Capitated Financial Alignment Demonstrations (MMPs)) and 1876 Cost Plans), Prescription Drug Plan sponsors (PDPs), and Programs of All-Inclusive Care for the Elderly (PACE) organizations report financial information demonstrating the organization has a fiscally sound operation. The FSRR is designed to capture financial data of these contracting entities. The Division of Finance and Benefits (DFB) within the Medicare Advantage Contract Administration Group (MCAG) of CMS is assigned the responsibility of reviewing ongoing financial performance of the contracting entities.

All contracting organizations must submit audited annual financial statements once per year. In addition to the annual submission audited, Health Plans with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth submit quarterly financial statements for fiscal soundness monitoring. Part D organizations are required to submit three (3) quarterly financial statements. Lastly, PACE organizations are required to file four (4) quarterly financial statements for the first three (3) years in the program. After the first three (3) years, PACE organizations with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth must submit quarterly financial statements for fiscal soundness monitoring. *Form Number:* CMS–906 (OMB control number: 0938–0496); *Frequency:* Quarterly and Yearly*; Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 251; *Total Annual Responses:* 1,004*; Total Annual Hours:* 335. (For policy questions regarding this collection contact Christa M. Zalewski at (410) 786–1971.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State-based Exchange, SBE, SBE Budget Template, SBE Enrollment Metrics, Open Enrollment; *Use:* The Patient Protection and Affordable Care Act, Public Law 111–148, enacted on March 23, 2010, and the Health Care and Education Reconciliation Act, Public Law 111–152, enacted on March 30, 2010 collectively, ''Affordable Care Act'', expanded access to health insurance for individuals and employees of small businesses through the establishment of new Affordable Insurance Exchanges (Exchanges), including the Small Business Health Options Program (SHOP). Beginning January 1, 2014, the Exchanges became operational. The Exchanges enhance competition in the health insurance market, expand access to affordable health insurance for millions of Americans, and provide consumers with a place to easily compare and shop for health insurance coverage.

States can choose to establish and operate a State-based Exchange (SBE) or a State-based Exchange on the Federal Platform (SBE–FP). States electing to operate as an SBE–FP rely on the Federal Healthcare.gov platform to carry out eligibility and enrollment functions. For states that do not elect to operate either an SBE or SBE–FP, the Secretary of the U.S. Department of Health and Human Services (HHS) will establish and operate a Federally-facilitated Exchange (FFE) in those states. *Form Number:* CMS–10371 (OMB control number: 0938–1119; *Frequency:* Occasionally; *Affected Public:* State, Local or Tribal Government; *Number of Respondents:* 23; *Total Annual Responses:* 343; *Total Annual Hours:* 7,317. (For policy questions regarding this collection contact Tiffany Y. Animashaun at *Tiffany.Animashaun@cms.hhs.gov*).

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

Administration for Children and Families

[OMB #: 0970–0531]

Proposed Information Collection and Submission for Office of Management and Budget Review; Fiscal Responsibility Act TANF Pilot Program 2025 Information Collection

AGENCY: Office of Family Assistance, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is proposing to reissue an information collection to request information from interested states for the Fiscal Responsibility Act of 2023 (FRA) Temporary Assistance for Needy Families (TANF) pilot program. This request is proposed under Office of Management and Budget (OMB) #: 0970–0531 and is a reissuing of a previously approved information collection to select states for the FRA pilot program.

DATES: *Comments due June 20, 2025.* OMB will make a decision about the collection of information after this public comment period ends and comments have been considered.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The FRA authorized a new opportunity for states to pilot program performance and accountability measures in TANF. Under the pilot, the U.S. Department of Health and Human Services (HHS) may select up to five state TANF grantees to negotiate performance benchmarks for work and family stability outcomes instead of adhering to the standard TANF Work Participation Rate. The ACF Office of Family Assistance (OFA) administers federal grant programs that foster family economic stability and independence, including the TANF program. As such, OFA is responsible for designing and carrying out the FRA TANF Pilot Program, including selecting the five states to participate in the pilot, working with the states to identify performance benchmarks and associated targets, and monitoring performance of the pilot states throughout the duration of the pilot.

ACF received approval for a previous information collection (Title: Fiscal Responsibility Act TANF Pilot Program; OMB #: 0970–0531) on July 17, 2024. Twenty-three states and territories responded to the information collection from July through September 2024. In November 2024, ACF announced the selection of five states to participate in the FRA TANF Pilot Program. In March 2025, the Trump Administration announced a new direction for the FRA TANF Pilot Program, ending pilot participation for the states selected in November of 2024 and communicating plans to issue a new request for pilot proposals aligned with the Administration's focus on promoting work and reducing dependency and the key measures of success related to those priorities. This new request to OMB is to collect information from states about their interest and suitability for participation in the new direction being taken for the FRA TANF Pilot Program.

OFA also intends to provide programmatic technical assistance (TA) to the pilot states. ACF's Office of

Planning, Research, and Evaluation (OPRE) studies ACF programs, including TANF, and the populations they serve through rigorous research and evaluation projects. OPRE will be responsible for the federal evaluation of the FRA TANF Pilots Program and intends to provide data- and evaluation-related TA to the pilot states.

Respondents: States operating TANF programs and interested in innovations within those programs focused on promoting work and reducing dependency. In accordance with title IV–A of the Social Security Act, states is defined as the 50 States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, and American Samoa. *See* 42 U.S.C. 619(5).

Annual Burden Estimates

The Proposal for TANF Pilot Program Participation is intentionally succinct and will be considered in combination with existing sources of administrative data. Therefore, ACF estimates that a state will spend approximately 10 hours compiling information and responding to the request. In the first issuing of this information collection in July 2024, ACF received responses from 23 states and territories. The estimated number of respondents in the table below is based on the number of responses received in the first round and ACF's expectations for number of responses in the second round.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
Proposal for TANF Pilot Program Participation	25	1	10	250

Authority: 42 U.S.C. 611(e).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–09098 Filed 5–20–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Product-Specific Guidance on Roflumilast; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a new draft guidance for industry entitled ''Draft Guidance on Roflumilast.'' The new draft guidance, when finalized, will provide product-specific recommendations on, among other things, the design of bioequivalence (BE) studies to support abbreviated new drug applications (ANDAs) for roflumilast topical cream.

DATES: Submit either electronic or written comments on the draft guidance by July 21, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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–2007–D–0369 for ''Draft Guidance on Roflumilast.'' Received comments 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 comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''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