

Administration of Psychotropic Medication to Unaccompanied Children

**OMB Information Collection Request
0970 - NEW**

Attachment A - Summary of Public Comments and ORR Responses

November 2024

Type of Request: New

Submitted By:
Office of Refugee Resettlement
Administration for Children and Families
U.S. Department of Health and Human Services

ORR received a comment letter from one commenter, class counsel in *Lucas R. v. Becerra* (No. 2:18-CV-05741 DMG PLA). ORR expresses its appreciation to class counsel for the thoughtful and detailed comments in response to this information collection request.

Psychotropic Medication Informed Consent (Form MMH-1)

1. The commenter noted that the sentence in the introductory text that states “Care providers must obtain informed consent from an authorized consenter before administering psychotropic medication to any child in ORR custody” does not align with the *Lucas R. Psychotropic Medications Settlement Agreement* (herein “the Settlement”), which also requires informed consent prior to increases in dosage with specific exceptions. The commenter recommended that ORR add a sentence directly after that statement that reads “New informed consent may also be required before increases in dosage.”

ORR Response: ORR concurs with the commenter’s recommendation and has added the statement “New informed consent may also be required before increases in dosage.” to the introductory text of the form.

2. The commenter noted that the Settlement required notice to both the Authorized Consenter and the ORR Division of Health for Unaccompanied Children (DHUC) within one week of an emergency administration and specifies that the Authorized Consenter and DHUC must be notified of “the reasons” for the emergency administration.

- a. In addition to the existing field for “Date Consenter Informed,” the commenter recommended that ORR add a “Date DHUC Informed” field.

ORR Response: ORR concurs with the commenter’s recommendation and has added a “Date DHUC Informed” field under the Emergency Medication section of the form.

- b. The commenter also recommended that ORR include a space to confirm that the Consenter and DHUC were informed of the reasons for the emergency administration. The commenter further noted that the proposed form does not need to document what was discussed with the Consenter and DHUC, just a place to confirm that the parties were informed.

ORR Response: ORR concurs with the commenter’s recommendation and has added a question to the form that asks, “Was the consenter and the Division of Health for Unaccompanied Children (DHUC) informed of the reasons for the administration of emergency medication?”

3. The commenter noted that the Settlement requires “An explanation that the Authorized Consenter may withdraw consent and request the Psychotropic Medication(s) be discontinued at any time.” The commenter recommended adding “at any time” to Topic #12 in the “Informed Consent Discussion Topics” section so that the topic reads “Explanation that

they may withdraw consent at any time after already given and informed of the next steps that will be taken if they do not consent.”

ORR Response: ORR concurs with the commenter’s recommendation and has added the phrase “at any time” to Topic #12.

4. The commenter noted that the proposed form does not reflect the specific documentation requirements set out by the Settlement when an Authorized Consenter is illiterate or chooses to waive written consent. Specifically, the Settlement requires the care provider to “certify in writing that the document was fully communicated to the Authorized Consenter in a language the consenter understands” if the Consenter is illiterate, and “document the waiver in the child’s case file” if the Consenter chooses to waive written consent.

- a. The commenter recommended adding a space to note if the Authorized Consenter is unable to read and, in that case, to certify that the document was fully communicated to them in a language the consenter understands.

ORR Response: ORR concurs with the commenter’s recommendation and has added place for the care provider to document whether the consenter is unable to read and certify that the information on the psychotropic medication prescribed for the child and the topics under the Informed Consent Discussion Topics section of the form were fully communicated to the consenter in a language that they understand.

- b. The commenter also recommended including a space to note if the Authorized Consenter waived written consent and to document the safety risks or undue burden that formed the basis of this waiver.

ORR Response: ORR concurs with the commenter’s first recommendation. ORR added a place for the care provider to document whether the consenter waived written consent and certify that written consent was explained to the consenter in a language that they understand and that information on the psychotropic medication prescribed for the child and the topics under the Informed Consent Discussion Topics section of this form were fully communicated to the consenter in a language that they understand.

ORR does not concur with the commenter’s second recommendation. The Settlement states that the consenter may choose to waive providing written consent in cases where doing so would result in safety risks or undue burden and that the care provider must document the waiver in the child’s case file. The Settlement does not require ORR to document additional details about why written consent would result in safety risks or undue burden. ORR’s proposed form meets the Settlement’s requirements and will allow the care provider to specify that the waiver was due to safety risks or undue burden; However, the form will not document specific details about the safety risks or undue burden.

5. The commenter stated that while the proposed form includes a section for the “Centralized Concurrence Unit” decision, the section lacks sufficient detail to correctly implement the Settlement.

- a. Documentation of Concurrence – The commenter noted that the Settlement requires that “[i]f CCU concurrence with a Psychotropic Medication prescription is sought and obtained, it shall be in writing and signed by a licensed psychiatrist or psychiatric nurse under the supervision of a psychiatrist, with a preference for a child and adolescent psychiatrist, if available.” The commenter recommended including fields for the name, signature, and title of the person providing CCU concurrence. In addition, the commenter recommended against using a separate form to document the CCU’s decision and stated that including all the required information on this consent form will better ensure compliance with the Settlement’s documentation requirements.

ORR Response: This form is intended for use by the care provider, who will not be responsible for obtaining CCU concurrence. ORR’s health insurance underwriter will facilitate obtaining CCU concurrence, therefore, ORR plans to use the documentation that will be produced through the underwriter’s process to meet the documentation requirements of the Settlement for CCU concurrence.

