Authority: 8 U.S.C. 412(a)(4).

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–31044 Filed 12–26–24; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Unaccompanied Children Bureau Incident Reporting (Office of Management and Budget #: 0970–NEW)

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 Bureau (UCB) to ensure that serious issues are elevated to ORR and that all incidents and the response to such incidents are documented and resolved in a way that protects the interests of children.

DATES: *Comments due* February 25, 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 above.

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 UCB is in the process of reorganizing its information collections to create more unique information collections that will contain fewer forms under each OMB control number. This will promote operational efficiency for UCB by decreasing the burden associated with renewing large collections and enabling UCB to create more purpose-specific information collections. In addition, this will facilitate OMB review by ensuring the scope of the collection is targeted and narrower than existing collections, resulting in clearer requests. As part of that reorganization effort, ORR plans to move the following forms into this new information collection:

- Child-Level Event (Form A–9A)
- Emergency Significant Incident Report (eSIR) (Form A–9B)
- Non-Emergency Significant Incident Report (non-eSIR)(Form A–9C)
- Historical Disclosure (Form A–9D)
- Behavioral Note (Form A–9E)
- Program-Level Event (PLE) Report (Form A–10)

In addition, ORR plans to revise the forms as follows to better align the forms with related reporting requirements and processes found in ORR agency guidance (*i.e.,* regulations, policies, and procedures), as well as improve the forms' organization, clarity, and functionality:

Child-Level Event (Form A–9A)

- Adjust the dropdown options for the ''Location of Event'' field to remove duplication and improve accuracy by:
  - Removing ''Group Home'' and ''Foster Home''
  - Rewording ''Community (field trip or outside the foster home)'' to ''Community''
  - Rewording ''U.S. Interior, not DHS or ORR custody'' to ''U.S. Interior (before entering DHS or ORR custody)''
- Adjust the dropdown options for ''Specify Location'' for accuracy by:
  - Rewording options to clarify when they are referring to locations inside the care provider facility
  - Adding an option for ''Individual Foster Home''
  - Adding the following options to select from if ''Community'' is selected in the ''Location of Event'' field
    - Hospital or other healthcare facility
    - School
    - Field Trip
    - Other
- Add the following fields:
  - Level of Care
  - Specify Out-of-Network Facility
  - Specify Out-of-Network Level of Care
- Reword the Date/Time Event Reported to Care Provider fields as follows since provider staff may have directly witnessed the event, as opposed to having it reported to them by a third-party:
  - Date Care Provider Became Aware of Event
  - Time Care Provider Became Aware of Event

Emergency Significant Incident Report (Form A–9B)

- Reword the subcategory ''Molestation (penetration or touching unrelated to official job duties of a child's buttocks, breasts, or anal, oral, or genital area by a body part or object'' to ''Molestation (intentional penetration or touching unrelated to official job duties of a child's genitalia, anus, groin, breast, inner thigh, buttocks, or mouth by a body part or object, including kissing, with intent to abuse, arouse, or gratify sexual desire)'' for added clarity.
- Remove the option of ''UC and UC consensual'' from the ''Type of Allegation'' dropdown field to align with the related regulation.

Non-Emergency Significant Incident Report (Form A–9C)

- For the ''Staff Code of Conduct & Boundary Violation'' category:
  - Reworded the subcategory ''Failing to report any knowledge, suspicion, or information about sexual abuse, sexual harassment, or inappropriate sexual behavior'' to ''Failing to report any knowledge, suspicion, or information about sexual abuse, sexual harassment, inappropriate sexual behavior, or any other form of abuse/neglect'' to clarify that other forms of abuse/neglect are also reportable
  - Added the following subcategories to better align with ORR agency guidance:
    - Failing to report a code of conduct violation
    - Engaging in sexual contact with anyone while on duty or while acting in the official capacity of their position
    - Threatening a child with incident reporting or behavioral notes to regulate their behavior or for any other reason
    - Threatening a child with legal, immigration, sponsor unification, or asylum case consequences to regulate their behavior or for any other reason

Historical Disclosure (Form A–9D)

