

2009, Public Law 110–417, as amended by Public Law 111–212, hereafter referred to as “the Act.” The Duncan Hunter National Defense Authorization Act of 2009 (Pub. L. 110–417) was enacted on October 14, 2008. Section 872 of this Act required the development and maintenance of an information system that contains specific information on the integrity and performance of covered Federal agency contractors and grantees.

The Federal Awardee Performance and Integrity Information System (FAPIS) was developed to address these requirements and has been superseded by the System for Award Management (SAM) at [SAM.gov](https://sam.gov). SAM provides users access to integrity information from the FAPIS reporting module in the Contractor Performance Assessment Reporting System (CPARS), proceedings information from the Entity Management section of the SAM database, and suspension/debarment information from the Exclusions section of SAM.

As required by 2 CFR part 200 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, effective January 1, 2016, Federal agencies are required to review and consider any information about the applicant that is in SAM before making any award in excess of the simplified acquisition threshold, defined in 41 U.S.C. 134, over the period of performance.

Non-Federal entities (NFEs) are required to disclose any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts), as required by 45 CFR part 75, Appendix XII, of the Uniform Guidance, for any period of time during the period of performance of an award/project.

## B. Annual Reporting Burden

### Proceedings Screening Question #1

*Respondents:* 19,152.  
*Responses per Respondent:* 1.  
*Total Annual Responses:* 19,152.  
*Hours per Response:* .1.  
*Total Response Burden Hours:* 1,915.

### Proceedings Screening Question #2

*Respondents:* 141.  
*Responded per Respondent:* 1.  
*Total Annual Responses:* 141.  
*Hours per Response:* .1.  
*Total Response Burden Hours:* 14.

### Proceedings Details

*Respondents:* 141.  
*Responses per Respondent:* 2.  
*Total Annual Responses:* 282.  
*Hours per Response:* .5.  
*Total Response Burden Hours:* 141.

## C. Public Comments

A 60-day notice was published in the **Federal Register** at 89 FR 25874 on April 12, 2024. No comments were received.

*Obtaining Copies:* Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing [GSARegSec@gsa.gov](mailto:GSARegSec@gsa.gov). Please cite OMB Control No. OMB Control No. 3090–0293, Reporting and Use of Information Concerning Integrity and Performance of Recipients of Grants and Cooperative Agreements, in all correspondence.

**Lois Mandell,**

*Director, Regulatory Secretariat Division,  
 General Services Administration.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Legal and Advocacy Services for Unaccompanied Children (Office of Management and Budget #0970–0565)

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

**ACTION:** Request for public comments.

**SUMMARY:** The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services is inviting public comment on revisions to an approved information collection. The request consists of several forms that allow the Unaccompanied Children (UC) Program to provide legal and advocacy services to unaccompanied children.

**DATES:** *Comments due* August 19, 2024. In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), ACF is soliciting public comment on the specific aspects of the information collection described above.

**ADDRESSES:** You can obtain copies of the proposed collection of information and submit comments by emailing [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). Identify all

requests by the title of the information collection.

#### SUPPLEMENTARY INFORMATION:

*Description:* This request is to remove two forms from this collection, add two new forms, move one form from a different information collection into this collection (with revisions), and revise three existing forms in this collection. ORR also proposes retitling this information collection “Legal and Advocacy Services for Unaccompanied Children.”

#### Discontinued Forms

ORR plans to remove the following forms from this information collection:

- *Motion for Change of Venue (Form L–7):* This instrument was created for the UC Path case management system and was intended to be used for filing a motion for change of venue for children transferring to a different ORR care provider program. However, the UC Path system was never implemented, and this form has never been used. In addition, this function is performed by an entity that is party to the proceedings, typically the child’s legal representative or Immigration and Customs Enforcement, because the decision to file a change of venue may affect the child’s immigration case. A change of venue is filed for cases where a Notice to Appear has been filed. Since neither ORR nor its care provider programs perform this function, the form is not needed.

- *Post Legal Status Plan (Form L–8):* The information collected in this form was incorporated into the Legal Services Plan section of the Category 4 Discharge Plan (Form R–9, currently approved under OMB #0970–0552). Therefore, ORR plans to discontinue this form.

