OPO in providing organs for transplant, pursuant to section 1138(a)(1)(C) of the Social Security Act (the Act) and our regulations at 42 CFR 482.45.

Section 1138(a)(1)(A)(iii) of the Act provides that a hospital must establish protocols which require the hospital to notify the designated OPO (for the service area in which it is located) of potential organ donors. Under section 1138(a)(1)(C) of the Act, every hospital must have an agreement only with its designated OPO to identify potential donors.

Section 1138(a)(2)(A) of the Act provides that a hospital may submit a request to the Secretary of the Department of Health and Human Services (the Secretary) for a waiver of the above requirements. If the requested waiver meets certain conditions specified in section 1138(a)(2)(A) of the Act, the Secretary shall grant the waiver and allow the hospital to have an agreement with an OPO other than the one designated by CMS. The Secretary may consider factors described in section 1138(a)(2)(B) of the Act when determining whether to grant the hospital's request for a waiver.

Section 1138(a)(2)(A) of the Act states that the Secretary shall grant a waiver if he determines that the waiver—(1) is expected to increase organ donations; and (2) will ensure equitable treatment of patients referred for transplants within the service area served by the designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement under the waiver. In making a waiver determination, section 1138(a)(2)(B) of the Act provides that the Secretary may consider factors that include but are not limited to: (1) cost effectiveness; (2) improvements in quality; (3) whether there has been any change in a hospital's designated OPO due to the changes made in definitions for metropolitan statistical areas; and (4) the length and continuity of a hospital's relationship with an OPO other than the hospital's designated OPO. The regulations identifying the relevant considerations are codified in 42 CFR 486.308(e) and (f).

II. Solicitation of Public Comments

Section 1138(a)(2)(D) of the Act states the Secretary shall publish a public notice of any waiver application received from a hospital within 30 days of receiving such application and offer interested parties the opportunity to submit written comments to the Secretary during the 60-day period beginning on the date such notice is published.

As part of the process of determining whether to grant a waiver, we will review the comments received. During the review process, we may consult with relevant parties, including but not limited to, the Health Resources and Services Administration's Division of Transplantation, the United Network for Organ Sharing, and our regional offices. If necessary, we may request clarifying information from the applying hospital or others. We will then make a final determination on the waiver request and notify the hospital and the designated and requested OPOs.

III. Hospital Waiver Request

As permitted by § 486.308(e), the following hospital has requested a waiver to enter into an agreement with an OPO other than the OPO designated for the service area in which the hospital is located:

Lexington Medical Center, Lexington, NC, is requesting a waiver to work with: LifeShare Carolinas (NCCM) 3621 Randolph Road, Suite 100, Charlotte, North Carolina 28211.

The Hospital's Designated OPO is: HonorBridge (NCNC), 1430 Westbrook Plaza Drive, Winston-Salem, North Carolina 27103.

IV. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

V. Response to Comments

We will consider all comments we receive by the date and time specified in the **DATES** section of this document.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Mehmet Oz, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2026–03277 Filed 2–18–26; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0554]

Submission for Office of Management and Budget Review; Placement and Transfer of Unaccompanied (Alien) Children Into Office of Refugee Resettlement Care Provider Facilities

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 comments on a request to extend approval of forms approved for the Placement and Transfer of Unaccompanied [Alien] Children into ORR Care Provider Facilities. Recently, ORR received emergency approval from the Office of Management and Budget (OMB) for form revisions that ensure that ORR can continue to properly enact its mandates and comply with all applicable authorities related to the placement of unaccompanied alien children into a restrictive placement. That approval updated the current expiration date for all forms under this OMB number to March 31, 2026. This notice includes an extension of approval for all forms under this OMB number, including the forms that were recently approved through emergency approval for 180 days.

DATES: *Comments due* March 23, 2026.

ADDRESSES: The public may view and comment on this information collection request at: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202602-0970-007.* You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ORR is seeking to continue data collection with all forms approved under OMB #: 0970–0554, including those for which OMB recently approved through an emergency approval. This current request is for a one-year extension during which time further revisions will be completed and submitted to OMB. Two public comment periods will take place during that future revision process.

ORR received emergency approval for the below-listed changes to the Notice of Placement in a Restrictive Setting (Form P–4) and Unaccompanied [Alien] Child Referral (aka Intakes Placement Checklist) (Form P–7). The changes are related to current administration priorities, to align the placement criteria in forms with the criteria found in 45 CFR 410.1105 and UAC Policy Guide sections 1.2.4 and 1.4.6 and to meet requirements in the *Lucas R.* Disabilities Settlement Agreement (Case No. 2:18–CV–05741 DMG PLA), and *Flores* litigation (Case No. CV85–4544–RJK (C.D. Cal. 1996)). Some of these are nonsubstantive in nature, but were submitted with the items that warranted emergency approval to ensure all updates were available for use as soon as possible. Additional changes were made in response to public comments.

Global Terminology Updates

Update terminology to align with ORR regulations and to comply with Executive Order 14168 *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government,* as well as other guidance from the current Administration.

Notice of Placement in a Restrictive Setting (Form P–4)

- Reorganize where some information/fields appear in the form for clarity.
- Add a ''Disability Considerations'' subsection in ''Section B: Placement Information'' to meet requirements found in the *Lucas R.* Disabilities Settlement Agreement.
- Remove ''Section B: ORR's Determination Related to Safety'' to align the form with ORR's regulation and policy guide.
- Update ''Section C: Reasons for Restrictive Placement'' to align the placement criteria in the form with ORR's regulation and policy guide and to comply with *Flores* litigation requirements.
- Add ''Translation'' subsection to ''Section E: Acknowledgement and Certification'' to help ORR monitor form compliance with translation requirements in its regulation.

