

completing the error rate reports, including their estimated burden hours for each report. All CCDF Lead Agencies required to submit the error rate reports were invited to participate, and 56 percent (29 out of 52 Lead Agencies) responded. Lead Agency respondents represented a geographically diverse group of states with a range in size as defined by the numbers of children and families served by CCDF. There were expected variations in responses which may reflect differences in states' administrative structures and complexity, staff capacity, reporting technology, interpretation of the survey questions, and other factors. However, even considering the range of responses and any outliers, OCC determined that the burden hours estimates should be lowered to reflect the survey results. In addition, to more accurately account for the work described by survey respondents, OCC further broke out the

estimated burden hours for the RRW into the following two parts: (1) the estimated hours needed for states to customize the standard RRW template to reflect their state's rules, policies, and procedures; and (2) the estimated hours needed for states to use the customized RRW to conduct each of the 276 case reviews.

• **Root Causes of Error:** OCC proposes to standardize the root causes of error in Item 19 of the ACF-404 State Improper Payment Report by creating a drop-down list of error cause choices. Currently, Lead Agencies enter free text to describe the causes of errors in their Federal error rate reviews. While this approach allows flexibility at the individual reporting level, inconsistent terminology and descriptions across states and reporting cycles makes it difficult to analyze, report, and track national and state-level error trends over time. Further, the current approach can

add additional burden to states during the report review and approval process because clarifications about error cause descriptions are often requested by Federal reviewers. We request comment on whether the proposed list of standardized error causes would meet Lead Agency reporting needs, and if not, what additional or different error causes should be included.

Respondents: CCDF grantees from states, the District of Columbia, and Puerto Rico.

Annual Burden Estimates: Burden estimates are shown based on the total burden over a 3-year period divided by three to show average annual burden estimates.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Sampling Decisions, Assurances, and Fieldwork Preparation Plan	52	1	35	1,820	607
ACF-403 Record Review Worksheet: <i>template</i>	52	1	63	3,276	1,092
ACF-403 Record Review Worksheet: <i>case record reviews</i>	52	276	3.0	43,056	14,352
ACF-404 State Improper Payments Report	52	1	66	3,432	1,144
ACF-405 State Improper Payments Report Corrective Action Plan	6	^a 2	24	288	96
Estimated Total Annual Burden Hours:					17,291

^a The total number of responses per respondent over 3 years ranges from 1–3, depending on how long it takes respondents to reduce the Improper Payment Rate to below the threshold. Respondents submit a *Corrective Action Plan* that covers a 1-year period; at the end of each year, if respondents have not reduced the Improper Payment Rate to below the threshold, they submit a new *Corrective Action Plan* for the following year. An average of two responses per respondent over a 3 year period is used to calculate annual burden estimates.

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: 45 CFR part 98 subpart K.

Mary C. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Administration of Psychotropic Medication to Unaccompanied Children (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 two forms that will allow the Unaccompanied Children (UC) Bureau to obtain informed consent from authorized consenters and informed

assent or agreement from unaccompanied children for the administration of psychotropic medication.

DATES: Comments due December 16, 2024. The Office of Management and Budget (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. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed

requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The ORR UC Bureau is proposing two new forms: *Psychotropic Medication Informed Consent* (Form MMH-1) and *Psychotropic Medication Assent Notice* (Form MMH-2). The proposed information collection is necessary to allow the ORR UC Bureau to comply with a court order and improve processes for the administration of psychotropic medication. 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

psychotropic medication claim, ORR is required, whenever possible, to obtain informed consent for the administration of psychotropic medication and provide certain information to the authorized consenter. Additionally, ORR is required to provide a written notice and obtain informed assent or agreement from children aged 14 or older before administering psychotropic medication. The psychotropic medication settlement agreement must be fully implemented by August 3, 2026, but data collection must be implemented by February 3, 2025, to ensure compliance with the Agreement.

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
Psychotropic Medication Informed Consent (Form MMH-1)	300	2	1.50	900
Psychotropic Medication Assent Notice (Form MMH-2)	300	1	0.75	225

Estimated Total Annual Burden Hours: 1,125.

Authority: 6 U.S.C. 279; 8 U.S.C. 1232; 45 CFR part 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) Psychotropic Medication 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-2024-D-4624]

Nonclinical Safety Assessment of Oligonucleotide-Based Therapeutics; Draft 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 draft guidance for industry entitled “Nonclinical Safety Assessment of Oligonucleotide-Based Therapeutics.” FDA is publishing this draft guidance which, when finalized, will provide recommendations on approaches for the

nonclinical safety evaluation of oligonucleotide-based therapeutics (ONTs) to support clinical development and marketing of these products. ONTs present unique challenges and opportunities in the nonclinical evaluation of safety that differ in many regards from those appropriate for small molecule drugs or therapeutic proteins.

DATES: Submit either electronic or written comments on the draft guidance by January 14, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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-2024-D-4624 for “Nonclinical Safety Assessment of Oligonucleotide-Based Therapeutics.” 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.