- Reword the ''Abuse Neglect in DHS Custody'' category to ''Violation of Civil Rights/Liberties in DHS Custody'' and replace the current subcategories with the following options to better reflect the types of reportable incidents:
  - Conditions of detention
  - Disability accommodation
  - Excessive force or inappropriate use of force
  - Fourth Amendment (confiscation of documents/property)
  - Intimidation, threat, or improper coercion

- Legal access/due process rights
- Undocumented separation from parent/legal guardian
- Undocumented separation from minor sibling
- Medical/mental health care
- Privacy Violation
- Religious Accommodation
- Retaliation
- Restraints or isolation
- Sexual abuse, sexual harassment, or inappropriate sexual behavior
- Previous enrollment in the U.S. Department of Homeland Security (DHS) Migrant Protection Protocols program

• Add a ''Notifications'' section to document notifications made to parties other than ORR.

Behavioral Note (Form A–9E)

• Change the title of the ''Incident Information'' section to ''Behavior Information'' and added the following fields:

- Type of Behavior, with the following options:
  - Positive behavior, habit, resilience, personal growth, skill-building, or another meritorious action/trait
  - Behavior that merits monitoring in the event a behavioral pattern emerges that requires intervention or support
- Is the behavior part of an established behavioral pattern?
- Is intervention or support required?

• In the Actions Taken section:

- Reword ''Staff Response and Intervention'' to ''Staff Response (if applicable)''
- Reword ''Follow-up and/or Resolution'' to ''Potential Consequence(s) of Continued Behavior''
- Reword ''Recommendations'' to ''Staff Intervention or Support''

Program-Level Event Report (Form A–10)

• Reword ''Program/Facility'' to ''Specify Program''.

• Add a field for ''Level of Care''.

• Reword ''Synopsis of Event'' to ''Short Synopsis''.

• Remove the category for ''Other''.

• Reword the category ''Death (non-UC)'' to ''Death of an Adult or non-UC Child''.

• Reword the category ''Major Disturbance'' to ''Threats to Safety'' and replace the current subcategories with:

- Trespassing/Intruder
- Threats to Children or Staff
- Weapon Found
- Vehicle Accident
- Cyber Breech, Attack, or Threat

• Reword the category ''Natural Disaster'' to ''Natural Disaster or Weather Event'' and replace the ''Other'' subcategory with ''Storm''.

• Add the following categories and subcategories:

- Facilities Issues, with subcategories for:
  - Environmental
  - Mechanical Malfunction
  - Imminent Risk to Safety
  - Maintenance
  - Staffing Shortage
- Video Monitoring Disruption
- Infectious Disease/Health and Safety Incident
- Power Outage/Disruption of Utilities (External)
- Incident Involving Unidentified Child, with subcategories for:
  - Code of Conduct Violation
  - Safety or Abuse/Neglect Concern
- Code of Conduct Violation Not Involving a Child, with subcategories for:
  - Failing to disclose staff misconduct witnessed on or off duty
  - Failing to self-disclose misconduct occurring on or off duty
- Unauthorized Photography, Video, or Surveillance
- Media Requests/External Questions
- IT Disruption/internet Outage
- Records Issues, with subcategories for:
  - Damaged Records
  - Unauthorized Destruction of Records
  - Lost Records

• Remove the following fields from the Incident Information section:

- Location of Incident (and Specify)
- Was the UAC or Anyone Else Injured? (If Yes, SIR must be created) (and Specify)
- Internal Investigation?
- Results/Findings of Investigation

• Reword the following fields from the Incident Information section:

- ''Description of Incident'' to ''Describe the event and explain the effect on the program's operations.''
- ''Was the UAC or Anyone Else Evacuated?'' to ''Were or are children being evacuated?''
- ''Staff Response and Intervention'' to ''Describe actions taken to mitigate the impact on children in care''

• Reword the field ''Follow-up and/or Resolution'' to ''Updates, Follow-up, and/or Resolution'' and move it into a new ''Addendum'' section.

