

Estimated Total Annual Burden Hours: 2,352.

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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects: ORR, Unaccompanied Children's Program, Division of Children's Services (DCS)

Title: Information Collection and Record Keeping for the Timely Placement and Release of Unaccompanied Children (UC) in ORR Care

OMB No.:

Description:

On March 1, 2003, the Homeland Security Act of 2002, Section 462, transferred responsibilities for the care and placement of unaccompanied children from the Commissioner of the Immigration and Naturalization Service to the Director of the Office of Refugee Resettlement (ORR). ORR is also governed by the provisions established by the Flores Agreement in 1997 and the William Wilberforce Trafficking Victims Protection Reauthorization Act (TVPRA) of 2008.

The ORR Unaccompanied Children's Program provides placement, care,

custody and services for UC until they can be successfully released to a sponsor, are repatriated to their home country, or able to obtain legal status.

Through cooperative agreements and contracts, ORR funds residential care providers that provide temporary housing and other services to unaccompanied children in ORR custody. These care provider facilities are State licensed and must meet ORR requirements to ensure a high level quality of care. They provide a continuum of care for children, including placements in ORR foster care, group homes, shelter, staff secure, secure, and residential treatment centers. The care providers provide children with classroom education, health care, socialization/recreation, vocational training, mental health services, access to legal services, and case management.

Under the law, ORR and its care providers are required to:

(1) Collect information about each UC who is entrusted to the care of ORR in order to determine the most appropriate and least restrictive placement, provide adequate services, and identify qualified sponsors for the timely release of the child or youth. ORR has developed instruments to assess the child or youth and his or her needs and conditions throughout his or her stay with ORR as well as the identification and assessment of potential sponsors. These instruments allow for consistency and compliance of standards across care providers and help ORR monitor programs and identify problems and issues that need corrective action.

(2) Keep up-to-date records to ensure the child or youth's safety and security and care and to provide accountability with all Federal and State, licensing, and other standards by care providers.

(3) Notify UC of their rights and responsibilities under the law, including notice about ORR services, the fact that they have the right to apply for Special Immigrant Juvenile (SIJ) status, and their legal responsibility to attend an immigration hearing.

These tasks are mainly conducted through the ORR online database (The UC Portal), which provides a central location for case records and the documentation of other activities (for example, when a child or youth is transferred to another facility). Many of these records are "auto-populated" on the UC Portal once the original data points are completed (such as DOB, A number, date of initial placement).

The data collection described here pertains to activities involving UC and care providers from initial intakes of UC into ORR care to his or her release from

ORR care. It does not cover information collection for potential sponsors (Submitted via separate OMB request in January 2015.)

ORR has applied the following assumptions to this request:

(1) Items related to tasks that are routine and customary for care providers and others are excluded. This includes quarterly or annual financial or other reports, grant related requests from ORR Project Officers or others for monitoring performance and progress, and third party notifications to other government agencies, such as U.S. Department of Homeland Security (DHS) or U.S. Department of Justice (DOJ). (For financial and other reports, Care Providers use templates posted on http://www.acf.hhs.gov/grants/grants_resources.html#reporting)

(2) Data collection and reporting requirements do not reflect those required by State or local licensing or accreditation requirements.

(3) Acknowledgement of receipt of information or other acknowledgements via signature by either the UC or the care provider or others are not included in this information request as these are administrative in nature in order to help care providers and UC track personal belongings, DHS related documents, medical records, and other important items required by the UC following release from ORR care.

The components of this information request include:

(1) UC Portal Capacity Report: Care providers complete the sections on "In Care" and "Beds in Reserve" as well as the section recording the UC who have been discharged on a daily basis so that ORR Intakes has a complete picture of available beds for UC placements.

(2) The Further Assessment Swift Track (FAST) Placement Tool (Versions for Secure and Staff Secure placements): Initially used by ORR Intakes to determine when a UC warrants a placement in Secure or Staff Secure Care. Care providers must use the tool to update a status for UC who are placed in Secure Care at least every 30 days. (Care providers are not required to re-use tool for UC who have been placed in Staff Secure Care).

(3) Placement Authorization: Auto-generated. Requires a signature from the care provider acknowledging a particular UC placement into their facility.

(4) Notice of Placement in Secure or Staff Secure Facility: Acknowledges UC's placement in a secure or staff secure care provider facility with signature of UC and facility witness.

(5) Initial Intakes Assessment: Biographical information is auto-

populated for care providers based on ORR information obtained at Intakes. Screens for trafficking or other safety concerns, special needs, danger to self and others, medical conditions, mental health concerns.

(6) UC Assessment: Care provider must complete within 7 days of UC's admission, covers biographic, family, legal, migration, medical, substance abuse, and mental health history.

(7) Individual Service Plan: Documents the services that have been provided (for example, number of counseling sessions, educational assessment and classes) and is updated every 30 days. When a child is transferred to a new facility, a new ISP is developed.

(8) UC Case Review Form: Documents any new information not indicated in the UC Assessment.

(9) New Sponsor Form: Identifies any potential sponsor(s) for a particular UC. In addition to serving as a record for a particular case, helps ORR track individuals who are attempting to sponsor numerous UC, which may suggest a possible trafficking or abuse situation.

