Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under sections 11001 and 11002 of the Inflation Reduction Act Information Collection Request (ICR) (CMS–10849, OMB 0938–1452); *Use:* Under the authority in sections 11001 and 11002 of the Inflation Reduction Act of 2022 (Pub. L. 117–169), the Centers for Medicare & Medicaid Services (CMS) is implementing the Medicare Drug Price Negotiation Program, codified in sections 1191 through 1198 of the Social Security Act (''the Act''). The Act establishes the Negotiation Program to negotiate maximum fair prices (''MFPs''), defined at 1191(c)(3) of the Act, for certain high expenditure, single source selected drugs covered under Medicare Part B and Part D. For the second year of the Negotiation Program, the Secretary of Health and Human Services (the ''Secretary'') will select up to 15 high expenditure, single source drugs covered under Part D for negotiation.

Negotiation Data Elements: The statute requires that CMS consider certain data from Primary Manufacturers as part of the negotiation process. To the extent that more than one entity meets the statutory definition of manufacturer (specified in section 1193(a)(1) of the Act) for a selected drug for purposes of initial price applicability year 2027, CMS will designate the entity that holds the New Drug Application(s) (NDA(s))/Biologics License Application(s) (BLA(s)) for the selected drug to be ''the manufacturer'' of the selected drug (hereinafter the ''Primary Manufacturer''). The Primary Manufacturer's data submissions include non-FAMP and related data for selected drugs for the purpose of establishing a ceiling price, as outlined in section 1193(a)(4)(A) of the Act, and the negotiation factors outlined in section 1194(e)(1) of the Act for the purpose of formulating offers and counteroffers process pursuant to section 1193(a)(4)(B) of the Act. Some of these data are held by the Primary Manufacturer and are not currently available to CMS. Data described in sections 1194(e)(1) and 1193(a)(4) of the Act must be submitted by the Primary Manufacturer.

Section 1194(e)(2) of the Act requires CMS to consider certain data on selected drugs and their alternative treatments. Because the statute does not specify where these data come from, CMS will allow for optional submission from Primary Manufacturers and the public. CMS will additionally review existing literature, conduct internal analyses, and consult subject matter and clinical experts on the factors listed in section 1194(e)(2) of the Act. Primary Manufacturers may optionally submit this information as part of their Negotiation Data Elements Information Collection Request Form. The public may also optionally submit evidence about the selected drugs and their alternative treatments.

Drug Price Negotiation Process: Any MFPs that are negotiated for the drugs selected for the second year of the Negotiation Program will apply beginning in initial price applicability year 2027. For initial price applicability year 2027, the negotiation period begins on the earlier of the date that the Primary Manufacturer enters into a Medicare Drug Price Negotiation Program Agreement or February 28, 2025.

Section 1194(b)(2)(C) of the Act provides that if the Primary Manufacturer does not accept CMS' written initial offer, the Primary Manufacturer may submit an optional written counteroffer no later than 30 days after the date of receipt of CMS' written initial offer. If the Primary Manufacturer chooses to develop and submit a written counteroffer to CMS' written initial offer during the drug price negotiation process for initial price applicability year 2027 in accordance with section 1194(b)(2)(C) of the Act, the Primary Manufacturer must submit the Statutory Written Counteroffer Form. *Form Number:* CMS–10849 (OMB control number: 0938–1452); *Frequency:* Once; *Affected Public:* Private sector, Business or other for-profit; *Number of Respondents:* 340; *Total Annual Responses:* 340; *Total Annual Hours:* 23,764 (For policy questions regarding this collection contact Elisabeth Daniel at 667–290–8793.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–27490 Filed 11–22–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: Services Provided to Unaccompanied Children (Office of Management and Budget #: 0970–0553)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, U.S. 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 the proposed information collection, including proposed changes. The request consists of several forms that will allow the Unaccompanied Children (UC) Bureau to continue providing statutorily mandated services to unaccompanied children in ORR care.

DATES: *Comments due* January 24, 2025. In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described in this notice.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ORR has undertaken a reorganization of its information collections to promote operational efficiency. The reorganization will result in more collections that contain fewer forms under a single Office of Management and Budget number. This information collection currently contains 22 unique forms (33 including alternative versions). Under the reorganization, ORR proposes to discontinue the use of six forms; transfer 10 forms to new information collections associated with Assessments and Home Studies/Post-Release Services; and revise five existing forms.