- b. Override of Denial of Consent – The commenter noted that the CCU section of the proposed form does not specify whether the CCU concurred because no Authorized Consenter was available or whether the CCU acted to override a Primary Consenter’s or Sponsor Consenter’s denial of consent. The commenter further noted that the Settlement requires specific procedures, including specific findings and documentation of attempts by the CCU and the care provider to contact the Primary Consenter or Sponsor Consenter. The commenter recommended that the form include a section for CCU Overrides with a checklist of required findings and documentation of required attempts by the CCU and the care provider to contact the Primary Consenter or Sponsor Consenter.

ORR Response: As noted above, the Settlement’s documentation requirements for CCU concurrence will be met using document produced by ORR’s health insurance underwriter. In addition, the form already includes a “Reason concurrence sought from CCU field” in which care providers will explain whether concurrence was sought because an authorized consenter was not available or to override the consenter’s denial of consent. Nevertheless, ORR updated the available dropdown options for the CCU’s Decision field to provide further detail on the reason for concurrence. The revised list of options now include:

- Concur (consenter unavailable)
- Concur (override denial of consent)
- Do Not Concur (consenter unavailable)
- Do Not Concur (sustain denial of consent)

Psychotropic Medication Assent Notice (Form MMH-2)

1. The commenter noted that the proposed form does not specify that the child may speak with the prescribing healthcare provider in private nor does it specify that the child be informed of the purpose of the medication(s) as required by the Settlement. The commenter further noted that some aspects of the “Explanation for the Child” section are not accurate or complete and provided a couple examples. Finally, the commenter stated that the “Explanation for the Child” is written at an adult reading level and is likely to be difficult for children to understand. The commenter recommended revising the explanation as follows (changes are underlined):

A doctor or nurse recommended that you take medicine. This medicine is expected to help you. ORR has permission for you to take the medicine from [circle one] (1) your parent or legal guardian; (2) a family member who applied to sponsor you; or (3) another doctor. During this conversation, we will talk about why the doctor or nurse thinks you should take medicine, what this medicine is supposed to do, and how this medicine might make you feel (known as side effects). As we talk about this medicine, please ask questions and tell me what you think about taking the medicine. If you do not know whether you want to take the medicine, we can talk about it.

If you want to talk privately with the doctor or nurse that recommended the medicine, we will ask them if they will speak with you. We also list their contact information on this document.

ORR Response: ORR generally concurs with the commenter’s recommendation and made edits similar to those proposed by the commenter. The Explanation for the Child section now reads as follows:

You were prescribed medication by a doctor or a nurse practitioner. This medicine is expected to help you. ORR obtained permission for you to take the medication from your parent/legal guardian or a family member who applied to sponsor you, or another doctor. During this conversation, we will talk about why the doctor or nurse thinks you should take this medicine, what this medicine is supposed to do, and how this medicine might make you feel (which are known as a side effects). As we discuss this medication with you, please ask questions and let us know your feelings about taking the medication. If you would like to talk privately with the doctor or nurse practitioner that prescribed the medication, we can ask them if they will speak with you. We also list their contact information on this document.

2. The commenter noted that the Settlement requires that children be informed of specific information as part of the assent conversation. The commenter further noted that the proposed form seems to incorporate these requirements into the “Explanation for the Child” section, but that contributes to the difficult reading level of the explanation. The commenter recommended that instead ORR add a separate section to complete with a list of questions/issues similar to the “Discussion Topics” section of the proposed Psychotropic

Medication Informed Consent form to ensure that the care provide covers all topics required by the Settlement. The commenter provided the following example list:

Discussion Topics

- *Recommendation for the prescribed psychotropic medication, Discussed/Not Discussed*
- *Child's treatment plan, Discussed/Not Discussed*
- *Purpose of medication, Discussed/Not Discussed*
- *Potential side effects, Discussed/Not Discussed*
- *Child's reactions and concerns, Discussed/Not Discussed*
- *Written notice that child may speak privately with prescribing healthcare provider, Discussed/Not Discussed*
- *Child's assent, Yes/No*

ORR Response: ORR concurs with the commenter's recommendation and added a Topics Discussed with the Child section to the form.

3. The commenter noted that the "Explanation for the Child" section states "We also list the doctor's contact information on this document" but the form does not include space for the prescriber's contact information. The commenter recommended that space be added to capture the prescriber's contact information the "Psychotropic Medication Information" section, next to the existing fields for the Prescriber's Name and Credentials/Title.

ORR Response: ORR concurs with the commenters recommendation and added a field for the prescriber's phone number in the Psychotropic Medication Information section.

4. The commenter noted that the term "Prescriber" will likely be difficult for a child to understand. The commenter recommended changing "Prescriber" to "Doctor or Nurse Who Recommended Medication" to make the form more child friendly.

ORR Response: ORR concurs with the commenters recommendation and updated the form to replace "Prescriber" with "Doctor or Nurse Who Recommended Medication."

5. The commenter noted that the Settlement requires the care provider to "attempt to seek informed assent or agreement from the UC" but the proposed form does not include a space to indicate whether the child provided their assent to take the medication. The commenter recommended that the form, at minimum, include a field to record whether the child provided their assent. The commenter also recommended that ORR consider adding questions to verify the child's understanding, such as "Why do you think this medicine was recommended for you?" and "What do you think about taking the medicine?"

ORR Response: ORR concurs with the commenter's first recommendation and added a field under the Record of Review with Child section that asks whether the child assented to taking the medication.

ORR does not concur with the commenter's second recommendation to add questions verifying the child's understanding. The purpose of the form is to verify the child's assent, not to document the child's responses to the information that is discussed with them.