

1. *The Vanguard Group, Inc., Malvern, Pennsylvania; on behalf of itself, its subsidiaries and affiliates, including investment companies registered under the Investment Company Act of 1940, other pooled investment vehicles, and institutional accounts that are sponsored, managed, or advised by Vanguard;* to acquire additional voting shares of United Community Banks, Inc., Blairsville, Georgia, and thereby indirectly acquire voting shares of United Community Bank, of Greenville, South Carolina.

B. *Federal Reserve Bank of Dallas* (Karen Smith, Director, Applications) 2200 North Pearl Street, Dallas, Texas 75201–2272:

1. *The John H. Young 2020 Trust, Edward E. Hartline and Gus K. Eifler as co-trustees, all of Houston, Texas;* to acquire additional voting shares of Central Bancshares, Inc., and thereby indirectly acquire voting shares of Central Bank, both of Houston, Texas.

Board of Governors of the Federal Reserve System, October 5, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–22064 Filed 10–7–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Informational Meeting: The Importation of Infectious Biological Agents, Infectious Substances and Vectors; Public Webinar

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public webinar.

SUMMARY: The HHS/CDC's Division of Select Agents and Toxins (DSAT) is hosting a public webinar to provide information about import permit regulations for infectious biological agents, infectious substances, and vectors. Besides the CDC, presenters will include representatives from the Department of Transportation, Animal and Plant Health Inspection Service, U.S. National Authority for Containment of Poliovirus, Customs and Border Protection, and the Department of Commerce, who will discuss key aspects involved in the importation of infectious biological agents, infectious substances, and vectors.

DATES: The webinar will be held December 2, 2021 from 11:00 a.m. to 4:00 p.m. (EST). Registration

instructions are found on the HHS/CDC Import Permit Program website, <https://www.cdc.gov/cpr/ipp/index.htm>.

ADDRESSES: The webinar will be broadcast from the Centers for Disease Control and Prevention, 1600 Clifton Road NE, Atlanta, Georgia 30329.

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin, Ph.D., Director, DSAT, Center for Preparedness and Response, CDC, 1600 Clifton Road NE, MS H–21–7, Atlanta, Georgia 30329. Telephone: (404) 718–2000; email: Irsat@cdc.gov.

SUPPLEMENTARY INFORMATION: This webinar is an opportunity for all interested parties (e.g., academic institutions; biomedical centers; commercial manufacturing facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; research facilities; exhibition facilities; and educational facilities) to obtain specific guidance and information regarding import permit regulations and the shipment of infectious biological materials. The webinar will provide information to those interested in applying for an import permit from federal agencies within the United States. Instructions for registration are found on the CDC Import Permit Program website, <https://www.cdc.gov/cpr/ipp/index.htm>.

Participants must register by November 26, 2021. This is a webinar-only event and there will be no on-site participation at CDC.

Dated: October 4, 2021.

Sandra Cashman,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2021–22044 Filed 10–7–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Placement and Transfer of Unaccompanied Children Into ORR Care Provider Facilities (0970–0554)

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 Children (UC) Program to place UC referred to ORR by federal agencies into care provider facilities and to transfer UC within the ORR care provider network.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about 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.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

SUPPLEMENTARY INFORMATION:

Description: ORR received several comments on this information collection in response to the **Federal Register** Notice published on January 19, 2021, (86 FR 5196) and has provided responses to those comments in its final submission to OMB. UC Path is critical to program operations and it is important that rollout of the new system not be delayed. Therefore, the below description details what will be included in the initial launch of the UC Path case management system and revisions based on public comments will be made after initial launch. ORR plans to conduct a deliberative review of commenters' suggestions and concerns and submit a request for revisions to this information collection request in January 2022. The upcoming information collection request will also include revisions based on feedback from UC Path system users (i.e., ORR grantee, contractor, and federal staff).

A. ORR plans to revise all 13 instruments currently approved under OMB #0970–0554, all of which will be incorporated into ORR's new case management system, UC Path. Five of the instruments contain revisions to the formatting, organization, or wording of field labels with no changes to the content. The remaining eight instruments contain changes in content. In addition, ORR plans to add four new instruments to this collection that will also be incorporated into UC Path. Finally, ORR plans to replace the term “unaccompanied alien child (UAC)” with “unaccompanied child (UC)”

throughout the instruments in this collection.

1. *Placement Authorization (Form P-1)*: This instrument is used by ORR to authorize a care provider to provide care and services to UC placed in their facility. Care providers sign the instrument to acknowledge certain responsibilities related to the care of the UC. ORR revised the formatting, but no changes were made to the content. The average burden minutes per response was increased from 1 to 5 minutes.

