IV. Provisions of the Final Notice

A. Comparison of the ADA's Standards and Requirements for Accreditation to the NSDSMES and the Medicare Application Requirements

We compared the ADA's diabetes outpatient self-management training accreditation requirements and survey process with the NSDSMES requirements and CMS application requirements in 42 CFR part 410, subpart H, as described in section II of this final notice.

We found the ADA's accreditation standards and process to be consistent with the NSDSMES standards and CMS requirements.

B. Term of Approval

Based on the review and observations described in section II of this final notice, we have determined that the ADA's requirements for diabetes outpatient self-management training meet our requirements. Therefore, we approve the ADA as a national accreditation organization for diabetes outpatient self-management training program that request participation in the Medicare program, effective September 27 2021 through September 27, 2027.

V. 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.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: September 22, 2021.

Lynette Wilson,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2021–20943 Filed 9–24–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Performance Review Board Membership

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice of performance review board membership.

5 U.S.C. 4314(c)(1) through (5) requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more Senior Executive Service (SES) Performance Review Boards (PRBs).

The PRB shall review and evaluate the initial summary rating of a senior executive's performance, the executive's response, and any higher-level review's comments on the initial summary rating. In addition, the PRB will review and recommend executive performance bonuses and pay increases.

5 U.S.C. 4314(c)(4) requires the appointment of board members to be published in the **Federal Register**. The following persons comprise a standing roster to serve as members of the SES PRB for the Centers for Medicare & Medicaid Services:

Jonathan Blum, Principal Deputy Administrator and Chief Operating Officer (serves as the Chair)
Tia Butler, Director, Office of Human Capital (serves as the Co-chair)
Elizabeth Fowler, Deputy Administrator and Director, Center of Medicare
Arielle Woronoff, Director, Office of Legislation
Karen Jackson, Deputy Chief Operating Officer
Elizabeth Richter, Deputy Center Director, Center for Medicare
Karen Shields, Deputy Center Director, Center for Medicaid and CHIP Services
Arrah Tabe-Bedward, Deputy Director, Center for Medicare and Medicaid Innovation
Jeffrey Wu, Deputy Director for Operations, Center for Consumer Information and Insurance Oversight

The Principal Deputy Administrator and Chief Operating Officer of the Centers for Medicare & Medicaid Services (CMS), Jonathan Blum, 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**.

FOR FURTHER INFORMATION CONTACT: Kathy Vaughn, 410–786–1050 or *katherine.vaughn@cms.hhs.gov.*

Vanessa Garcia,

Federal Register Liaison.

[FR Doc. 2021–20886 Filed 9–24–21; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Administration and Oversight of the Unaccompanied Children Program (OMB #0970–0547)

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 monitor care provider facility compliance with federal laws and regulations, legal agreements, and ORR policies and procedures; and perform other administrative tasks.

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 6, 2021, (86 FR 545) 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 six instruments currently approved under OMB #0970–0547. Four of the revised instruments will be incorporated into ORR's new case management system, UC Path. The other two revised instruments are and will remain PDF instruments. In addition, ORR plans to add four new instruments to this collection—two will be incorporated into UC Path and two will be in PDF format. ORR also plans to remove one currently approved instrument from this collection. Finally, ORR plans to replace the term ''unaccompanied alien child (UAC)'' with ''unaccompanied child (UC)'' throughout the instruments in this collection.

1. Care Provider Facility Tour Request (Form A–1A): This instrument is used by advocacy groups, faith-based organizations, researchers, government officials, and other stakeholders to request tours of ORR care provider facilities. After the request is received, ORR documents its decision and details regarding date and location of the tour, if applicable, and provides the completed form to the requester. No revisions are currently requested; ORR plans to continue use of this form as-is.

2. Notice to UC for Flores Visits (Forms A–4 & A–4s): This instrument is used by care provider facilities to notify UC of upcoming visits by *Flores* counsel (lawyers and volunteers from the organization that originally participated in the creation of the Flores Settlement Agreement) and allows UC to add their name to a sign-up sheet if they are willing to speak with *Flores* counsel. ORR updated the Spanish translation of this PDF instrument.

3. Authorization for Release of Records (Form A–5): This instrument is used by attorneys, legal service providers, government agencies, and other stakeholders to request UC case file records. In most cases, requesters are required to obtain the signature of the subject of the record request (UC or their parent/legal guardian or sponsor) and a witness. ORR made the following revisions:

- Added a section in which ORR-funded legal service providers are required to certify their representation of the child.
- Added a separate area where sponsors may authorize the release of their records.
- Updated the required supporting documentation for a representative of a federal/state government agency or the National Center for Missing and Exploited Children to further require that the requester specify the scope of their investigation and provide a case reference number.
- Clarified in the instructions that ORR will not release any records that are clearly outside of the scope of a government agency's investigation absent a court-issued subpoena or order.

