Authority: Authorized and appropriated by Social Security Act section 513.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–23261 Filed 12–17–25; 8:45 am]

BILLING CODE 4184–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0599]

Proposed Information Collection Activity; Office of Refugee Resettlement Services for Survivors of Torture Program Data Points and Performance Progress Report

AGENCY: Office of Refugee Resettlement, 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) Office of Refugee Resettlement (ORR) intends to continue collecting demographic, programmatic, and outcome data on Services for Survivors of Torture (SOT) grant recipients and the clients they serve. ORR collects information from the grantee cohort under the Survivors of Torture Program Data Points (PDP) and Program Performance Progress Report (PPR) (Office of Management and Budget (OMB) #: 0970–0599; Expiration date: February 28, 2026) to learn more about the populations served; the types and effectiveness of services provided; methods, challenges, and facilitators of implementing services; and grant recipients' progress towards programmatic goals. Revisions are proposed as described in the discussion section that follows.

DATES: Comments due February 17, 2026.

ADDRESSES: 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. 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: ORR proposes to continue to use the PDP Form and PPR, with revisions, to collect data on the Services for SOT grant recipients and their clients. The Recipients will continue to report their PDP through the ORR Refugee Arrivals Data System (RADS), an information technology platform used for enhanced data collection and record keeping.

Grant recipients will provide aggregated data on new and continuing clients annually, including demographic information, characteristics related to experiences of torture, services received, length of service, and wellbeing across six outcome domains.

Grant recipients will also provide information about community attendance at trainings and pro-bono services donated to the program. In the PPR, grant recipients will provide program narrative and program metric information on grant-funded activities and progress towards grant goals semi-annually.

Information collected will be used in aggregate by ORR to provide reports to stakeholders, including a required Report to Congress, and responses to funding requests.

ORR has made changes to the data collection, which include removing a total of twelve subcategories for two program indicators and reducing the frequency of reporting percentage-based outcomes in the program metrics. ORR has also added one subcategory in one program indicator. Overall, these changes have reduced the estimated reporting burden by 30 percent.

Respondents: Services for SOT grant programs (this may include non-profit social service, health, and higher education organizations, states, municipalities, and for-profit organizations).

Annual Burden Estimates

Estimated annual burden has been updated to reflect a reduction in estimated time per response from an average of 6 hours per response to an average of 4 hours per response.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
PDP Form	35	1	4.2	147
PPRs—Parts A and B	35	2	4.2	294
Total Annual Burden	.....	.....	.....	441

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: Section 5(a) of the ''Torture Victims Relief Act of 1998,'' Public Law 105–320 (22 U.S.C. 2152 note) Assistance for Treatment of Torture Victims.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–23145 Filed 12–17–25; 8:45 am]

BILLING CODE 4184–46–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0554]

Correction to Published Federal Register Notice; Office of Management and Budget Review Placement and Transfer of Unaccompanied [Alien] Children Into Office of Refugee Resettlement Care Provider Facilities

AGENCY: Office of Refugee Resettlement, Administration for Children and

Families, Department of Health and Human Services.

ACTION: Notice; correction.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services published a notice in the **Federal Register** on September 30, 2025 inviting public comments on a request to extend approval of forms approved for the Placement and Transfer of Unaccompanied [Alien] Children into ORR Care Provider Facilities. Prior to publishing the notice, ORR received emergency approval from the Office of Management and Budget (OMB) for revisions to two forms included in this collection of forms: Form P–7 and Form P–4. The incorrect version of form P–7 was inadvertently approved and distributed for public comment.

FOR FURTHER INFORMATION CONTACT: ACF Paperwork Reduction Act Staff; *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection. The correct version of P–7 is now available here: *https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202512-0970-002*.

DATES: *Comments due* January 20, 2026.

SUPPLEMENTARY INFORMATION:

Correction

Federal Register Document Number 2025–18927 (90 FR 46898) requested public comment on information collection materials to be submitted to OMB for extension beyond the current expiration date of February 28, 2025. The incorrect version of form P–7 was inadvertently approved and distributed for public comment, but is now available here: *https://www.reginfo.gov/public/do/PRAICList?ref_nbr=202512-0970-002* and available for comment by emailing *infocollection@acf.hhs.gov.*

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–23265 Filed 12–17–25; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4395]

Use of Real-World Evidence To Support Regulatory Decision-Making for Medical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance entitled ''Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices.'' FDA is issuing this guidance to clarify how FDA evaluates real-world data (RWD) to determine whether they are of sufficient quality for generating real-world evidence (RWE) that can be used in FDA regulatory decision-making for medical devices. This final guidance supersedes the final guidance, ''Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices,'' issued August 31, 2017, and provides expanded and updated recommendations.

DATES: The announcement of the guidance is published in the **Federal Register** on December 18, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2023–D–4395 for ''Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices.'' 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.