(10) Transfer Request and Tracking Form: Auto-populated and used to obtain ORR permission for transfer to another care facility. (Filled out by both ORR and care providers) and used to document when a UC is transferred from one facility to another (requires signatures of both facilities).

(11) Long Term Foster Care Placement Memo: When ORR identifies a placement of a UC with a long term foster care facility, the long term foster care provider or national VOLAG receiving the transfer request completes the memo and sends to ORR to ensure

continuity of services and tracking of records for a UC.

(12) Travel Request form for UC Long Term Foster Care: Must be filled out by program at least 10 days prior to travel start date.

(13) Notice of Transfer to ICE Chief Counsel and Change of Address: Required so that the Chief Counsel of ICE may file a Motion for Change of Venue and/or Change of Address with the Executive Office for Immigration Review (EOIR), if applicable, to ensure immigration hearing may proceed.

(14) Care Provider Release Checklist: Care providers must complete and affirm that all documents, forms, and steps are completed in the release process.

(15) Release Request: Provides care provider recommendation for release of a UC to a sponsor. All releases must be approved by ORR prior to UC release.

(16) Discharge Notification: Includes date and type of discharge (transfer, home country, sponsor release) and is sent to ICE.

(17) Verification of Release: Signed by sponsor as notification that named UC has been released according to the law. Sponsor must also acknowledge agreement with the provisions of the Sponsor Care Agreement pertaining to the minor's care, safety, and well-being, and the sponsor's responsibility for ensuring the minor's presence at all future proceedings before the Department of Homeland Security and EOIR.

(18) Child Advocate Referral and Appointment Form: Used by the Child Advocate Program to recommend that ORR appoint an independent child advocate for a victim of child trafficking or in other cases involving vulnerable children.

(19) Notice of Rights Handout and Notice of Rights and Provision of Services: Care providers are required to provide to all UC under the Flores v. Reno Settlement Agreement.

(20) Legal Service Provider List for UC: List of organizations who offer free legal representation and help for UC with State and Federal courts, immigration hearings, and appeals. Required under the Flores Settlement Agreement.

(21) URM Application: Certain populations of children and youth in ORR custody may become eligible for the Unaccompanied Refugee Minors Program, which is a State administered foster care program. In such instances the care provider facility or other interested party may complete this application form on behalf of the child.

(22) Withdrawal of Application or Declination of Placement Form: If a youth who has submitted an application for the URM Program wishes to withdraw this application, or if he or she has been offered placement and wishes to decline this placement, the youth must complete this form.

(23) Standard Shelter Tour Request: Used by members of the public and the media to submit to care providers in order to tour a shelter facility.

Respondents: UC in ORR care and custody (they are generally referred to ORR from the DHS) and who are then referred to ORR's Network of Care Providers.

Staff in ORR's Care Provider Network, including those in shelter care, secure and staff secure care, foster care, and residential treatment centers.

Approved sponsors of UC released from ORR care.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
UC Portal Capacity Report	50	1	.16/hour	8
Further Assessment Swift Track (FAST) Placement Tool	2,320	1	.25/hour	580
Placement Authorization Form	58,000	1	.1/hour	5,800
Notice of Placement in Secure or Staff Secure Facility	2,320	1	.1/hour	232
Initial Intakes Form	58,000	1	.25/hour	14,500
UC Assessment	58,000	1	.50/hour	29,000
Individual Service Plan	58,000	1	.25	14,500
UC Case Review Form	58,000	1	.50/hour	29,000
New Sponsor Form	55,200	1	.25/hour	13,800
Transfer Request and Tracking Form	1,000	1	.25/hour	250
Long Term Foster Care Placement Memo	279	1	.1/hour	28
Travel Request Form for UC Long Term Foster Care	20	1	.25/hour	5
Notice of Transfer to ICE Chief Counsel and Change of Address	2,320	1	.1/hour	232
Care Provider Release Checklist	55,200	1	.1	5,520
Release Request	55,200	3	.25 hour	41,400
Discharge Notification	716	1	.25/hour	179
Verification of Release	55,200	1	.1/hour	5,520
Child Advocate Referral and Appointment Form	250	1	.50	125
Notice of Rights Handout and Notice of Rights and Provision of Services	58,000	1	.1/hour	5,800

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Legal Service Provider List for UC	58,000	1	.1	5,800
URM Application	350	1	1	350
Withdrawal of Application or Declination of Placement Form	10	1	.1/hour	1
Standard Shelter Tour Request	60	1	.1/hour	6

Estimated Total Annual Burden Hours: 172,636.

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-2012-N-0961]

Agency Information Collection Activities; Proposed Collection; Comment Request; Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection entitled "Environmental Impact Considerations."

DATES: Submit either electronic or written comments on the collection of information by November 9, 2015.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA 305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the 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, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the

Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information listed below.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Environmental Impact Considerations—21 CFR Part 25

OMB Control Number 0910-0322

FDA is requesting OMB approval for the reporting requirements contained in the FDA collection of information "Environmental Impact Considerations." The National Environmental Policy Act (NEPA) (42 U.S.C. 4321-4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an