#### New Forms

ORR plans to add the following new forms to this information collection:

- *Case Status Summary for Executive Office for Immigration Review (Form L–9):* This form is completed by the Federal Field Specialist (FFS) or care provider and sent to the Executive Office for Immigration Review (EOIR) in advance of a child’s immigration hearing. The form provides basic information needed to ensure that EOIR has accurate information on the child’s case status. A copy of the form is also shared with the child’s legal service provider or attorney of record and child advocate (if applicable).

- *Recommended States List (Form L–11):* This form is completed by legal service providers for children without viable sponsorship options or where the child is expected to remain in ORR custody for 3 or more months. The form

provides a recommended list of states where long-term foster care programs are present, taking into account the child's potential immigration case.

### Forms Transferred From a Different Information Collection

ORR plans to transfer the *Child Advocate Recommendation and Appointment form* into this information collection (currently approved under OMB #0970-0553). ORR also plans to move Section B: Recommendation and Appointment and Section C: ORR Approval into a separate form to better facilitate the referral, recommendation, and appointment process. The separate form containing the information collected in Sections B and C will be completed by fewer than 10 respondents and is, therefore, not subject to PRA and is not included in this request.

In addition, ORR plans to make the following revisions to the current content:

- Rename the form *Child Advocate Referral* (Form L-12A).
- Replace "UC" with "child" throughout the form.
- Add fields for the Title, Email, and Phone Number of the referrer.
- Split the field to for the name of the child into three separate fields for First Name, Second or Middle Name, and Last Name(s).
- Add the following fields for additional information about the child that will assist the child advocate contractor in making recommendations:
  - Other Language(s) Spoken.
  - Is the child in ORR custody?
  - Was the child at another ORR care provider facility?
  - If yes, provide the care provider name.
  - Child's length of care in ORR custody.
  - Does the child have legal representation?
  - If yes, provide the following information for the legal representative: Name, Phone, Email.
- Revise the list of reasons for referral to better reflect the most common reasons child advocate referrals are made.
- Revise the burden estimate to reflect the number of child advocate referrals made from April 2023 through March 2024. The annual number of respondents increased from 216 to 300 and the annual number of responses per respondent increased from 5 to 19.

### Revisions to Existing Forms

ORR plans to make the following revisions to existing form in this information collection:

- *Request for Specific Consent to Juvenile Court Jurisdiction (Form L-1)*:
  - Replace "UC" with "child" throughout the form.
  - Revised Section D: Next Steps to align with the UC Program Foundational Rule (45 CFR 410).
  - Revise the burden estimate to reflect the number of requests for specific consent received in FY 2023. The annual number of respondents decreased from 40 to 31.
- *Specific Consent Request Case Summary (Form L-2)*:
  - Remove the instruction to complete an internal clearance form because that is no longer part of the process.
  - Update the email address where the form is submitted.
  - Add text fields for the email addresses of the case manager and FFS to better facilitate communication when UC Program headquarter staff have follow-up questions.
  - Replace "UC" with "child" throughout the form.
  - Revise the available dropdown options for the Level of Care field to align with the UC Program Foundational Rule (45 CFR 410).
  - Revise the burden estimate to reflect the number of case summaries completed in FY 2023 and account for an increase in the number of care provider facilities. The annual number of respondents increased from 216 to 300 and the annual number of responses per respondent decreased from 0.2 to 0.1.
- *Acknowledgement of Receipt of Legal Resource Guide (Form LRG-4)*:
  - Change form number from LRG-5 to LRG-4.
  - Retitle form *Acknowledgement of Receipt of Legal Resource Guide* (formerly titled *Legal Service Provider List for UC in ORR Care*).
  - Remove the information provided on the first page and the list of legal service providers and their contact information. ORR plans to incorporate this information into a separate document and children will acknowledge receipt of that document in this form.
  - Revise the list of documents provided to children to reflect forthcoming revisions and consolidation of legal resource guide documents.
  - Remove requirement for children to initial each list item to reduce burden for the child.
  - Add instructions to put an "X" in the signature line in cases where the child is unable to sign the form and add a text field for the care provider to document the reason the child was

unable to sign (e.g., child is 2 years old). This will assist ORR in monitoring compliance with requirements to complete this form.