The UC Bureau is requesting to discontinue the use of six forms created for the UC Path case management system, which was never implemented. Except where indicated below, the UC Path versions of these forms contain features and/or logic not replicated in the UC Portal, and have never been used, thus maintaining these forms is unnecessary. These forms include:

- Long Term Foster Care Travel Request (Form S–14)—UC Path version only. UC Bureau plans to revise and continue using the UC Portal version.
- Home Study/Post-Release Service (HS/PRS) Provider Entity (Form S–21A).
- Home Study/Post-Release Service (HS/PRS) Subcontractor Entity (Form S–21B).
- Home Study/Post-Release Service (HS/PRS) Primary Provider Profile (Form S–21C).
- Home Study/Post-Release Service (HS/PRS) Subcontractor Profile (Form S–21D).

- Sponsor Application (Form S–24).

Additionally, the following forms currently approved under this collection will be transferred to two new information collections proposed separately. The proposed new collections will encompass forms pertaining to Assessments and Home Study/Post-Release Services (HS/PRS). These forms include:

- Assessments Information Collection
  - Sponsor Assessment (Form S–5)
  - Adult Contact Profile (Form S–7)
  - Initial Intakes Assessment (Form S–8)
  - Assessment for Risk (Form S–9)
  - UC Assessment (Form S–11)
  - UC Case Review (Form S–12)
  - Individual Service Plan (Form S–13)
- Home Study/Post-Release Services Information Collection
  - Home Study Assessment (Form S–6)
  - Post-Release Service (PRS) Referral (Form S–19)
  - Post-Release Service (PRS) Report (Form S–22)
  - Home Study Referral (Form S–26)

Finally, the UC Bureau plans to keep the following forms in this information collection and make revisions as noted below. These forms are completed by foster parents or case managers or clinicians at care provider facilities to request approval for a child to travel outside the local community with their foster parent; to update the child's biographic information and admit them into the program; to authorize and document the child's contact with others outside the program; to document outreach performed on the child's behalf by care providers; and, to capture high-level milestones in the child's case. These forms are documentary in nature and a critical component of the child's case file. ORR funded care providers must always remain compliant with ORR and state licensing requirements per the Unaccompanied Children Program Foundational Rule, 45 CFR 410.1302(a); proposed revisions that remove or simplify form fields attesting to or documenting program compliance do not exempt programs from satisfying these requirements. The following revisions are currently proposed for each form:

- Foster Care Travel Request (Form S–14):
  - Remove ''Long-term'' from the form's title to clarify this form may be used for children in all foster care settings.
  - Add ''physical location of the child'' field to the UC Basic Information section, consistent with changes made to the UC Case Status (S–27) form; this field will auto-populate data from the UC Portal Discharge Tab.
  - Clarify that the name of the individual with whom the child is traveling must be an adult.
  - Remove Personal Vehicle information section from the form to align UC travel request data collection with domestic child welfare practices.
  - Add Health Safety Travel Plan section to the form to document how the child's health conditions, if applicable, may be effectively managed while traveling with their foster family, and plan for how the foster family will handle any health-related emergencies which may occur during travel.
  - Simplify the Travel Request Approval section by removing the following fields:
    - Reason Travel Request is being submitted to ORR/DCS for approval:
    - Is the travel request in accordance with state guidelines?
    - Purpose of travel and trip summary:
    - Are there any identified safety concerns in this child's background?
    - Is there any indication of flight risk?
  - Add a summary approval field with an open text comment space for approving officials to document their rationale for denial.
  - Adjust the burden estimate to account for an increase in the number of care provider facilities completing the form (form now used for children in all foster care settings, not just long-term foster care) and number of children placed in ORR care, and to reflect a decrease in the overall number of fields the respondent will need to complete. The annual number of respondents increased from 30 to 138, the annual number of responses per response increased from 8 to 178, and the average burden hours per response decreased from 0.33 hours to 0.25 hours.
- Admission (Form S–18):
  - Replace ''UAC'' with ''UC'' throughout the form to conform with UC Bureau standard terminology as established in UC Program Foundational Rule, 45 CFR 410.
  - Add ''Nonbinary'' to dropdown menu options for Gender.
  - Add ''physical location of the child'' filed to the UC Basic Information section, consistent with changes made to the UC Case Status (S–27) form; this field will auto-populate data from the UC Portal Discharge Tab.
  - Adjust the burden estimate to account for an increase in the number of care provider facilities and number of children placed in ORR care. The annual number of respondents increased from 216 to 300 and the annual number of responses per response increased from 278 to 327.
- UC Authorized/Restricted Call List and Call Log (Form S–20):
  - Replace ''UAC'' with ''UC'' throughout the form to conform with UC Bureau standard terminology as established in UC Bureau Foundational Rule.
  - Add ''Call Supervision Required?'' field to the Authorized Contacts List; content will auto-populate on the call logs display tab and reference the corresponding field in the Family/Friend contact profile. When entering this data, respondents will select from a ''Yes/No'' dropdown menu to indicate if contact between the child and named individual must be supervised by care provider staff.
  - Add the following fields to the UC Call Log to support data tracking related to UC Bureau Policy Guide Section 3.3.10 Calls, Visitation, Mail and Email:
    - ''Call Duration'' with an open text field for the care provider staff to document the length of the call.
    - ''Supervision Required?'' which will auto-populate ''Yes'' or ''No'' based on the corresponding field in the contact profile.
    - ''Supervised By:'' with an open text field for the care provider to identify which staff member supervised the call.
    - Call Method with dropdown options to specify if the contact was made by phone or video call.
  - Adjust the burden estimate to account for an increase in the number of care provider facilities and number of children placed in ORR care, as well as revisions to policies on phone calls in UC Bureau Policy Guide Section 3.3.10–Calls, Visitation, Mail and Email. The annual number of respondents increased from 216 to 300 and the annual number of responses per response increased from 6,981 to 15,711.
- Case Manager Call Log and Case Notes (Form S–23):
  - Replace ''UAC'' with ''UC'' throughout the form to conform with UC Bureau standard terminology as established in UC Program Foundational Rule.
  - Adjust the burden estimate to account for an increase in the number of care provider facilities and number of children placed in ORR care. The annual number of respondents increased from 216 to 300 and the annual number of responses per response decreased from 8,426 to 8,183.
- UC Case Status (Form S–27):
  - Assigned a tracking number to the form (S–27).
  - Add ''Physical Location of the Child'' Field to the UC Basic Information Section. This will auto-populate with data sourced from the UC

