

coverage options provided under [Medicare Advantage] in order to promote an active, informed selection among such options.”

The Panel is also authorized by section 1114(f) of the Act (42 U.S.C. 1314(f)) and section 222 of the Public Health Service Act (42 U.S.C. 217a). The Secretary signed the charter establishing this Panel on January 21, 1999 (64 FR 7899, February 17, 1999) and approved the renewal of the charter on January 21, 2011 (76 FR 11782, March 3, 2011).

Pursuant to the amended charter, the Panel advises and makes recommendations to the Secretary of Health and Human Services and the Administrator of the Centers for Medicare & Medicaid Services (CMS) concerning optimal strategies for the following:

- Developing and implementing education and outreach programs for individuals enrolled in, or eligible for, Medicare, Medicaid and the Children’s Health Insurance Program (CHIP).
- Enhancing the federal government’s effectiveness in informing Medicare, Medicaid and CHIP consumers, providers and stakeholders pursuant to education and outreach programs of issues regarding these and other health coverage programs, including the appropriate use of public-private partnerships to leverage the resources of the private sector in educating beneficiaries, providers and stakeholders.
- Expanding outreach to vulnerable and underserved communities, including racial and ethnic minorities, in the context of Medicare, Medicaid and CHIP education programs.
- Assembling and sharing an information base of “best practices” for helping consumers evaluate health plan options.
- Building and leveraging existing community infrastructures for information, counseling and assistance.
- Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under health care reform.

The current members of the Panel are: Samantha Artiga, Principal Policy Analyst, Kaiser Family Foundation; Joseph Baker, President, Medicare Rights Center; Philip Bergquist, Manager, Health Center Operations, CHIPRA Outreach & Enrollment Project and Director, Michigan Primary Care Association; Marjorie Cadogan, Executive Deputy Commissioner,

Department of Social Services; Jonathan Dauphine, Senior Vice President, AARP; Barbara Ferrer, Executive Director, Boston Public Health Commission; Shelby Gonzales, Senior Health Outreach Associate, Center on Budget & Policy Priorities; Jan Henning, Benefits Counseling & Special Projects Coordinator, North Central Texas Council of Governments’ Area Agency on Aging; Warren Jones, Executive Director, Mississippi Institute for Improvement of Geographic Minority Health; Cathy Kaufmann, Administrator, Oregon Health Authority; Sandy Markwood, Chief Executive Officer, National Association of Area Agencies on Aging; Miriam Mobley-Smith, Dean, Chicago State University, College of Pharmacy; Ana Natale-Pereira, Associate Professor of Medicine, University of Medicine & Dentistry of New Jersey; Megan Padden, Vice President, Sentara Health Plans; Winston Wong, Medical Director, Community Benefit Director, Kaiser Permanente and Darlene Yee-Melichar, Professor & Coordinator, San Francisco State University. The agenda for the September 16, 2013 meeting will include the following:

- Welcome and Listening Session with CMS Leadership
- Recap of the Previous (June 24, 2013) Meeting
- Affordable Care Act Initiatives
- An Opportunity for Public Comment
- Meeting Summary, Review of Recommendations and Next Steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make a presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

Authority: Sec. 222 of the Public Health Service Act (42 U.S.C. 217a) and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR 102–3).

(Catalog of Federal Domestic Assistance Program No. 93.733, Medicare—Hospital Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: August 27, 2013.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2013–21241 Filed 8–29–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: U.S. Repatriation Program Forms.

OMB No.: 0970—NEW.

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. 321 through 329). Further refinements occurred in response to Executive Order (EO) 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 EO 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.

Overall, the Program manages two major activities, Emergency and Non-emergency Repatriation Activities. The ongoing routine arrivals of individual repatriates and the repatriation of individuals with mental illness constitute the Program Non-emergency activities. Emergency activities are comprised of group repatriations (evacuations of 50–500 individuals) and emergency repatriations (evacuations of 500 or more individuals). Operationally, these activities involve different kinds of preparation, resources, and implementation. However, the core Program policies and administrative procedures are essentially the same. The Program provides services through agreements with local repatriation service providers (e.g. States, federal agencies, non-governmental agencies, etc.). For the purpose of this Program, local repatriation service provider (local provider) has the same definition of "agency" as defined under 45 CFR 212.1(i).

1. *The HHS Repatriation Program Emergency and Group Processing Form:* Under 45 CFR parts 211 and 212, ORR 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 emergencies and group repatriations. Individuals interested in receiving Repatriation assistance will complete appropriate portions of this form. State personnel will utilize this form as a guide to perform an initial eligibility and needs assessment. An authorized federal staff from the ACF will make final eligibility determinations through the approval of this form.

