federal building innovations in planning, design, and operations to reduce costs, enable agency missions, enhance human health and performance, and minimize environmental impacts.

The purpose of the GBAC Meeting is to convene experts in buildings, including architects, material suppliers, construction contractors, environment, health, security and transportation to accelerate the successful transformation of the Federal building portfolio to sustainable technologies and practices.

The *Building and Grid Integration Task Group, Phase II* will build on the recommendations of the first phase of this Task Group, to prioritize federal building and grid integration strategies and develop implementation plans and scenarios with future rate structures, including consideration of EVs and energy storage.

The *Data-Integrated Building Systems Task Group* will document and recognize data-integrated building system (*e.g.,* smart building system) use cases that demonstrate the business case and quantify the multiple benefits of integrating building technologies and systems.

The conference calls will allow the task groups to develop consensus recommendations to the full Committee, which will, in turn, decide whether to proceed with formal advice to GSA based upon these recommendations.

Meeting participants will provide advice and expertise regarding how the Office of Federal High-Performance Buildings can most effectively accomplish its mission. Subcommittees will present their findings to the full committee for feedback and direction. Participants will discuss topics about which the Committee would like to engage, especially those related to market failures that the Federal government might substantially impact with cost-effective solutions.

Procedures for Attendance and Public Comment

Contact Mr. Michael Bloom at *michael.bloom@gsa.gov* to register to attend the in-person meeting or listen to any of these conference calls. To attend any of these events, submit your full name, organization, email address, and phone number, and which you would like to attend. Requests to attend the conference calls must be received by 5:00 p.m. EDT; on Friday, January 4, 2019 (GSA will be unable to provide technical assistance to any listener experiencing technical difficulties. Testing access to the Web meeting site before the calls is recommended). Requests to attend the May 16, 2019 meeting must be received by 5:00 p.m., EDT, on Friday, January 4, 2019.

Contact Mr. Bloom to register to comment during the May 16, 2019 meeting public comment period. Registered speakers/organizations will be allowed a maximum of five (5) minutes each, and will need to provide written copies of their presentations. Requests to comment at the meeting must be received by 5:00 p.m., EDT, on Friday, January 4, 2019. Written comments may be provided to Mr. Bloom by the same deadline.

May 16, 2019 Meeting Agenda

- Updates and introductions.
- Building-grid integration task group findings & recommendations.
- Lunchtime speaker (TBD).
- Data-integrated building systems task group findings & recommendations.
- Additional topics proposed by Committee members.
- Public comment.
- Next steps and closing comments.

Dated: December 12, 2018.

Kevin Kampschroer,

Federal Director, Office of Federal High-Performance Buildings, General Services Administration.

[FR Doc. 2018–27437 Filed 12–18–18; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: U.S. Repatriation Program Forms

OMB No.: 0970–0474

Description: The United States (U.S.) Repatriation Program was established by Title XI, Section 1113 of the Social Security Act (Assistance for U.S. Citizens Returned from Foreign Countries) to provide temporary assistance to U.S. citizens and their dependents who have been identified by the Department of State (DOS) as having returned, or been brought from a foreign country to the U.S. because of destitution, illness, war, threat of war, or a similar crisis, and are without available resources immediately accessible to meet their needs. The Secretary of the Department of Health and Human Services (HHS) was provided with the authority to administer this Program. On or about 1994, this authority was delegated by the HHS Secretary to the Administration for Children and Families (ACF) and later re-delegated by ACF to the Office of Refugee Resettlement. The Repatriation Program works with States, Federal agencies, and non-governmental organizations to provide eligible individuals with temporary assistance for up to 90-days. This assistance is in the form of a loan and must be repaid to the Federal Government.

The Program was later expanded in response to legislation enacted by Congress to address the particular needs of persons with mental illness (24 U.S.C. Sections 321 through 329). Further refinements occurred in response to Executive Order (E.O.) 11490 (as amended) where HHS was given the responsibility to ''develop plans and procedures for assistance at ports of entry to U.S. personnel evacuated from overseas areas, their onward movement to final destination, and follow-up assistance after arrival at final destination.'' In addition, under E.O. 12656 (53 CFR 47491), ''Assignment of emergency preparedness responsibilities,'' HHS was given the lead responsibility to develop plans and procedures in order to provide assistance to U.S. citizens and others evacuated from overseas areas.

In order to effectively and efficiently manage these legislative authorities, the Program has been divided into two major activities, Emergencies and Non-Emergencies Repatriation Activities. Operationally, these two Program activities involve different kinds of preparation, resources, and implementation. However, the core Program statute, regulations, policies and administrative procedures for these two Programs are essentially the same. The ongoing routine arrivals of individual repatriates and the repatriation of individuals with mental illness constitute the Program Non-emergency activities. Emergency Activities are characterized by contingency events such as civil unrest, war, threat of war or similar crisis, among other incidents. Depending on the type of event, number of evacuees and resources available, ACF will provide assistance utilizing two scalable mechanisms, emergency repatriations or group repatriations. Emergency repatriations assume the evacuation of 500 or more individuals, while group repatriations assume the evacuation of 50–500 individuals.

The Program provides services through agreements with the States, U.S. Territories, Federal agencies, and Non-governmental agencies. The list of Repatriation Forms is as follows:

1. *The HHS Repatriation Program: Emergency and Group Processing Form:*

Under 45 CFR 211 and 212, HHS is to make findings setting forth the pertinent facts and conclusions according to established standards to determine whether an individual is an eligible person. This form allows authorized staff to gather necessary information to determine eligibility and needed services. This form is to be utilized during emergency repatriation activities. Individuals interested in receiving Repatriation assistance will complete appropriate portions of this form. State personnel assisting with initial intake activities will use this form as a guide to perform a preliminary eligibility assessment. An authorized federal staff from the ACF will make final eligibility determinations.

2. *The HHS Repatriation Program: Privacy and Repayment Agreement Form:* Under 45 CFR 211 and 212, individuals who receive Program assistance are required to repay the federal government for the cost associated to the services received. This form authorizes HHS to release personal identifiable information to partners for the purpose of providing services to eligible repatriates. In addition, through this form, eligible repatriates agree to accept services under the terms and conditions of the Program. Specifically, eligible repatriates commit to repay the federal government for all temporary services received through the Program. This form is to be completed by eligible repatriates or authorized legal custodians. Exemption applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

3. The HHS Repatriation Program: Refusal of Temporary Assistance Form: For individuals who are eligible to receive repatriation assistance but opt to relinquish services, this form is utilized to confirm and record repatriate's decision to refuse receiving Program assistance. This form is to be completed by eligible repatriates or authorized legal custodian. Exemption applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

4. *The HHS Repatriation Program: Emergency and Group Repatriation Financial Form:* Under Section 1113 of the Social Security Act, HHS is authorized to provide temporary assistance directly or through utilization of the services and facilities of appropriate public or private agencies and organizations, in accordance with agreements providing for payment, as may be determined by HHS. This form is to be utilized and completed by agencies that have entered into an agreement with ORR to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services.

5. *The HHS Repatriation Program: Non-emergency Monthly Financial Statement Form:* Under Section 1113 of the Social Security Act, HHS is authorized to provide temporary assistance directly or through arrangements, in accordance with agreements providing for payment, as may be determined by HHS. This form is to be utilized and completed by the States and other authorized ORR agencies to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services, associated to the direct provision of temporary assistance to eligible repatriates.

6. *The HHS Repatriation Program: Repatriation Loan Waiver and Deferral Request Form:* In accordance with 45 CFR 211 & 212 individuals who have received Repatriation assistance may be eligible to receive a waiver or deferral of their repatriation loan. This form is to be completed by eligible repatriates, authorized legal custodian, or authorized agency/individual. Exemption applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

7. *The HHS Repatriation Program: Temporary Assistance Extension Request Form:* Under 45 CFR 211 & 212 temporary assistance may be furnished beyond the 90 days eligibility period if the repatriate meets the qualifications established under Program regulations. This form is to be completed by the eligible repatriate, authorized legal custodian, or the authorized agency/individual. This form should be submitted to ORR or its designated grantee generally 14 -day prior to the expiration of the 90 days eligibility period.

8. *The HHS Repatriation Program: State Request for Federal Support Form:* During emergency repatriation activities, States activated by ORR are to use this form to request support and/or assistance from HHS, including but not limited to required pre-approval of expenditures, augmentation of State personnel, funding, reimbursement, among other things.

Respondents: Designated state, federal, and/or non-governmental agencies/individuals and eligible repatriates. Responders are authorized by 42 U.S.C. 1313 and 24 U.S.C. 321–329; Executive Order 12656 (as amended by E.O. 13074, February 9, 1998; E.O. 13228, October 8, 2001; E.O. 13286, February 28, 2003); and regulations found under 45 CFR 211 & 212.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
The HHS Repatriation Program: Emergency and Group Processing Form.	25,000 or more depending on the Emergency.	1	0.30	7,500 or more.
The HHS Repatriation Program: Privacy and Repayment Agreement Form.	1,000 will increase during emergencies.	1	0.05	50 or more.
The HHS Repatriation Program: Refusal of Temporary Assistance Form.	15 or more	1	0.05	0.75 or more.
The HHS Repatriation Program: Emergency and Group Repatriation Financial Form.	15 or more	1	0.30	4.5 or more.
The HHS Repatriation Program: Non-emergency Monthly Financial Statement Form.	52 or more	12	0.30	187 or more.
The HHS Repatriation Program: Repatriation Loan Waiver and Referral Request Form.	800 or more	1	0.30	240 or more.
The HHS Repatriation Program: State Request for Federal Support.	20 or more	1	0.30	6 or more.
The HHS Repatriation Program: Temporary Assistance Extension Request Form.	50 or more	1 or more	0.30	15 or more.

Estimated Total Annual Burden Hours: 8,003.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning 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. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–27398 Filed 12–18–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–5966]

Breakthrough Devices Program; 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 or Agency) is announcing the availability of the final guidance entitled ''Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff.'' This guidance document describes policies that FDA intends to use to implement the new Breakthrough Devices Program, established by the 21st Century Cures Act (Cures Act). The Breakthrough Devices Program supersedes and combines elements from FDA's Expedited Access Pathway (EAP), which was intended to facilitate the development and expedite review of certain devices that demonstrate the potential to address unmet medical needs, as well as the Priority Review Program, which implemented statutory criteria for granting priority review to premarket approval applications (PMAs) and applied those criteria to other types of premarket submissions for medical devices. This guidance is intended to clarify certain principles and features of the new program, the designation criteria for Breakthrough Devices, the designation request review process, the process for withdrawing from the program, as well as the recommended information device manufacturers should provide in their designation request for entrance into the program.

DATES: The announcement of the guidance is published in the **Federal Register** on December 19, 2018.

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–2017–D–5966 for ''Breakthrough Devices Program; Guidance for Industry and Food and Drug Administration Staff.'' 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.

- 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.gpo.gov/fdsys/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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for