4. Notification of Concern (Form A–7): This instrument is used by home study and post-release service caseworkers, care provider case managers, and the ORR National Call Center to notify ORR of certain concerns that arise after a UC is released from ORR custody. This is a new instrument that ORR plans to add to this collection.

5. Event (Form A–9): This instrument is used by ORR care provider programs to document high-level information about situations that must be reported to ORR. Creating an *Event* is the first step in creating any type of incident report (see forms A–10A to A–10C below), *PLE Report* (see form A–10D below), or *Notification of Concern* (see form A–7 above). After an *Event* is created, an incident report or *Notification of Concern* is created for each UC involved in the incident and linked to the *Event.* For program-level events, one *PLE Report* is created and linked to the *Event. Event* information is visible in each individual report/notification report. This instrument was previously approved as part of ORR's various incident reports (Forms A–10A to A–10D). ORR is listing it separately, as a new instrument, to better align instruments in this collection with how data will be entered in UC Path. Some fields that were previously entered in each incident report have been moved into this instrument so that they only need to be entered once. The form also contains several new fields that capture additional information about the location and timeframe of the event. Please note that internal form number A–9 was previously assigned to the Program-Level Event Report.

6. Emergency Significant Incident Report (SIR) and Addendum (Form A–10A): This instrument is used by ORR care provider programs to inform ORR of urgent situations in which there is an immediate threat to a child's safety and well-being that require instantaneous action. In some cases, an Emergency SIR Addendum may be required to provide additional information obtained after the initial report. ORR made the following revisions:

- Revised the available options for the category and subcategory fields.
- Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.
- Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.
- Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.
- Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated and notification emails can be sent from within the UC Path system.
- Updated internal form numbering so that reports and addendums fall under the same form number.

7. Significant Incident Report (SIR) and Addendum (Form A–10B): This instrument is used by ORR care provider programs to inform ORR of situations that affect, but do not immediately threaten, the safety and well-being of a child. In some cases, an SIR Addendum may be required to provide additional information obtained after the initial report. ORR made the following revisions:

- Revised the available options for the category and subcategory fields.
- Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.
- Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.
- Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.
- Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated and notification emails can be sent from within the UC Path system.
- Updated internal form numbering so that reports and addendums fall under the same form number.

8. Sexual Abuse Significant Incident Report (SA/SIR) and Addendum (Form A–10C): This instrument is used by ORR care provider programs to inform ORR

of allegations of sexual harassment, sexual abuse, and inappropriate sexual behavior that occurred while the UC was in ORR custody. In some cases, an SA/SIR Addendum may be required to provide additional information obtained after the initial report. ORR made the following revisions:

○ Revised the available options for the category and subcategory fields.

○ Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.

○ Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.

○ Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.

○ Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated and notification emails can be sent from within the UC Path system.

○ Updated internal form numbering so that reports and addendums fall under the same form number.

9. Program-Level Event (PLE) Report and Addendum (Form A–10D): This instrument is used by ORR care provider programs to inform ORR of events that may affect the entire care provider facility, such as an active shooter or natural disaster. An updated PLE Report is required for events that occur over multiple days or if the situation changes regarding the event. ORR made the following revisions:

○ Revised the available options for the category and subcategory fields.

○ Added fields to capture additional detail on individuals involved in the incident, actions taken, and video footage.

○ Added fields to capture additional information related to reporting of incidents to child protective services, state licensing agencies, and local law enforcement.

○ Added a disposition field to indicate whether the incident is closed or if the incident is open and further action is required.

○ Updated functionality for the list of individuals who need to be notified of the incident so that it is auto-populated and notification emails can be sent from within the UC Path system.

○ Updated internal form numbering so that reports and addendums fall under the same form number.

10. Hotline Alert (Form A–12): ORR is discontinuing this instrument. In UC Path, the ORR National Call Center will use the Notification of Concern instead of the Hotline Alert.

11. Key Personnel Minimum Qualifications Checklist and Attestation (Form A–14): This instrument is used by ORR care provider programs to request hiring approval for key positions, as required in the ORR cooperative agreement, and, if applicable, request a waiver of minimum qualifications when appropriately justified. This is a new instrument that ORR plans to add to this collection and is currently approved under OMB #0970–0558.

