

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
RFP and Contract	50	4.5	4	900	300
Emergency Funding Request	21	1	2	42	14
Biennial Reports	54	1.5	1.5	121.5	40.5
Advance Planning Document	44	3.6	120	19,008	6,336
Operational Advance Planning Document	10	3	30	900	300
Independent Verification and Validation (ongoing)	3	12	10	360	120
Independent Verification and Validation (semiannually)	4	6	16	384	128
Independent Verification and Validation (quarterly)	10	12	30	3,600	1,200
System Certification	3	3	240	2,160	720

Estimated Total Annual Burden Hours: 9,158.50.

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: 45 CFR part 95, subpart F.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023-24211 Filed 11-1-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; State Plan for Grants to States for Refugee Resettlement (Office of Management and Budget #0970-0351)

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) is requesting a 3-year extension of the State Plan for Grants to States for Refugee Resettlement (Office of Management and Budget #0970-0351, expiration 6/30/2024). ORR is proposing changes to the form.

DATES: *Comments due within 60 days of publication.* 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: A State Plan is a required comprehensive narrative description of the nature and scope of a state's or Replacement Designee's (RD) Refugee Resettlement Program and provides assurances that the program will be administered in conformity with the specific requirements stipulated in 45 CFR 400.4-400.9. The State Plan must include all applicable state or RD procedures, designations, and certifications for each requirement as well as supporting documentation. The

plan assures ORR that the state or RD is capable of administering refugee assistance and coordinating employment and other social services for eligible caseloads in conformity with specific requirements.

ORR proposes the following changes to the previously approved State Plan for Grants to States for Refugee Resettlement:

- streamlining/formatting multiple sections of the form, including technical corrections
- enhancing requirements for collaboration and engagement and expanding the non-discrimination aspects
- standardizing sections of the template related to health to reduce burden by clarifying text and removing duplicative parts
- streamlining sections related to the unaccompanied children to reduce burden by providing better options for responses and selections and by removing unnecessary and confusing text to ensure consistency regarding assurances

Respondents: State agencies and RDs under 45 CFR 400.301(c) administering or supervising the administration of programs.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
State Plan for Grants to States for Refugee Resettlement	59	1	18	1,062

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: 8 U.S.C. 1522 of the Immigration and Nationality Act (the Act) [Title IV, Sec. 412 of the Act] for each state agency requesting federal funding for refugee resettlement under 8 U.S.C. 524 [Title IV, Sec. 414 of the Act].

Mary Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-2809]

Advisory Committee; Patient Engagement Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the renewal of the Patient Engagement Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the Patient Engagement Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the October 6, 2025, expiration date.

DATES: Authority for the Patient Engagement Advisory Committee would have expired on October 6, 2025, unless the Commissioner had formally determined that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Letise Williams, Office of the Center

Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5407, Silver Spring, MD 20993-0002, 301-796-8398, Letise.Williams@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Patient Engagement Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established to provide advice to the Commissioner. The Patient Engagement Advisory Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective devices for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee provides advice to the Commissioner of Food and Drugs or designee on complex scientific, issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes, and device-related quality of life measures or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

Pursuant to its Charter, the Committee shall consist of a core of nine voting members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities who are knowledgeable in areas such as clinical research, patient experience, and healthcare needs of patient groups in the United States, or who are experienced in the work of patient and health professional organizations, methodologies for patient reported outcomes and eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects, as well as other relevant areas. Members will be invited

to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as either as Special Government Employees or non-voting representatives. Federal members will serve as Regular Government Employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who serves as an individual, but who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic.

The Commissioner or designee shall also have the authority to select members of other scientific and technical FDA advisory committees (normally not to exceed 10 members) to serve temporarily as voting members and to designate consultants to serve temporarily as voting members when: (1) expertise is required that is not available among current voting standing members of the Committee (when additional voting members are added to the Committee to provide needed expertise, a quorum will be based on the combined total of regular and added members); or (2) to comprise a quorum when, because of unforeseen circumstances, a quorum is or will be lacking. Because of the size of the Committee and the variety in the types of issues that it will consider, FDA may, in connection with a particular committee meeting, specify a quorum that is less than a majority of the current voting members. The Agency's regulations (21 CFR 14.22(d)) authorize a committee charter to specify quorum requirements.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees,