

under the authority of the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. Chapter 35).

VII. Executive Order 12866 Statement

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget.

Dated: March 15, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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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 Human Services Emergency Preparedness and Response (OHSEPR). 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 to provide assistance to U.S. citizens and others evacuated from overseas.

In order to effectively and efficiently manage these legislative authorities, the Program has been divided into two major activities, Emergency and Non-Emergency Repatriation. 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 using 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. *Emergency and Group Processing Form (RR-01):* During an emergency repatriation, individuals complete portions of this form to apply for repatriation assistance. Then State personnel use the form to perform a preliminary eligibility assessment. Authorized ACF staff make final eligibility decisions.

2. *Emergency and Group Repatriation Financial Form (RR-02):* States and supporting agencies complete this form if they have entered into an agreement

with OHSEPR allowing for reimbursement of reasonable and allowable costs during emergency repatriation activities.

3. *Repatriation Loan Waiver and Deferral Request Form (RR-03):* Eligible repatriates, authorized legal custodians, or authorized state staff complete this form to request a waiver or deferral of a repatriation loan.

4. *Non-Emergency Monthly Financial Statement Form (RR-04):* States and other authorized OHSEPR agencies use this form to request reimbursement of reasonable and allowable costs for the provision of temporary assistance during non-emergency activities.

5. *Privacy and Repayment Agreement Form (RR-05):* This form authorizes HHS to release personally identifiable information to appropriate agencies for the purpose of providing services. In addition, through this form, eligible repatriates or authorized legal custodians agree to accept services under the Program’s terms and conditions, which include repaying the federal government for services received.

6. *Refusal of Temporary Assistance Form (RR-06):* Eligible repatriates or authorized legal custodians use this form to confirm and record their decision to relinquish repatriation services.

7. *Temporary Assistance and Extension Request Form (RR-07):* To request an extension of assistance beyond the 90-day eligibility period, eligible repatriates, authorized legal custodians, or authorized state staff submit this form to OHSEPR or its designated grantee generally 14 days prior to the expiration of the repatriate’s eligibility period.

8. *Emergency and Group Repatriation State Request for Federal Support Form (RR-08):* During emergency repatriation activities, OHSEPR-activated states must use this form to request support and/or assistance from the federal government, including but not limited to augmentation of personnel, funding, and reimbursement.

Respondents: Designated state, federal, and/or non-governmental agencies and 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

| Form | Number of respondents | Frequency of the response | Average burden hours per response | Total annual burden hours |
|---|-----------------------|---------------------------|-----------------------------------|---------------------------|
| Emergency and Group Processing Form | 25,000 | 1 | 0.30 | 7,500 |
| Privacy and Repayment Agreement Form | 25,000 | 1 | 0.05 | 1,250 |
| Refusal of Temporary Assistance Form | 15 | 1 | 0.05 | 0.75 |
| Emergency and Group Repatriation Financial Form | 15 | 1 | 0.30 | 4.5 |
| Non-Emergency Monthly Financial Statement Form | 52 | 12 | 0.30 | 187 |
| Repatriation Loan Waiver and Deferral Request Form | 800 | 1 | 0.30 | 240 |
| Emergency and Group Repatriation State Request for Federal Support Form | 20 | 1 | 0.30 | 6 |
| Temporary Assistance and Extension Request Form | 50 | 1 | 0.30 | 15 |

Estimated Total Annual Burden Hours: 9203.25.

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, 330 C St. SW, Washington, DC 20201, 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.

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-0914]

Review and Update of Device Establishment Inspection Processes and Standards; 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 the draft

guidance entitled “Review and Update of Device Establishment Inspection Processes and Standards.” FDA is issuing this draft guidance document to comply with changes to the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the FDA Reauthorization Act of 2017 (FDARA), which requires that FDA review and update, as needed, the processes and standards applicable to inspections (other than for-cause) of domestic and foreign medical device establishments in place as of August 18, 2017. This draft guidance describes how FDA will implement uniform inspection processes and standards. The draft guidance also describes standardized methods of communication during the inspection process and identifies practices for investigators and device establishments to facilitate the continuity of inspections of such establishments. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by May 28, 2019 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-2019-D-0914 for “Review and Update of Device Establishment Inspection Processes and Standards.” 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