2. *Authorization for Medical, Dental, and Mental Health Care (Form P-2)*: This instrument is used by ORR to authorize a care provider to provide medical, dental, and mental health care services to UC placed in their facility. Care providers sign the instrument to acknowledge certain responsibilities related to the care of the UC. ORR revised the formatting, but no changes were made to the content. The average burden minutes per response was increased from 1 to 5 minutes.

3. *Notice of Placement in a Restrictive Setting (Form P-4/4s)*: This instrument is used by care providers to document and inform UC of the reason they have been placed in a restrictive setting. ORR revised the formatting, but no changes were made to the content.

4. *Long Term Foster Care Placement Memo (Form P-5)*: This instrument is used by care providers to ensure placement in a foster home that meets the UC's needs and continuity of services. ORR revised the formatting and the order in which the fields appear. ORR added two new questions asking respondents to (1) describe any special skills or training of the foster family or group home, and (2) provide any further available information and/or considerations about the time line for physical transfer of the minor.

5. *UC Referral (formerly titled Intakes Placement Checklist and Add New UC) (Form P-7)*: This instrument is used by federal agencies to refer UC to ORR custody and by ORR Intakes staff to place UC in an ORR care provider facility. It also contains a checklist that is used by ORR Intakes staff to determine whether initial placement in a restrictive setting is appropriate for a UC. ORR combined two of its current instruments, *Intakes Placement Checklist* and *Add New UC*, into one instrument. The average burden minutes per response was increased from 15 to 60 minutes, plus an additional 30 minutes if the placement checklist must be completed. In addition, ORR made the following revisions:

- Moved the "Immigration Status at Referral" field to the *UC Profile* instrument.

- Created a new "Parent/Legal Guardian Separation" section. This section contains five fields, and replaces the single question on the current version of the *Add New UC* instrument.

- Created a new "MPP Information" section to capture information about enrollment in the Migrant Protection Protocol (MPP) program. This section contains two fields.

- Moved the field "Related to Other UC(s)?" to the *UC Profile* instrument.

- Moved fields related to family groups to the *UC Profile* and *Family Group Entity* instruments.

- Added the following fields to the "Apprehension and Referral Information" section: "Referring Sector Name," "POC Primary Email," "POC Secondary Email," and "Referring Sector Code."

- Moved fields in the "Parent/Relative Information" section to the *UC Profile* instrument.

- Renamed the "Notes" field in the "Referral Notes" section to "Apprehension/Journey Notes" and added a new field, "Referral Cancellation Reason."

- Renamed the "ORR Placement Information" section to "Placement Request" and added the following fields: "Required Placement Request," "Placement Requested Date/Time," "Program/Facility," "Not Accepted Reason," "Placement Decision Date/Time," "Placement Notes," and "Override Stop Placement Reason."

- Added a new section titled "Special Placement Request" that contains the fields found in the "Placement Determination" section of the current version of the *Intakes Placement Checklist*.

- Created a new "Criminal Information" section. This section contains nine fields, and replaces the two questions on criminal charges and acting as a footguide on the current version of the *Add New UC* instrument.

- A new section titled "Criminal Charges" as added to capture more detailed information if the UC has any criminal charges, which contains nine fields.

- A new "Detention Facilities" section as created to capture more detailed information if the UC was ever held in a detention facility. This section contains nine fields.

- Added a new "Documents" section where documents related directly to the UC's referral may be uploaded.

- Added a new "Entry Team" section in which read and/or write access can be granted to individuals who need access privileges to the record, but do not typically need such privileges for a referral record.

- Revised the *Intakes Placement Checklist* as follows:

- Reorganized the checklist into distinct sections for staff secure and secure placement criteria.

- Removed "UC will be turning 18 year of age in the next month" as an escape risk criteria.

- Removed the "Danger to Self" section.

- Revised the lists of criminal offenses in both the staff secure and secure sections.

- Added a new "Initial Health Information" section to capture more detailed information about the UC's health. This section contains 31 fields.

6. *Care Provider Checklist for Transfers to Influx Care Facilities (Form P-8)*: This instrument is used by care providers to ensure that all criteria for transfer of a UC to an influx care facility have been met. ORR revised the formatting and reworded some field labels, but no changes were made to the content.

7. *Medical Checklist for Non-Influx Transfers (Form P-9A)*: This instrument is used by care providers to ensure that UC are medically cleared for transfer within the ORR care provider network, excluding transfer to an influx care facility. ORR revised the formatting and reworded the questions. In addition, ORR removed the question asking if the child is free of all medical conditions requiring specialist care.