In response to public comments:

- Reword the introductory language on the first page to better align with the Unaccompanied Children Program Foundational Rule.
- Add a reminder that all parties must each provide a detailed summary in Section D.
- Add instructions in Section D that all parties must list all the evidence they relied on to make their recommendation.

Unaccompanied [Alien] Child Referral (aka Intakes Placement Checklist) (Form P–7)

ORR has two versions of Form P–7 approved under this information collection. The first version, titled Unaccompanied [Alien] Child Referral, was created for the UAC Path system, which was never implemented. The second version, titled Intakes Placement Checklist, is a PDF version that is currently in use. ORR is only proposing revisions to the PDF version of this form.

- Change form title from ''Intakes Placement Checklist'' to ''Intakes Restrictive Placement Checklist'' to better align the form's title with its purpose.
- Reorganize ''Section B: Heightened Supervision Facility Criteria'' and ''Section C: Secure Facility Criteria'' for clarity.
- Update criteria and supporting factors in Sections B and C to align with ORR's regulation and policy guide.
- Add follow-up questions in Sections B and C to document what information was relied on the make the placement determination and clarify whether each placement criterion was met.
- Reword field labels and add a field to document the reason for the recommended level of care in ''Section D: Placement Determination''

In response to public comments:

- Add fields that allow the user to note what information was in the referral regarding the child having a suspected disability (when applicable)
- Add language clarifying that the evidence used when evaluating a child for placement in a restrictive setting must be saved in the child's case file.
- Add language reiterating the requirement to place children in the least restrictive setting that is in their best interest.
- Add reminders regarding how significant incident reports may and may not be used as a basis for placement in a restrictive setting.
- Remove checkbox options for petty theft and status offenses from Section B, Criterion 3.
- Reword the introductory text in Section C: Secure Facility Criteria to better align with the Unaccompanied Children Program Foundational Rule.
- Reword the supporting factors for Criterion 2 under Section C: Secure Facility Criteria to better align with the Unaccompanied Children Program Foundational Rule.
- Correct an error in which language for heightened supervision facilities was accidentally pasted into the Placement Eligibility section under Section C: Secure Facility Criteria.
- Update the signature block for the Placements Supervisor in Section D: Placement Determination to make clear the Placements Leads may also make final level of care determinations.

Respondents: ORR grantee and contractor staff; unaccompanied alien children; and other federal agencies.

Annual Burden Estimates

These burden estimates include burden related to the revisions described above and currently approved forms for which we are not proposing any changes. ORR updated the burden hours for all forms to reflect a decrease in the number of children referred to ORR and a decrease in the number of care provider facilities. ORR also updated the estimated costs for all forms to reflect more recent wage data from the Bureau of Labor Statistics. Finally, ORR updated the average burden hours per response for the Notice of Placement in a Restrictive Setting (Form P–4) from 0.33 hours to 0.5 hours.

Form P–18 was transferred under Legal and Advocacy Services for Unaccompanied Alien Children (OMB# 0970–0565) when the collection was last approved on May 25, 2025, so the associate burden has been removed from this collection.

Information collection title	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual total burden hours
Placement Authorization (Form P–1)	220	446	0.08	7,850
Authorization for Medical, Dental, and Mental Health Care (Form P–2)	220	446	0.08	7,850
Notice of Placement in a Restrictive Setting (Form P–4)	6	83	0.50	249
Long Term Foster Care Placement Memo (Form P–5)	115	7	0.25	201

Information collection title	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual total burden hours
Unaccompanied [Alien] Child Referral (aka Intakes Restrictive Placement Checklist) (Form P–7)	40	2,394	1.00	95,760
Care Provider Checklist for Transfers to Influx Care Facilities (Form P–8)	220	2	0.25	110
Medical Checklist for Non-Influx Transfers (Form P–9A)	220	8	0.08	141
Medical Checklist for Transfers to Influx Care Facilities (Form P–9B)	220	5	0.17	187
Transfer Request (Form P–10A)—Grantee Case Manager	220	11	0.25	605
Transfer Request (Form P–10A)—Contractor Case Coordinator	275	11	0.17	514
Placement Confirmation (Form P–10B)—Grantee Case Manager	220	11	0.17	411
Placement Confirmation (Form P–10B)—Contractor Case Coordinator	275	11	0.17	514
Transfer Summary and Tracking (Form P–11)	220	11	0.17	411
Bed Configuration Module (Form P–12A)	220	12	0.17	449
Bed Assignment and Capacity Overview Module (Form P–12B)	220	435	0.17	16,269
Program Entity (Form P–12C)	220	12	0.50	1,320
Unaccompanied [Alien] Child Profile (Form P–13)	220	435	0.75	71,775
ORR Transfer Notification—ORR Notification to ICE Chief Counsel of Transfer of UC and Request to Change Address/Venue (Form P–14)	220	11	0.17	411
Family Group Entity (Form P–15)	40	75	0.08	240
Influx Transfer Manifest (Form P–16)	3	12	0.33	12
Influx Transfer Manual and Prescreen Criteria Review (Form P–17)	220	52,232	0.50	5,745,520
Estimated Annual Burden Hours Total				5,950,799

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; 45 CFR part 410; *Flores* v. *Reno* Settlement Agreement (No. CV85–4544–RJK (C.D. Cal. 1996)); *Lucas R. et al.* v. *Becerra et al.* Disabilities Settlement Agreement (Case No. CV 18–5741–DMG (PLAx)).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–03282 Filed 2–18–26; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 065

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 065'' (Recognition List Number: 065), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments on the notice at any time. These modifications to the list of recognized standards are applicable February 19, 2026.

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards 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–2004–N–0451 for ''Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 065.'' 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. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 065.

- 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