EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN FOR THE 2025–2027 MEPS–IC

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Prescreener Questionnaire	18,900	1,575	38.76	$61,047
Establishment Questionnaire	21,900	7,300	38.76	282,948
Plan Questionnaire	18,900	7,970	38.76	308,898
Total	59,700	16,845	n/a	652,893

* Based upon the mean hourly wage for Compensation, Benefits, and Job Analysis Specialists occupation code 13–1141, at *https://www.bls.gov/oes/current/oes131141.htm* (U.S. Department of Labor, Bureau of Labor Statistics.)

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 5, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–26207 Filed 11–12–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Objective Work Plan/On-Going Progress Report (Office of Management and Budget #0970–0452)

AGENCY: Administration for Native Americans, 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) 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 #0970–0452, expiration September 30, 2026). Changes are proposed only to the report.

DATES: Comments due January 13, 2025. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

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 information in the OPR is collected on a semi-annual basis to monitor the performance of grantees and better gauge grantee progress.

The OPR information collection is conducted in accordance with sec. 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 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 sec. 806 [42 U.S.C. 2991–d 1](a)(1).

The report was revised based on a review by ANA and feedback from grantees, which identified some data elements that could be eliminated and areas that could be clarified.

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.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information

technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

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

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–26230 Filed 11–12–24; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5057]

Public Workshop on Optimizing the Use of Real-World Evidence in Regulatory Decision-Making for Drugs and Biological Products—Looking Forward; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public workshop titled ''Optimizing the Use of Real-World Evidence in Regulatory Decision-Making for Drugs and Biological Products—Looking Forward.'' The purpose of the public workshop is to provide interested parties with an update on FDA's current activities related to real-world evidence (RWE) and to share accomplishments, ongoing challenges, and future opportunities. The public workshop will discuss potential next steps to promote the continued evolution and consistent application of real-world data (RWD) in drug development. This public workshop will be convened and supported by a cooperative agreement between FDA and the Duke University, Duke-Margolis Institute for Health Policy.

DATES: The public workshop will be held on December 12, 2024, from 12:30 p.m. to 5 p.m., Eastern Time. Either electronic or written comments on this public workshop must be submitted by January 13, 2025. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held in-person at the Bethesda North Marriott & Conference Center, 5701 Marinelli Rd., North Bethesda, MD 20852 and virtually using the Zoom platform.

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 January 13, 2025. 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–2024–N–5057 for ''Optimizing the Use of Real-World Evidence in Regulatory Decision-Making for Drugs and Biological Products—Looking Forward.'' 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 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.

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–3161, *Dianne.Paraoan@fda.hhs.gov* or *CDER-RWE@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The volume and complexity of RWD available to support drug development have increased substantially over the past several decades. This increase, combined with enhanced computing power and emerging technologies, is transforming how drugs are developed.