

participation for Long-Term Care (LTC) facilities that must be met in order to participate in the Medicare and Medicaid Programs. LTC facilities include skilled nursing facilities (SNFs) as defined in section 1819(a) of the Social Security Act in the Medicare program and nursing facilities (NFs) as defined in 1919(a) of the Act in the Medicaid program. SNFs and NFs provide skilled nursing care and related services for residents who require medical or nursing care, or rehabilitation services for the rehabilitation of injured, disabled, or sick persons. In addition, NFs provide health-related care and services to individuals who because of their mental or physical condition require care and services (above the level of room and board) which can be made available to them only through institutional facilities, and is not primarily for the care and treatment of mental diseases. SNFs and NFs must care for their residents in such a manner and in such an environment as will promote maintenance or enhancement of the quality of life of each resident and must provide to residents services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident, in accordance with a written plan of care, which describes the medical, nursing, and psychosocial needs of the resident and how such needs will be met and is updated periodically.

The primary users of this information will be State agency surveyors, CMS, and the LTC facilities for the purposes of ensuring compliance with Medicare and Medicaid requirements as well as ensuring the quality of care provided to LTC facility residents. The ICs specified in the regulations may be used as a basis for determining whether a LTC is meeting the requirements to participate in the Medicare program. In addition, the information collected for purposes of ensuring compliance may be used to inform the data provided on CMS' Nursing Home Compare website and as such used by the public in considering nursing home selections for services.

We are revising this information collection request to include new requirements proposed at 42 CFR 483.35 and 483.71. The proposed requirements

were discussed in detail in the proposed rule that published September 6, 2023 (88 FR 61352). The discussion related to proposed requirements and the associated information collection burden begins on page 61391. Subsequent to publishing the 60-day **Federal Register** (89 FR 26892), the final rule (89 FR 40876) finalized the new requirements. Based upon our analysis of the public comments received on the proposed rule, we revised our burden estimates by adding a burden estimate for LTC facilities to solicit and consider any input received by residents, resident representatives, and family members. *Form Number:* CMS-10573 (OMB control number: 0938-1363); *Frequency:* Occasionally; *Affected Public: Private Sector:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 15,600; *Total Annual Responses:* 18,687,318 *Total Annual Hours:* 30,206,846. (For policy questions regarding this collection contact Diane Corning at 410-786-8486.)

William N. Parham, III

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Services for Unaccompanied Children With Disabilities (New Collection)

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 comment on the proposed collection. The request consists of one form that will allow the Unaccompanied Children (UC) Bureau

to provide services to unaccompanied children identified as having a disability.

DATES: *Comments due September 23, 2024.* 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: The ORR UC Bureau is proposing a new form, the *Individualized Section 504 Service Plan* (Form S-25). The proposed information collection is necessary to allow the ORR UC Bureau to comply with a court order and improve service delivery for unaccompanied children identified as having a disability. On June 29, 2018, Plaintiffs filed their federal class action lawsuit in the Central District of California, western division, captioned *Lucas R. et al v. Becerra et al* (Case No. 2:18-CV-05741 DMG PLA), asserting claims under the Flores consent decree, the Trafficking Victims Protection Reauthorization Act, the Due Process clause, and the First Amendment. Plaintiffs allege violation of unaccompanied children rights in decisions regarding family reunification, placement in restrictive facilities, services for children with disabilities, administration of psychotropic medication, and access to legal assistance. On May 3, 2024, the Court granted final approval for the settlement agreements of the Plaintiffs' claims for disabilities, psychotropic medication, and legal assistance. As part of the settlement agreement for the disabilities claim, ORR is required to develop and implement individualized Section 504 service plans for any child identified as having a disability. The disabilities settlement agreement must be fully implemented by May 3, 2025.

Respondents: Care provider grantees and contractors

Annual Burden Estimates:

Form	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Individual Section 504 Service Plan (Form S-25)	300	7	3	6,300

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; *Flores v. Reno* Settlement Agreement, No. CV85-4544-RJK (C.D. Cal. 1996); *Lucas R. et al v. Becerra et al* (Case No. 2:18-CV-05741 DMG PLA) Disabilities Settlement Agreement

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-2059]

Providing Over-the-Counter Monograph Submissions in Electronic Format; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Providing Over-the-Counter Monograph Submissions in Electronic Format." This guidance is intended to assist submitters by describing the electronic over-the-counter (OTC) monograph submissions requirement in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and providing recommendations and other information on how to send such OTC monograph submissions to FDA in electronic format. This guidance finalizes the draft guidance of the same title issued on September 28, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on July 25, 2024.

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."

Instructions: All submissions received must include the Docket No. FDA-2022-D-2059 for "Providing Over-the-Counter Monograph Submissions in Electronic Format." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper

submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-402-7945, Trang.Tran@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: