

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-10146 Notice of Denial of Medicare Prescription Drug Coverage

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 Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage; *Use:* Part D plan sponsors are required

to issue the Notice of Denial of Medicare Prescription Drug Coverage notice when a request for a prescription drug or payment is denied, in whole or in part. The written notice must include a statement, in understandable language, the reasons for the denial and a description of the appeals process.

The purpose of this notice is to provide information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process. *Form Number:* CMS-10146 (OMB control number 0938-0976); *Frequency:* Daily; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 743; *Total Annual Responses:* 2,631,728; *Total Annual Hours:* 657,932. (For policy questions regarding this collection contact: Coretta Edmondson at 410-786-0512.)

Dated: July 31, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023-16549 Filed 8-2-23; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Objective Work Plan/On-Going Progress Report (Office of Management and Budget #0970-0452)

AGENCY: Administration for Native Americans, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families' (ACF) Administration for Native Americans (ANA) is requesting a 3-year extension to the Ongoing Progress Report (OPR) and the Objective Work Plan (OWP) (Office of Management and Budget

(OMB) #0970-0452, expiration September 30, 2023). There are no changes requested to the forms.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

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. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: There are no changes proposed to the OPR or OWP.

The OPR information collection is conducted in accordance with section 811 [42 U.S.C. 2992] of the Native American Programs Act and will allow ANA to report quantifiable results across all program areas. It also provides grantees with parameters for reporting their progress and helps ANA better monitor and determine the effectiveness of their projects. The information in the OPR is collected on a semi-annual basis to monitor the performance of grantees and better gauge grantee progress.

The OWP information collection is conducted in accordance with 42 U.S.C. of the Native American Programs Act of 1972, as amended. This collection is necessary to evaluate applications for financial assistance and determine the relative merits of the projects for which such assistance is requested, as set forth in section 806 [42 U.S.C. 2991-d 1](a)(1). The information in the OWP is collected at time of application to detail the project goal, objectives, activities and outputs.

Respondents: Federally and state recognized tribes, Native Pacific Islanders, tribal Colleges and Universities, Native non-profits, and consortia.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Objective work plan	300	1	3	900	300
On-Going Progress Report	200	2	1	400	133

Estimated Total Annual Burden Hours: 433.

Authority: Section 806 [42 U.S.C. 2991d–1](a)(1) and sec. 811 [42 U.S.C. 2992].

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–16588 Filed 8–2–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1635]

Prescription Drug User Fee Act Waivers, Reductions, and Refunds for Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals Under the President's Emergency Plan for Acquired Immunodeficiency Syndrome Relief; 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 draft guidance for industry entitled “PDUFA Waivers, Reductions, and Refunds for Fixed-Combinations and Single-Entity Versions of Previously Approved Antiretrovirals under PEPFAR.” The draft guidance describes circumstances under which an applicant may be eligible for a barrier-to-innovation waiver under the Prescription Drug User Fee Act (PDUFA) for certain new drug applications (NDAs) for single-entity (SE) antiretroviral (ARV) and fixed-combination (FC) ARV drug products for the treatment or prevention of human immunodeficiency virus-one (HIV–1). The draft guidance is also intended to help applicants request a barrier-to-innovation waiver under those circumstances.

DATES: Submit either electronic or written comments on the draft guidance by October 2, 2023 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–2018–D–1635 for “PDUFA Waivers, Reductions, and Refunds for Fixed-Combinations and Single-Entity Versions of Previously Approved

Antiretrovirals under PEPFAR.”

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 and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.