12. ORR Waiver Request (Form A–15): This instrument is used by ORR care provider programs to request a waiver of a permissible regulatory, policy, procedure, or cooperative agreement requirement. ORR considers waiver requests when appropriately justified and when the safety and well-being of children in ORR custody would not be adversely affected. ORR does not have the authority to waive federal or state statute or state regulations and may only waive certain provisions of federal regulations where specified by the regulation. This is a new instrument that ORR plans to add to this collection and is currently approved under OMB #0970–0558.

B. ORR plans to remove the term ''alien'' from the title of this information collection and revise it to read ''Administration and Oversight of the Unaccompanied Children Program.''

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.

- Emergency Significant Incident Report and Addendum (Form A–10A)
- Significant Incident Report and Addendum (Form A–10B)
- Sexual Abuse Significant Incident Report and Addendum (Form A–10C)
- Program-Level Event Report and Addendum (Form A–10D)

Respondents: ORR grantee and contractor staff; advocacy groups, faith-based organizations, researchers, and government officials; attorneys, legal service providers, child advocates, and government agencies; and other stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual total burden hours
Respondents				
Care Provider Facility Tour Request (Form A–1A)	200	1	10	33
Notice to UC for Flores Visits (Forms A–4 & A–4s)	20	1	15	5
Authorization for Release of Records (Form A–5)	4,000	1	15	1,000
Notification of Concern (Form A–7)	60	75	15	1,125
Event (Form A–9)	276	160	10	7,360
Emergency Significant Incident Report and Addendum (Form A–10A)	216	14	60	3,024
Significant Incident Report and Addendum (Form A–10B)	216	491	60	106,056
Sexual Abuse Significant Incident Report and Addendum (Form A–10C)	216	47	60	10,152
Program Level Event (Form A–10D)	216	7	60	1,512
Key Personnel Minimum Qualifications Checklist and Attestation (Form A–14)	235	9	10	353
ORR Waiver Request (Form A–15)	235	2	20	157

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden minutes per response	Annual total burden hours
Estimated Annual Burden Hours Total				130,777
Record Keepers				
Care Provider Facility Tour Request (Form A–1A)	216	1	120	432
Authorization for Release of Records (Form A–5)	216	19	20	1,368
Estimated Annual Burden Hours Total				1,800

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. 2021–20918 Filed 9–24–21; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1978–N–0018]

Amending Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use; Over the Counter Monograph Proposed Order; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of an over-the-counter (OTC) monograph proposed order (order ID OTC000008) entitled ''Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use.'' FDA is issuing this proposed order to amend and revise the deemed final administrative order concerning nonprescription sunscreen drug products (Deemed Final Order) established by the enactment of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). This proposed order, if finalized, would replace the Deemed Final Order in its entirety with new conditions under which nonprescription sunscreen drug products would be determined to be generally recognized as safe and effective (GRASE) under the Federal Food, Drug, and Cosmetic Act (FD&C Act). It also sets forth certain characteristics that would establish that a sunscreen drug product is not GRASE.

DATES: Submit electronic comments on the proposed order by 11:59 p.m. Eastern Time at the end of November 12, 2021.

ADDRESSES: You may submit comments to Order ID OTC000008 as follows. Please note that late, untimely filed comments will not be considered. Comments must be submitted electronically on or before November 12, 2021. The *https://www.regulations.gov* will accept comments at any time until 11:59 p.m. Eastern Time at the end of November 12, 2021.

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 information that you or a third party may not wish to be publicly posted, such as medical information or 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 electronically in the manner detailed in ''Instructions.''

Instructions: All submissions received must include the Order ID Number OTC000008 and the Docket No. FDA–1978–N–0018 for ''Amending Over-the-Counter (OTC) Monograph M020: Sunscreen Drug Products for OTC Human Use.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable on *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—Under section 505G(d) of the FD&C Act (21 U.S.C. 355h(d)), FDA must make any information submitted by any person with respect to this order available to the public upon submission, with limited exceptions. FDA will not make public information pertaining to pharmaceutical quality information, unless such information is necessary to establish standards under which a drug is generally recognized as safe and effective under section 201(p)(1) of the FD&C Act (21 U.S.C. 321(p)(1)) (see section 505G(d)(2)(B) of the FD&C Act). FDA will also not make public information that is of the type contained in raw datasets (see section 505G(d)(2)(B) of the FD&C Act). To submit a comment with this specific confidential information that you do not wish to be made publicly available, electronically submit two copies of the comment as an attachment to your comment submission. One copy will include the information that you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information. The second copy, which will have the claimed information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Any information marked as ''confidential'' will not be disclosed except in accordance with section 505G(d) of the FD&C Act, and other applicable disclosure law.

Docket: For access to the docket to read background documents or the electronic comments received, go to