8. *Medical Checklist for Transfers to Influx Care Facilities (Form P-9B)*: This instrument is used by care providers to ensure that UC are medically cleared for transfer to an influx care facility. ORR revised the formatting and instructions, reworded most questions, and clarified which questions are only applicable to influx care facilities located on Department of Defense sites. ORR also added four new questions that ask about sexually transmitted disease, injection drug use, allergies, and the completion of lab and diagnosis field in UC Path.

9. *Transfer Request (Form P-10A)*: This instrument is used by care provider facilities, ORR contractor staff, and ORR federal staff to process

recommendations and decisions for transfer of a UC within the ORR care provider network for non-influx transfers. ORR revised the formatting and reworded many of the section titles and fields. In addition, ORR made the following revisions to this instrument:

- In the "Transfer Request" section, ORR removed the field "Requested Date" and added the following fields: "Status," "Transfer Type," "High Priority," "Transfer Cancellation Reason," "Case Coordinator," and "Legal Eligibility."

- Added the following fields to the “Case Coordinator Recommendation” section: “Pending Information,” “FFS Authorized to Proceed,” and “Add to Waitlist?”

- Moved fields related to the UC’s attorney of record from the “Reason for Transfer Request” section to the “Casefile Summaries” section.

- Added a new “Transfer Designation” section containing three fields.

- Added a “Remand for Further Information” to the “ORR Decision” section.

- Removed the “Transfer Packet” section.

- Added the following fields to the “COA–COV” section: “Specify UC Special Needs” and “Other Change Venue Cause.”

- Added a new “Entry Team” section in which read and/or write access can be granted to individuals who need access privileges to the record, but do not typically need such privileges for a referral record.

- Added a new “Documents” sections where documents related directly to the UC’s transfer may be uploaded.

- Added a new “Program Referrals” section in which care providers can search for programs that fit the UC’s transfer criteria and make referrals.

10. *Influx Transfer Request (Form P–10B)*: This instrument is used by care provider facilities and ORR federal staff to process recommendations and decisions for transfers to an influx care facility. This is a new instrument that ORR plans to add to this collection.

11. *Transfer Summary and Tracking (formerly titled Transfer Request and Tracking Form) (Form P–11)*: This instrument is used by care providers to track the physical transfer of the UC and their belongings. ORR revised the formatting and reworded some of the fields. ORR also removed the field “FINS Number” and added the fields “Gender” and “Gender Other.”

12. *Program Entity (formerly titled UC Portal Capacity Report) (Form P–12)*: This instrument is used by care providers and ORR to track certain information related to care provider programs, such as location, contact information, bed capacity, state licensure, grant information, monitoring, and program census. ORR greatly expanded this instrument to track multiple types of information related to care provider programs. The average burden minutes per response was increased from 5 to 30 minutes. In addition to bed capacity, this instrument contains the following information:

- An overview of the program that includes name, status, parent entity, type, address, region, and acceptable placement types;

- Various program points of contact;

- Stakeholder information (child advocate program, legal service provider, field office juvenile coordinator);

- Information related to the program’s state licensing agency and licensing status;

- Information related to the program’s Administration for Children and Families grant;

- Fields tracking the reason and dates of stop placements, if applicable;

- Information related to the program’s ORR monitoring schedule;
- Sections that list all events and incident reports created for the program (cleared as separate instruments in OMB #0970–0547);

- Census information and the ability to initiate prescreening for transfers to influx care facilities (cleared as *Influx Transfer Manual and Prescreen Review* in this collection);

- An area to add individuals to the program’s team (e.g., assigned Federal Field Specialist, Project Officer);

- An area to upload documents related to the facility and its operations and/or compliance; and

- An auto-populated capacity dashboard to track available beds.

13. *UC Profile (formerly titled Add New UC) (Form P–13)*: This instrument is used by referring federal agencies and care providers to create a profile for a UC from which all information related to their case can be accessed.

Previously, the purpose of this instrument was to (1) create an initial profile and (2) receive/process referrals. The function of receiving/processing referrals and the related fields from the *Add New UC* instrument were moved to the *UC Referral* instrument, as noted above in the description of changes for *UC Referral*. The function of creating an initial profile in the system and related fields containing basic UC information remain with this instrument. However, the purpose of this instrument has been expanded. It now acts as a hub where users can assess all records related to a UC’s case. Most of the records accessible from the UC Profile are being cleared as separate instruments, either in this or another one of ORR’s information collections. The sections being cleared under this instrument are as follows: Profile Information, Program Designation, Legal—Immigration, Legal—Administrative, System Information, Apprehended Relationships, Other Relationships, Adult Contact Relationships, Entity

Team, and Documents. The average burden minutes per response was increased from 15 to 45 minutes.

