instrumental in bringing attention to emerging issues in chronic HIV infection with actionable opportunities for prevention, including cardiovascular disease, fragility fractures, renal and hepatic disease, and cancers. The HOPS remains an important source for multi-year trend data concerning conditions and behaviors for which data are not readily available elsewhere, including: Rates of opportunistic illnesses, rates of comorbid conditions (*e.g.,* hypertension, obesity, diabetes) and antiretroviral drug resistance.

Data will be collected through medical record abstraction by trained abstractors and by telephone or internet-based, computer-assisted interviews at nine funded study sites in six U.S. cities. Collection of data abstracted from patient medical records provides data in five general categories: Demographics and risk behaviors for HIV infection; symptoms; diagnosed conditions (definitive and presumptive); medications prescribed (including dose, duration, and reasons for stopping); all laboratory values, including CD4+ T-lymphocyte (CD4+) cell counts, plasma HIV–RNA determinations, and genotype, phenotype, and trophile results. Data on visit frequency, AIDS, and death are acquired from the clinic chart.

Data collected using a brief Telephone Audio-Computer Assisted Self-Interview (T–ACASI) survey or an identical Web-based Audio-Computer Assisted Self-Interview (ACASI) include: Age, sex at birth, use of alcohol and drugs, cigarette smoking, adherence to antiretroviral medications, types of sexual intercourse, condom use, and disclosure of HIV status to partners.

We anticipate that 450 new HOPS study participants will be recruited annually into the HOPS from a pool of HIV-infected individuals currently in HIV-care at the nine aforementioned clinics (50 patients per site). Patients are approached during one of their routine clinic visits to participate in the HOPS. Patients interested in participating in the HOPS are given detailed information about the nature of the study and provided with written informed consent that must be completed prior to enrollment.

The 450 newly enrolled participants each year will be added to the database of existing participants such that approximately 2,500 participants will be seen in the HOPS each year. Medical record abstractions will be completed on all HOPS participants, and impose no direct burden on HOPS study participants.

Participation of respondents is voluntary. There is no cost to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
HOPS study Patients	Consent form	450	1	15/60	113
HOPS Study Patients	Behavioral survey	2,500	1	7/60	292
Total					405

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[CFDA Number: 93.604]

Announcement of the Award of an Urgent Single-Source Grant to the Center for Survivors of Torture in Dallas, TX.

AGENCY: Office of Refugee Resettlement, ACF, HHS.

ACTION: Announcement of the award of an urgent single-source grant to the Center for Survivors of Torture to provide mental health services for victims of torture.

SUMMARY: The Administration for Children and Families (ACF), Office of Refugee Resettlement (ORR) announces the award of an urgent single-source grant in the amount of $250,000 to the Center for Survivors of Torture (CST) in Dallas, TX, to ensure incoming refugee populations in Texas have access to mental health services.

DATES: The project period for the award is July 1, 2014 through September 29, 2015.

FOR FURTHER INFORMATION CONTACT: Kenneth Tota, Deputy Director, Office of Refugee Resettlement, 901 D. Street SW., Washington, DC 20047. Telephone: 202–401–4858. Email: *kenneth.tota@acf.hhs.gov.*

SUPPLEMENTARY INFORMATION: CST is the only accredited mental health care provider of specialized torture survivor mental health treatment services in Texas and the surrounding area. Many refugees have been victims of torture. Approximately 48,000 individual refugees reside in the areas covered by CST. Texas is a top resettlement location with one of the highest concentrations of refugees in the United States. In the past few years, an increasing need for mental health services has been associated with refugee populations from Iraq, Burma, and Bhutan who have suffered trauma and torture due to war and genocide in those countries. Currently, the U.S. refugee resettlement program is seeing a rise in refugees from the Democratic Republic of Congo (DRC). The United Nations High Commissioner for Refugees has determined this group is particularly at risk due to decades of extreme violence in DRC and recent arrivals have shown a compelling need for mental health services upon resettlement.