• Add the following fields from the Incident Information section:

- Does the program need immediate guidance or resources?
- Was or is the facility locked down or sheltered in place?
- Has or will the program's ability to provide healthcare services be affected?
- Does the program have adequate resources to provide care for children for duration of the event?
- Did or will the event affect the program's bed capacity?
- Specify Effect on Bed Capacity, with options for:
  - Beds need to come offline
  - Unable to receive additional children
  - Children need to be transferred to another program

• Add new areas to document reporting to and the outcome of investigations conducted by the following parties:

- Child Protective Services
- Office of the Inspector General (OIG)
- Department of Homeland Security (DHS)
- Office on Trafficking in Persons

Revisions Applied to Multiple Forms

• Change ''UC'' to ''child'' or ''children'' where possible [all forms].

• Update the field in the ''UC Basic Information'' section as follows to align with how information is currently displayed [all forms]:

- Remove the following fields:
  - LOC
  - Age
  - Current Location
- Add system-generated ''Portal ID'' field
- Reword fields as follows:
  - ''A No.'' to ''A#''
  - ''Child's Country of Birth'' to ''Country of Birth''
  - ''LOS'' to ''Length of Stay''
- Reorganized the order in which the fields appear

• Add a field for ''Physical Location of the Child'' in the ''UC Basic Information Section''.

• For the ''How was this child involved?'' and ''Were other unaccompanied children involved'' fields [eSIR and non-eSIR]:

- Use terms better aligned with child welfare best practices for incidents involving children by rewording ''Victim'' to ''Impacted'' and ''Perpetrator'' to ''Exhibiting.''
- Allow users to select multiple options since a child may play multiple roles in an incident. This includes situations where the child is both exhibiting problematic behaviors and impacted due to past trauma or victimization.

• In the ''Actions Taken'' section [eSIR, non-eSIR, and Historical Disclosure]:

- Add the following fields to better track compliance with requirements in ORR agency guidance:

- Was or will the child be referred to the local legal service provider for a follow-up legal consultation?
- Was or will the child be referred for appointment of a child advocate?

○ Add the following fields to better track what healthcare services may be required because of the incident [eSIR, non-eSIR, and Historical Disclosure]:
- Was the child hospitalized and/or receive serious medical services? [eSIR only]
- Was or will the child be referred for healthcare services?
- Specify Type(s) of Healthcare Services (with options for Medical, Mental Health/Behavioral, and Dental)
- Describe the healthcare services that were or will be provided

○ Replace the ''Follow-up Regarding Individuals Involved'' field, which is duplicative of other fields in the section, with ''Actions Taken for Witnesses'' [eSIR and non-eSIR]

• Add a new ''Immediate Phone Call Notifications'' section to better track compliance with policy requirements [eSIR and PLE Report].

• In the Reporting section:

○ Replace the yes/no radio button options for fields that ask if the incident was investigated with a dropdown field that includes the following options: ''Yes,'' ''No,'' ''To Be Determined,'' ''Unknown'' [eSIR, non-eSIR, Historical Disclosure, and PLE Report]

○ Add a ''Disposition of Investigation'' field for reports made to state licensing, child protective services, and local law enforcement to better track outcomes when the incident is investigated by those parties [eSIR, non-eSIR, Historical Disclosure, and PLE Report]

○ Add a new area to document reports to and the outcome of investigations conducted by the ORR Division of Child Protection Investigations (DCPI) [eSIR, non-eSIR, Historical Disclosure, and PLE Report]

○ Add a new area to document when an Incident Review form (currently approved under OMB# 0970–0564) must be completed and a place to upload the completed form [eSIR and non-eSIR]

• Update the auto-populated information in the ''ORR Notifications'' table to align with policy and replace the ''Email'' and ''Phone'' columns with columns for ''Method of Notification'' and ''Specify'' (for when ''Other'' is selected) [eSIR and PLE Report].

• Remove the ''ORR Notifications'' table since notifications are made by ORR's SIR Triage Team, not the care provider [non-eSIR and Historical Disclosure].

• Update the auto-populated information in the ''Other Notifications'' table to align with policy and add options for ''Messaging app'' and ''Mail'' for the ''Method of Notification'' field [eSIR and non-eSIR].