14. *ORR Transfer Notice—Notice of Transfer to ICE Chief Counsel—Change of Address/Change of Venue (Form P–14)*: This instrument is used by care providers to notify the Department of Homeland Security (DHS) of the transfer of a UC within the ORR care provider network so that DHS may file a Motion for Change of Venue and/or Change of Address with the Executive Office for Immigration Review to ensure the UC’s immigration case is transferred to the local immigration court, if applicable. ORR revised the formatting, but no changes were made to the content.

15. *Family Group Entity (Form P–15)*: This instrument is used by the ORR Intakes Team to associate UCs who are members of the same family with each other. This is a new instrument that ORR plans to add to this collection.

16. *Influx Transfer Manifest (Form P–16)*: This instrument is used by designated care provider staff and ORR staff to plan, track, and notify stakeholders of group transfers to an influx care facility. This is a new instrument that ORR plans to add to this collection.

17. *Influx Transfer Manual and Prescreen Review (Form P–17)*: This instrument is used by designated care provider staff to evaluate each UC’s eligibility to be transferred to an influx care facility. Care provider staff review and update information on daily during times of influx. This is a new instrument that ORR plans to add to this collection.

B. ORR plans to remove the term “alien” from the title of this information collection and revise it to read “Placement and Transfer of Unaccompanied Children into ORR Care Provider Facilities.”

C. ORR intends to conduct a phased rollout of the UC Path system. Beginning fall 2021, ORR plans to roll the UC Path system out to a small group of care provider programs. ORR will gradually expand use of the system to other programs and expects all care provider programs will be using UC Path by spring 2022. To ensure continuity of operations, care provider programs will need the ability to continue using instruments in the UC Portal system while they are waiting to transition over to the UC Path system. Therefore, ORR proposes continued use of the following UC Portal (ORR’s current case management system) instruments, concurrently with the UC Path versions of the same instruments, until all care provider programs are using UC Path.

- 1. Placement Authorization (Form P-1)
- 2. Authorization for Medical, Dental, and Mental Health Care (Form P-2)
- 3. Intakes Placement Checklist
- 4. Transfer Request (Form P-10A)
- 5. Transfer Summary and Tracking (formerly titled Transfer Request and Tracking Form) (Form P-11)
- 6. UC Portal Capacity Report (Form P-12)
- 7. Add New UC (Form P-13)
- 8. ORR Transfer Notification—Notice of Transfer to Immigration and Customs Enforcement’s (ICE) Chief Counsel—Change of Address/Change of Venue (Form P-14)

Respondents: ORR grantee and contractor staff, other federal agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual total burden hours
Placement Authorization (Form P-1)	216	278	5	5,004
Authorization for Medical, Dental, and Mental Health Care (Form P-2)	216	278	5	5,004
Notice of Placement in a Restrictive Setting (Form P-4/4s)	15	34	20	170
Long Term Foster Care Placement Memo (Form P-5)	30	3	15	23
UC Referral (Form P-7)	16	3,250	60	52,000
UC Referral—Intakes Placement Checklist (Form P-7)	16	9	30	72
Care Provider Checklist for Transfers to Influx Care Facilities (Form P-8) ...	216	10	15	540
Medical Checklist for Transfers (Form P-9A)	216	27	5	486
Medical Checklist for Influx Transfers (Form P-9B)	216	63	10	2,268
Transfer Request (Form P-10A)—Grantee Case Manager	216	37	25	3,330
Transfer Request (Form P-10A)—Contractor Case Coordinator	250	37	20	3,083
Influx Transfer Request (Form P-10B)	216	63	25	5,670
Transfer Summary and Tracking (Form P-11)	216	37	10	1,332
Program Entity (Form P-12)	216	12	30	1,296
UC Profile (Form P-13)	216	241	45	39,042
ORR Transfer Notification—ORR Notification to ICE Chief Counsel of Transfer of UC and Request to Change Address/Venue (Form P-14)	216	37	10	1,332
Family Group Entity (Form P-15)	16	188	5	251
Influx Transfer Manifest (Form P-16)	3	12	20	12
Influx Transfer Manual and Prescreen Criteria Review (Form P-17)	216	43,333	30	4,679,964
Estimated Annual Burden Hours Total				4,800,879

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 B. Jones,
ACF/OPRE Certifying Officer.
 [FR Doc. 2021-21999 Filed 10-7-21; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-1262]

Surgical Staplers and Staples for Internal Use—Labeling Recommendations; 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, we, or Agency) is announcing the availability of a final guidance entitled “Surgical Staplers and Staples for Internal Use—Labeling Recommendations.” FDA is issuing this

guidance to provide labeling recommendations for surgical staplers and staples for internal use. These labeling recommendations are being issued because malfunctions and misuse associated with these devices have resulted in serious adverse events, including deaths.

DATES: The announcement of the guidance is published in the **Federal Register** on October 8, 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.”