volume reduction surgery. This information is available at www.cms.gov/MedicareApprovedFacilitie/LVRS/list.asp#TopOfPage.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XIV: Medicare-Approved Bariatric Surgery Facilities (April through June 2024)

Addendum XIV includes a listing of Medicare-approved facilities that meet minimum standards for facilities modeled in part on professional society statements on competency. All facilities must meet our standards in order to receive coverage for bariatric surgery procedures. On February 21, 2006, we issued our decision memorandum on bariatric surgery procedures. We determined that bariatric surgical procedures are reasonable and necessary for Medicare beneficiaries who have a body-mass index (BMI) greater than or equal to 35, have at least one co-morbidity related to obesity and have been previously unsuccessful with medical treatment for obesity. This decision also stipulated that covered bariatric surgery procedures are reasonable and necessary only when performed at facilities that are: (1) certified by the American College of Surgeons (ACS) as a Level 1 Bariatric Surgery Center (program standards and requirements in effect on February 15, 2006); or (2) certified by the American Society for Bariatric Surgery (ASBS) as a Bariatric Surgery Center of Excellence (BSCOE) (program standards and requirements in effect on February 15, 2006).

There were no additions, deletions, or editorial changes to Medicare-approved facilities that meet CMS' minimum facility standards for bariatric surgery that have been certified by ACS and/or ASMBS in the 3-month period. This information is available at www.cms.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage.

For questions or additional information, contact Sarah Fulton, MHS (410-786-2749).

Addendum XV: FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials (April through June 2024)

There were no FDG-PET for Dementia and Neurodegenerative Diseases Clinical Trials published in the 3-month period.

This information is available on our website at www.cms.gov/MedicareApprovedFacilitie/PETDT/list.asp#TopOfPage.

For questions or additional information, contact David Dolan, MBA (410-786-3365).

[FR Doc. 2024–16040 Filed 7–19–24; 8:45 am]

BILLING CODE 4120–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; 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* September 20, 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 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.

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) Psychotropic Medication Settlement Agreement.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–16043 Filed 7–19–24; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2442]

Recommendations for Investigational and Licensed COVID–19 Convalescent Plasma; Guidance for Industry; 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 a final guidance for immediate implementation entitled ''Recommendations for Investigational and Licensed COVID–19 Convalescent Plasma; Guidance for Industry.'' The purpose of this guidance is to provide FDA's recommendations to blood establishments for the submission of a Biologics License Application (BLA) for the manufacture of COVID–19 convalescent plasma intended for transfusion in patients with immunosuppressive disease or receiving immunosuppressive treatment in either the outpatient or inpatient setting. The guidance also provides FDA's recommendations for investigational new drug applications (INDs) for investigational COVID–19 convalescent plasma for transfusion.

DATES: The announcement of the guidance is published in the **Federal Register** on July 22, 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–2024–D–2442 for ''Recommendations for Licensed COVID–19 Convalescent Plasma; Guidance for Industry.'' 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