 28, 2009. The Statement delegated specific provisions of the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, Public Law 110–457, section 235 from the Assistant Secretary for Children and Families to the Director of the Office of Refugee Resettlement. This amendment modifies the Statement to authorize the Director of the Office of Refugee Resettlement to redelegate the listed authorities contained within the Statement.

DATES: This amendment of the April 28, 2009, Statement of Organization, Functions and Delegation of Authority is effective on date of signature.

FOR FURTHER INFORMATION CONTACT: Toby Biswas, Director of Policy, Division of Unaccompanied Children Policy, Unaccompanied Children Bureau, Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services, Washington, DC, (202) 205–4440 or *UCPolicy-RegulatoryAffairs@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION:

The first paragraph of the Statement of Organization, Functions and Delegation of Authority issued in the **Federal Register** on April 28, 2009 (74 FR 19232) currently reads as follows:

''Notice is hereby given that I delegate to the Director of the Office of Refugee Resettlement the following authority delegated to the Assistant Secretary for Children and Families by the Secretary of the Department of Health and Human Services (HHS) under the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, Public Law 110–457, section 235.''

This paragraph is amended to read as follows:

''Notice is hereby given that I have delegated to the Director of the Office of Refugee Resettlement, with authority to re-delegate, the following authority delegated to the Assistant Secretary for Children and Families by the Secretary of the Department of Health and Human Services (HHS) under the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008, Public Law 110–457, section 235.''

The intention of this amendment is to provide notice to the public of the Assistant Secretary's delegation of authority provided in subsequent portions of the notice, as well as the authority to redelegate the listed authorities.

All other provisions of the Statement of Organization, Functions and Delegation of Authority issued in the **Federal Register** on April 28, 2009 (74 FR 19232) will remain unchanged.

Meg Sullivan,

Principal Deputy Assistant Secretary for the Administration for Children and Families, performing the delegable duties of the Assistant Secretary for Children and Families.

[FR Doc. 2025–00262 Filed 1–8–25; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher; ALYFTREK (vanzacaftor, tezacaftor, and deutivacaftor)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a 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 priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the application for ALYFTREK (vanzacaftor, tezacaftor, and deutivacaftor), approved December 20, 2024, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394.

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 the application for ALYFTREK (vanzacaftor, tezacaftor, and deutivacaftor) tablets 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 ALYFTREK (vanzacaftor, tezacaftor, and deutivacaftor), go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: January 3, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–00341 Filed 1–8–25; 8:45 am]

BILLING CODE 4164–01–P