CST services are critical to meeting the mental health needs of individuals who have survived torture. They provide evaluation and counseling to children, adolescents, adults, couples, and families. Additionally, CST offers group therapy, psychosocial activities, and medication management. In addition to these direct services, CST also provides training on refugee mental health issues to other organizations in the area, including schools, health clinics, and social services agencies. During the period of April 1, 2013 through March 31, 2014, CST provided free comprehensive mental health services to 355 ORR clients. More than 82 percent of these clients experienced a reduction in symptoms.

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

Melody Wayland,

Senior Grants Policy Specialist, Office of Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1081]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic; Availability

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 (the PRA).

DATES: Fax written comments on the collection of information by February 5, 2015.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0701. 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, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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 on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic; Availability (OMB Control Number 0910–0701)—Extension

The guidance includes recommendations for planning, notification, and documentation for firms that report postmarketing adverse events. The guidance recommends that each firm's pandemic influenza continuity of operations plan (COOP) include instructions for reporting adverse events, including a plan for the submission of stored reports that were not submitted within regulatory timeframes. The guidance explains that firms that are unable to fulfill normal adverse event reporting requirements during an influenza pandemic should: (1) Maintain documentation of the conditions that prevent them from meeting normal reporting requirements; (2) notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist and when the reporting process is restored; and (3) maintain records to identify what reports have been stored.

Based on the number of manufacturers that would be covered by the guidance, we estimate that approximately 5,000 firms will add the following to their COOP: (1) Instructions for reporting adverse events; and (2) a plan for submitting stored reports that were not submitted within regulatory timeframes. We estimate that each firm will take approximately 50 hours to prepare the adverse event reporting plan for its COOP.

We estimate that approximately 500 firms will be unable to fulfill normal adverse event reporting requirements because of conditions caused by an influenza pandemic and that these firms will notify the appropriate FDA organizational unit responsible for adverse event reporting compliance when the conditions exist. Although we do not anticipate such pandemic influenza conditions to occur every year, for purposes of the PRA, we estimate that each of these firms will notify FDA approximately once each year, and that each notification will take approximately 8 hours to prepare and submit.

Concerning the recommendation in the guidance that firms unable to fulfill normal adverse event reporting requirements maintain documentation of the conditions that prevent them from meeting these requirements, maintaining records to identify what adverse event reports have been stored, and when the reporting process is restored. We estimate that approximately 500 firms will each need approximately 8 hours to maintain the documentation and approximately 500 firms will each need approximately 8 hours to maintain the records. Therefore, the total recordkeeping burden that would result from the guidance would be 258,000 hours.

The guidance also refers to previously approved collections of information found in FDA's adverse event reporting requirements in 21 CFR 310.305, 314.80, 314.98, 600.80, 606.170, 640.73, 1271.350, and part 803. These regulations contain collections of information that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520) and are approved under OMB control numbers 0910–0116, 0910–0291, 0910–0230, 0910–0308, 0910–0437, and 0910–0543. In addition, the guidance also refers to adverse event reports for nonprescription human drug products marketed without an approved application and dietary supplements required under sections 760 and 761 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379aa and 379aa–1), which include collections of information approved under OMB control numbers 0910–0636 and 0910–0635.

In the **Federal Register** of August 11, 2014 (79 FR 46839), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment. The comment said that during an influenza pandemic, FDA should not put forth a policy of reduced reporting, especially for newly approved drugs and vaccines. The comment recommended that FDA ask companies to modify their contingency plans by either leveraging the company's remote call center locations not affected by the pandemic or by outsourcing their safety reporting to such locations. The comment stated that at minimum, FDA should require weekly reporting or establish a threshold number of reports that a company must report to FDA. The comment added that FDA should specifically require reporting on newly approved drugs or vaccines for which there is little safety information.

FDA response: The Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic does not describe an approach of reduced reporting during an influenza pandemic. Rather, the guidance states that ''normal adverse event reporting processes should be maintained to the maximum extent possible'' (see section III.C.1, page 3).