- Add a field for care provider program name.
- Revise the burden estimate to account for an increase in the number of care provider facilities and in the number of children placed in ORR care, and report the burden for care providers and unaccompanied children separately to improve accuracy of the estimate. The annual number of respondents increased from 216 to 300 for care providers and 121,669 unaccompanied child respondents were added. The annual number of responses per respondent increased from 556 to 817 for care providers and the responses per respondent for children is two (2).
- ORR plans to translate the form into Spanish and other languages commonly spoken by unaccompanied children.

### Revisions to Burden Estimates Only for Existing Forms

- *Notice of Attorney Representation (Form L-3)*:
    - Previously, the annual number of respondents was overestimated at 13,000. ORR is changing that estimate to 10,000 (which will still be higher than the number of forms submitted in the previous year) based on the actual number of children who received direct representation through ORR's legal service provider contractor and rounded up to account for an expected increase in direct representation and forms submitted by outside attorneys.
  - *UC Legal Information (Form L-4)*:
    - Revise the burden estimate to account for an increase in the number of care provider facilities and in the number of children placed in ORR care. The annual number of respondents increased from 216 to 300 and the annual number of responses per respondent increased from 241 to 406.
  - *Legal Service Provider Record (Form L-6)*:
    - Revise the burden estimate to account for an increase in the number of care provider facilities and in the number of children placed in ORR care. The annual number of respondents increased from 216 to 300 and the annual number of responses per respondent increased from 241 to 406.
- Respondents:* ORR grantee and contractor staff, unaccompanied children, parents/legal guardians of unaccompanied children, attorneys of record and legal service providers.
- Annual Burden Estimates:*

| Instrument                                                                             | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Annual total burden hours |
|----------------------------------------------------------------------------------------|------------------------------|------------------------------------|-----------------------------------|---------------------------|
| Request for Specific Consent to Juvenile Court Jurisdiction (Form L-1) .....           | 31                           | 1.0                                | 0.25                              | 8                         |
| Specific Consent Request Case Summary (Form L-2) .....                                 | 300                          | 0.1                                | 0.33                              | 10                        |
| Notice of Attorney Representation (Form L-3) .....                                     | 10,000                       | 1.0                                | 0.25                              | 2,500                     |
| UC Legal Information (Form L-4) .....                                                  | 300                          | 406.0                              | 1.00                              | 121,800                   |
| Legal Service Provider Record (Form L-6) .....                                         | 300                          | 406.0                              | 0.08                              | 9,744                     |
| Case Status Summary for Executive Office of Immigration Review (Form L-9) .....        | 300                          | 5.0                                | 0.17                              | 255                       |
| Recommended States List (Form L-11) .....                                              | 60                           | 10.0                               | 0.33                              | 198                       |
| Child Advocate Referral (Form L-12A)-Respondents .....                                 | 300                          | 19.0                               | 0.25                              | 1,425                     |
| Child Advocate Referral (Form L-12A)-Recordkeepers .....                               | 1                            | 5,601.0                            | 0.33                              | 1,848                     |
| Acknowledgment of Receipt of Legal Resource Guide (LRG-4)-Unaccompanied Children ..... | 121,669                      | 2.0                                | 0.25                              | 60,835                    |
| Acknowledgment of Receipt of Legal Resource Guide (LRG-4)-Care Providers .....         | 300                          | 817.0                              | 0.25                              | 61,275                    |
| Estimated Annual Burden Hours Total: .....                                             | .....                        | .....                              | .....                             | 259,898                   |

*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)

Mary C. Jones,  
ACF/OPRE Certifying Officer.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-D-1981]

#### Facility Readiness: Goal Date Decisions Under Generic Drug User Fee Amendments; 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 a final guidance for industry entitled "Facility

Readiness: Goal Date Decisions Under GDUFA." This guidance provides information to applicants on how FDA will use information related to a facility's readiness for inspection as certified on Form FDA 356h to set a goal date for an original abbreviated new drug application (ANDA). This guidance incorporates a program enhancement agreed upon by the Agency and industry as part of the negotiations relating to reauthorization of the Generic Drug User Fee Amendments (GDUFA) and as described in "GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027" (GDUFA III commitment letter). This guidance finalizes the draft guidance of the same title issued on October 7, 2022.

**DATES:** The announcement of the guidance is published in the **Federal Register** on June 18, 2024.

**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-2022-D-1981 for "Facility Readiness: Goal Date Decisions Under GDUFA." 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