Revisions to Burden Estimates

• *Child-Level Event (Form A–9A):* Revise the burden estimate to account for an increase in the number of care provider facilities and to align with the actual number of forms submitted per year. The annual number of respondents increased from 216 to 300 and the annual number of responses per response increased from 160 to 262.

• *Emergency Significant Incident Report (eSIR) (Form A–9B):* Revise the burden estimate to account for an increase in the number of care provider facilities and to align with the actual number of forms submitted per year. The annual number of respondents increased from 216 to 300 and the annual number of responses per response decreased from 26 to 10.

• *Non-Emergency Significant Incident Report (non-eSIR)(Form A–9C):* Revise the burden estimate to account for an increase in the number of care provider facilities and to align with the actual number of forms submitted per year. The annual number of respondents increased from 216 to 300 and the annual number of responses per response decreased from 261 to 62.

• *Historical Disclosure (Form A–9D):* Revise the burden estimate to account for an increase in the number of care provider facilities and to align with the actual number of forms submitted per year. The annual number of respondents increased from 216 to 300 and the annual number of responses per response decreased from 163 to 139.

• *Behavioral Note (Form A–9E):* Revise the burden estimate to account for an increase in the number of care provider facilities and to align with the actual number of forms submitted per year. The annual number of respondents increased from 216 to 300 and the annual number of responses per response decreased from 137 to 90.

• *Program-Level Event (PLE) Report (Form A–10):* Revise the burden estimate to account for an increase in the number of care provider facilities and to align with the actual number of forms submitted per year. The annual number of respondents increased from 216 to 300 and the annual number of responses per response decreased from 7 to 6.

Respondents: Care provider programs.

Annual Burden Estimates

ESTIMATED TOTAL ANNUAL BURDEN HOURS

Form	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual total burden hours
Child-Level Event (Form A–9A)	300	262.0	0.17	13,362
Emergency Significant Incident Report (Form A–9B)	300	10.0	1.50	4,500
Non-Emergency Significant Incident Report (Form A–9C)	300	62.0	1.50	27,900
Historical Disclosure (Form A–9D)	300	139.0	1.50	62,550
Behavioral Note (Form A–9E)	300	90.0	0.50	13,500
Program Level Event (Form A–10D)	300	6.0	1.00	1,800
Estimated Annual Burden Hours Total	.....	.....	.....	123,612

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; 45 CFR 410; 45 CFR 411.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–30851 Filed 12–26–24; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5381]

Modifications to Labeling of Buprenorphine-Containing Transmucosal Products for the Treatment of Opioid Dependence

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that we have concluded that certain statements set forth in the FDA-approved labeling for buprenorphine-containing transmucosal products for the treatment of opioid dependence (BTODs) related to the recommended maintenance dosage and dosage adjustments during pregnancy can be modified. We believe that certain statements in BTOD labeling can be modified because the labeling for these products may be misinterpreted by some as establishing a maximum dosage when none exists. FDA is concerned that misinterpretation of these labeling statements may be adversely impacting patients' access to BTODs. We encourage sponsors of approved applications for BTODs to submit supplemental new drug applications (NDAs) (labeling supplements) to modify these labeling statements as described in this notice.

FOR FURTHER INFORMATION CONTACT: Kimberly Compton, Center for Drug Evaluation and Research (HFD–170), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 3168, Silver Spring, MD 20993, 301–796–1191, *kimberly.compton@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. FDA-Approved BTODs

Buprenorphine is a mu-opioid receptor partial agonist and a kappa-opioid receptor antagonist. BUPRENEX (buprenorphine hydrochloride (HCl)) injection (under NDA 018401) is a schedule III controlled substance under the Controlled Substances Act (CSA) and was the first buprenorphine product to be approved in the United States (approved in 1981) for management of moderate to severe pain. Other buprenorphine products were subsequently approved for the treatment of opioid use disorder (OUD) [1] and are also controlled under schedule III of the CSA.[2] BTODs have been approved by FDA since 2002. BTODs are available both as products containing buprenorphine alone and as fixed combination drug products containing buprenorphine and naloxone. BTODs include ZUBSOLV (buprenorphine HCl and naloxone HCl) sublingual tablets; SUBOXONE (buprenorphine HCl and naloxone HCl) sublingual film (for sublingual or buccal use); Buprenorphine and Naloxone Sublingual Film; and Buprenorphine and Naloxone Sublingual Tablets.