Portal Discharge Tab, presented as an appendix to the form.

○ Add ''Concurrent Planning: Additional Potential Sponsors'' segment to Family Reunification Section with the following fields (which will auto-populate from the Sponsor Assessment (Form S–5, currently approved under this information collection):

- Potential Sponsor Name.
- Relationship to Child.
- Sponsor Category.

○ Split the ''Know Your Rights Presentation and Legal Screening'' into two distinct fields to capture the completion date for each more accurately, acknowledging that they typically are not completed on the same day.

○ Add ''Back-Up Case Manager'' segment to Case Manager Information Section to designate an alternative Case Manager who may take actions on behalf of the primary Case Manager when they are unavailable. The corresponding fields mirror those for primary case manager and will either be system-generated or auto-populate with user account data already entered the system. The fields include:

- Back-up Case Manager Name.
- Back-up Case Manager Email Address.
- Back-up Case Manager Phone Number.
- Back-up Case Manager Organization.
- Assigned on (MM/DD/YYYY).

○ Adjust the burden estimate to account for an increase in the number of care provider facilities and number of children placed in ORR care, as well as the addition of the above listed new segments and fields. The annual number of respondents increased from 216 to 300, the annual number of responses per respondent increased from 278 to 327, and the average burden hours per response increased from 0.08 hours to 0.25 hours.

Respondents: ORR grantee and contractor staff.

Annual Burden Estimates:

ANNUAL BURDEN ESTIMATE FOR RESPONDENTS

Form	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual total burden hours
Foster Care Travel Req. Form (S–14)	138	178	0.25	6,141
Admission (S–18)	300	327	0.33	32,373
UC Authorized/Restricted Call List and Call Log (S–20)	300	15,711	0.08	377,064
Case Manager Call Log and Case Notes (S–23)	300	8,183	0.08	196,392
UC Case Status (S–27)	300	327	0.25	24,525
Estimated Annual Burden Hours Total				636,495

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.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–27505 Filed 11–22–24; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0180]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 26, 2024.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0810. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Clearance for the Collection of Quantitative Data on Tobacco Products and Communications

OMB Control Number 0910–0810—Extension

This information collection supports FDA programs. Under section 1003(d)(2)(D) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(D)), FDA is authorized to conduct educational and public information programs. Under this umbrella, FDA's Center for Tobacco Products (CTP) conducts research and uses a variety of media to inform and