

(Authority: 42 U.S.C. 9858(a)(5); 42 U.S.C. 9835; and 42 U.S.C. 9844)

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Administration and Oversight of the Unaccompanied Alien Children Program (OMB #0970-0547)

**AGENCY:** Office of Refugee Resettlement, Administration for Children and Families, Department of Health and Human Services.

**ACTION:** Request for public comment.

**SUMMARY:** The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is inviting public comments on revisions to an approved information collection. The request consists of several forms that allow the Unaccompanied Alien Children (UAC) Program to monitor care provider facility compliance with federal laws and regulations, legal agreements, and ORR policies and procedures; and perform other administrative tasks.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

#### SUPPLEMENTARY INFORMATION:

*Description:* ORR plans to revise six of the eight instruments currently approved under OMB #0970-0547. Four of the revised instruments will be incorporated into ORR's new case management system, UAC Path. The other two revised instruments are and will remain PDF instruments. In addition, ORR plans to add two new

instruments to this collection, both of which will be incorporated into UAC Path. Finally, ORR plans to remove one currently approved instrument from this collection.

**1. Care Provider Facility Tour Request (Form A-1A):** This instrument is used by advocacy groups, faith-based organizations, researchers, government officials, and other stakeholders to request tours of ORR care provider facilities. After the request is received, ORR documents its decision and details regarding date and location of the tour, if applicable, and provides the completed form to the requester. No revisions are currently requested; ORR plans to continue use of this form as-is.

**2. Notice to UAC for Flores Visits (Forms A-4 & A-4s):** This instrument is used by care provider facilities to notify UAC of upcoming visits by Flores counsel (lawyers and volunteers from the organization that originally participated in the creation of the Flores Settlement Agreement) and allow UAC to add their name to a sign-up sheet if they are willing to speak with Flores counsel. ORR updated the Spanish translation of this PDF instrument.

**3. Authorization for Release of Records (Form A-5):** This instrument is used by attorneys, legal service providers, government agencies, and other stakeholders to request UAC case file records. In most cases, requesters are required to obtain the signature of the subject of the record request (UAC or their parent/legal guardian or sponsor) and a witness. ORR made the following revisions:

- Added a section in which ORR-funded legal service providers are required to certify their representation of the child.
- Added a separate area where sponsors may authorize the release of their records.
- Updated the required supporting documentation for a representative of a federal/state government agency or the National Center for Missing and Exploited Children to further require that the requester specify the scope of their investigation and provide a case reference number.
- Clarified in the instructions that ORR will not release any records that are clearly outside of the scope of a government agency's investigation absent a court-issued subpoena or order.

**4. Notification of Concern (Form A-7):** This instrument is used by home study and post-release service caseworkers, care provider case managers, and the ORR National Call Center to notify ORR of certain concerns that arise after a UAC is released from ORR custody. This

is a new instrument that ORR plans to add to this collection.

**5. Event (Form A-9):** This instrument is used by ORR care provider programs to document high-level information about situations that must be reported to ORR. Creating an *Event* is the first step in creating any type of incident report (see forms A-10A to A-10C below), *PLE Report* (see form A-10D below) or *Notification of Concern* (see form A-7 above). After an *Event* is created, an incident report or *Notification of Concern* is created for each UAC involved in the incident and linked to the *Event*. For program-level events, one *PLE Report* is created and linked to the *Event*. *Event* information is visible in each individual report/notification report. This instrument was previously approved as part of ORR's various incident reports (Forms A-10A to A-10D). ORR is listing it separately, as a new instrument, to better align instruments in this collection with how data will be entered in UAC Path. Some fields that were previously entered in each incident report have been moved into this instrument so that they only need to be entered once. The form also contains several new fields that capture additional information about the location and timeframe of the event. Please note that internal form number A-9 was previously assigned to the Program-Level Event Report.

**6. Emergency Significant Incident Report (SIR) and Addendum (Form A-10A):** This instrument is used by ORR care provider programs to inform ORR of urgent situations in which there is an immediate threat to a child's safety and well-being that require instantaneous action. In some cases, an Emergency SIR Addendum may be required to provide additional information obtained after the initial report. ORR made the following revisions:

- Revised the available options for the category and subcategory fields.
- Added a question asking whether the incident is related to gang/cartel crimes, activities, or affiliation.
- Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.
- Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.
- Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.
- Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated

and notification emails can be sent from within the UAC Path system.

- Updated internal form numbering so that reports and addendums are fall under the same form number.