2. *The U.S. Repatriation Program Privacy and Repayment Agreement*

Form: Under 45 CFR parts 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 ORR 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 services received while in the Program. This form is to be completed by eligible repatriates or authorized legal custodian. Exception applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

3. *Relinquish Repatriation Services 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 Program assistance. This form is to be completed by eligible repatriates or authorized legal custodian. Exception applies to unaccompanied minors and individuals eligible under 45 CFR 211, if no legal custodian is identified.

4. *The U.S. Repatriation Program Emergency Financial Form:* Under Section 1113 of the Social Security Act, ORR 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 ORR. This form is to be utilized and completed by ORR local providers to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services, after emergency activities.

5. *The U.S. Repatriation Program Non-Emergency Reimbursement Form:* Under Section 1113 of the Social Security Act, ORR is authorized to provide temporary assistance directly or through arrangements, in accordance

with agreements providing for payment, as may be determined by ORR. This form is to be utilized and completed by ORR local providers to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services.

6. *The U.S. Repatriation Program Financial Waiver Request Form:* In accordance with 45 CFR parts 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 the repatriation local provider. Exception applies to unaccompanied minors and individuals eligible under 45 CFR part 211, if no legal custodian is identified.

7. *The U.S. Repatriation Program Temporary Assistance Extension Request Form:* Under 45 CFR parts 211 & 212 temporary assistance may be furnished beyond the 90 days eligibility period. This form is to be completed by the eligible repatriates, authorized legal custodian, or the repatriation local provider. This form should be submitted to ORR or its authorized grantee 14 days prior to the expiration of the 90 days eligibility period.

8. *The U.S. Repatriation Program Individual Case Management Report and Financial Claim Form:* Under Section 1113 of the Social Security Act, ORR is authorized to provide temporary assistance directly or through agreements with public and private agencies. This form is to be utilized and completed by ORR local provider to request reimbursement of reasonable and allowable costs, both administrative and actual temporary services. This form should also be utilized by the local repatriation provider for submit case updates. This forms is to be completed by authorized local providers.

Respondents: Repatriation Program local repatriation service provider and individuals repatriated or evacuated by DOS from overseas.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
U.S. Repatriation Program Emergency and Group Processing Form.	500 or more	1	0.15	75 or more.
U.S. Repatriation Program Privacy and Repayment Agreement Form.	1000 or more	1	0.05	50 or more.
U.S. Repatriation Program Relinquish Temporary Assistance Form	50 or more	1	0.05	0.8 or more.
U.S. Repatriation Program Emergency and Group Financial Form	4 or more	1	0.20	4 or more.
U.S. Repatriation Program Non-emergency Monthly Financial Statement Form.	53 or more	1	0.20	10.6 or more.

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
U.S. Repatriation Program Loan Waiver Request Form	100 or more	1	1	100 or more.
U.S. Repatriation Program Temporary Assistance Extension Request Form.	500 or more	1	0.20	100 or more.
U.S. Repatriation Program Individual Case Management Report	1000 or more	1 or more	0.20	200 or more.

Estimated Total Annual Burden Hours: 540.4.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded 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. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

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.

Robert Sargis,
Reports Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0519]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry # 108 on How To Submit Information in Electronic Format to the Center for Veterinary Medicine Using the Food and Drug Administration Electronic Submission Gateway

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 30, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0454 and title "Guidance for Industry # 108 on How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry # 108 on How To Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway—21 CFR 11.2 (OMB Control Number 0910-0454)—Extension

The Center for Veterinary Medicine (CVM) accepts certain types of submissions electronically with no requirement for a paper copy. These types of documents are listed in public docket 97S-0251 as required by § 11.2 (21 CFR 11.2). CVM's ability to receive and process information submitted electronically is limited by its current information technology capabilities and the requirements of the Electronic Records; Electronic Signatures final regulation. CVM's guidance entitled "Guidance for Industry # 108: How to Submit Information in Electronic Format to CVM Using the FDA Electronic Submission Gateway" outlines general standards to be used for the submission of any information by email. The likely respondents are sponsors for new animal drug applications.

In the **Federal Register** of May 16, 2013 (78 FR 28851), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR Part and Form FDA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 11.2; Form FDA 3538	65	2.4	156	.08 (5 minutes)	13 (Rounded from 12.5)

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.