The first BTODs approved were SUBUTEX (buprenorphine HCl) sublingual tablets (NDA 020732)and SUBOXONE (buprenorphine HCl and naloxone HCl) sublingual tablets (NDA 020733).[3] Approval of these products was based, in part, on clinical studies of Buprenorphine Sublingual Tablets with and without Naloxone Sublingual Tablets, and on studies of sublingual administration of a more bioavailable ethanolic solution of buprenorphine (Ref. 1). Dosing recommendations were based on data from one trial of both buprenorphine products and two trials of the ethanolic solutions. In a double-blind, parallel-group, 16-week study, 731 subjects were randomized to receive 1 of 4 dosages of buprenorphine ethanolic solution: 1 milligram (mg), 4 mg, 8 mg, and 16 mg. For comparison purposes 1 mg of solution would be equivalent to less than 2 mg of buprenorphine in sublingual tablets; 4 mg, 8 mg, and 16 mg of buprenorphine in the solution would be roughly equivalent to 6 mg, 12 mg, and 24 mg of buprenorphine in sublingual tablets, respectively. Buprenorphine (administered once daily) was titrated to a maintenance dosage over 1 to 4 days and continued for 16 weeks. Based on retention in treatment and the percentage of thrice-weekly urine samples negative for non-study opioids, the three highest tested dosages of the ethanolic solution (*i.e.,* 4 mg, 8 mg, and 16 mg once daily dosages) were superior to the 1 mg once daily dosage. This study and the additional information submitted to support the approval of SUBUTEX and SUBOXONE demonstrated Buprenorphine Sublingual Tablets are effective from 4 mg to 24 mg once daily. The ''Dosage and Administration'' section of the original labeling for these products in describing the appropriate maintenance dosage read, in part:

The dosage of SUBOXONE should be progressively adjusted in increments/decrements of 2 mg or 4 mg to a level that holds the patient in treatment and suppresses opioid withdrawal effects. This is likely to be in the range of 4 mg to 24 mg per day depending on the individual [Ref. 1].

In 2011, the Agency took several actions including the approval of two additional strengths, updates to the labeling, and modifications to the risk evaluation and mitigation strategy (REMS) for SUBUTEX and SUBOXONE sublingual tablets (Refs. 2, 3, 4, 5). The goals of the REMS for SUBUTEX and SUBOXONE were to mitigate the risks of accidental overdose, particularly in the pediatric population, and to mitigate the risks of misuse and abuse, as well as to inform patients of the serious risks associated with use of these products (Refs. 2, 4*).* It was at this time and within the context of addressing these concerns that the application holder for SUBUTEX and SUBOXONE proposed changes to the ''Dosage and Administration'' section of the approved labeling. For SUBOXONE, FDA approved the following language related to the maintenance dosage in the ''Dosage and Administration'' section of the labeling (SUBUTEX shares similar language in its labeling (Ref. 5)):

- SUBOXONE sublingual tablet is indicated for maintenance treatment.
- The recommended target dosage of SUBOXONE sublingual tablet is 16 mg/4 mg buprenorphine/naloxone/day as a single daily dose.
- The dosage of SUBOXONE sublingual tablet should be progressively adjusted in increments/decrements of 2 mg/0.5 mg or 4 mg/1 mg buprenorphine/naloxone to a level that holds the patient in treatment and suppresses opioid withdrawal signs and symptoms.
- The maintenance dose of SUBOXONE sublingual tablet is generally in the range of 4 mg/1 mg buprenorphine/naloxone to 24 mg/6 mg buprenorphine/naloxone per day depending on the individual patient. Dosages higher than this have not been

[1] For the purposes of this notice, the terms *opioid dependence* and *opioid use disorder* are used interchangeably.

[2] 21 CFR 1308.13(e).

[3] Approvals of Subutex and Suboxone sublingual tablets were withdrawn on September 15, 2022 (87 FR 50337, August 16, 2022).