7. *Significant Incident Report (SIR) and Addendum (Form A-10B)*: This instrument is used by ORR care provider programs to inform ORR of situations that affect, but do not immediately threaten, the safety and well-being of a child. In some cases, an SIR Addendum may be required to provide additional information obtained after the initial report. ORR made the following revisions:

- Revised the available options for the category and subcategory fields.
- Added a question asking whether the incident is related to gang/cartel crimes, activities, or affiliation.

- Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.

- Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.

- Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.

- Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated and notification emails can be sent from within the UAC Path system.

- Updated internal form numbering so that reports and addendums are fall under the same form number.

8. *Sexual Abuse Significant Incident Report (SA/SIR) and Addendum (Form*

*A-10C)*: This instrument is used by ORR care provider programs to inform ORR of allegations of sexual harassment, sexual abuse, and inappropriate sexual behavior that occurred while the UAC was in ORR custody. In some cases, an SA/SIR Addendum may be required to provide additional information obtained after the initial report. ORR made the following revisions:

- Revised the available options for the category and subcategory fields.

- Added a question asking whether the incident is related to gang/cartel crimes, activities, or affiliation.

- Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.

- Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.

- Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.

- Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated and notification emails can be sent from within the UAC Path system.

- Updated internal form numbering so that reports and addendums are fall under the same form number.

9. *Program-Level Event (PLE) Report and Addendum (Form A-10D)*: This instrument is used by ORR care provider programs to inform ORR of events that may affect the entire care provider facility, such as an active shooter or natural disaster. An updated PLE Report is required for events that

occur over multiple days or if the situation changes regarding the event. ORR made the following revisions:

- Revised the available options for the category and subcategory fields.

- Added a question asking whether the incident is related to gang/cartel crimes, activities, or affiliation.

- Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.

- Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.

- Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.

- Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated and notification emails can be sent from within the UAC Path system.

- Updated internal form numbering so that reports and addendums are fall under the same form number.

10. *Hotline Alert (Form A-12)*: ORR is discontinuing this instrument. In UAC Path, the ORR National Call Center will use the Notification of Concern instead of the Hotline Alert.

*Respondents*: ORR grantee and contractor staff; advocacy groups, faith-based organizations, researchers, and government officials; attorneys, legal service providers, child advocates, and government agencies; and other stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual total burden hours
Care Provider Facility Tour Request (Form A-1A) .....	200	1	10	33
Notice to UAC for Flores Visits (Forms A-4 & A-4s) .....	20	1	15	5
Authorization for Release of Records (Form A-5) .....	4,000	1	15	1,000
Notification of Concern (Form A-7) .....	60	75	15	1,125
Event (Form A-9) .....	276	160	10	7,360
Emergency Significant Incident Report and Addendum (Form A-10A) .....	216	14	60	3,024
Significant Incident Report and Addendum (Form A-10B) .....	216	491	60	106,056
Sexual Abuse Significant Incident Report and Addendum (Form A-10C) .....	216	47	60	10,152
Program Level Event (Form A-10D) .....	216	7	60	1,512
Estimated Annual Burden Hours Total .....	.....	.....	.....	130,267

*Comments*: 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.

*Authority:* 6 U.S.C. 279; 8 U.S.C. 1232; Flores v. Reno Settlement Agreement, No. CV85–4544–RJK (C.D. Cal. 1996).

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2019–D–4048]

#### Safer Technologies Program for Medical Devices; 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 a final guidance entitled “Safer Technologies Program for Medical Devices.” This final guidance describes a new, voluntary program for certain medical devices and device-led combination products that are reasonably expected to significantly improve the safety of currently available treatments or diagnostics that target an underlying disease or condition associated with morbidities and mortalities less serious than those eligible for the Breakthrough Devices Program. Devices and device-led combination products are eligible for this program if they are subject to review under a premarket approval application (PMA), De Novo classification request (“De Novo request”), or premarket notification (510(k)), taking into account the specific eligibility factors described in this guidance. Consistent with the Agency’s statutory mission to protect and promote public health, FDA believes that this “Safer Technologies Program” or “STeP” will help patients have more timely access to these medical devices and device-led combination products by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, De Novo marketing authorization, and 510(k) clearance.

**DATES:** The announcement of the guidance is published in the **Federal Register** on January 6, 2021.

**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–2019–D–4048 for “Safer Technologies Program for Medical Devices.” 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, 240–402–7500.

- **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.govinfo.gov/content/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, 240–402–7500.

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 information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled “Safer Technologies Program for Medical Devices” to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002 or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

**FOR FURTHER INFORMATION CONTACT:** Christina Savisaar, Center for Devices