++ Section 416.50(e)(3) to clearly identify that if a State court has not deemed a patient incompetent, any legal representative or surrogate designated by the patient in accordance with State law may exercise the patient's rights to the extent allowed by State law.

CMS also reviewed TJC's comparable survey processes, which were conducted as described in section III. of this final notice, and yielded the following areas where, as of the date of this notice, TJC has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Clarifying TJC's survey activity for Life Safety Code (LSC) related to the length of time required to complete an LSC/Health Care Facilities Code (HCFC) survey, as the survey activity will depend upon various circumstances (for example, age & condition, size of ASC/building, construction type, number of stories, sprinkler system, essential electric system, etc.).

++ Updating TJC's survey procedures to ensure all areas of the LSC/HCFC are surveyed and reflected in TJC's Surveyor Activity Guide.

++ Providing clarification to its Surveyor Activity Guide indicating that the 2012 edition of the NFPA Life Safety Code and NFPA 99 applies to ASCs.

++ Clarifying that any LSC/HCFC waivers can only be granted by CMS, in accordance with § 416.44(c)(2).

++ Providing additional surveyor training as it relates to scope, manner and degree of citations related to medication administration, physical environment, and Life Safety Code, in accordance with the State Operations Manual (SOM) Appendix L, Task 4.

++ Providing additional surveyor education comparable to CMS' Principles of Documentation, specifically to ensure records reviewed and reported on TJC's survey report to the facility are clear.

++ Revising TJC's process to ensure the appropriate sample of patient records is reviewed during surveys based on ASC case volume.

B. Term of Approval

Based on our review described in section III. and section V. of this final notice, we approve TJC as a national accreditation organization for ASCs that request participation in the Medicare program. The decision announced in this final notice is effective September 1, 2024 through September 1, 2030. In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years.

VI. Collection of Information and Regulatory Impact Statement

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 Vanessa Garcia, who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–15816 Filed 7–17–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Request for Assistance for Child Victims of Human Trafficking

AGENCY: Office on Trafficking in Persons, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF), Office on Trafficking in Persons (OTIP) is requesting a three-year extension of the form: Request for Assistance (RFA) for Child Victims of Human Trafficking (Office of Management and Budget (OMB) #0970–0362, expiration 09/30/2024). Burden estimates have been updated based on observed increases in the volume of requests received. The RFA form and estimated time per response remains the same.

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. 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 Trafficking Victims Protection Act (TVPA) of 2000, as amended, directs the Secretary of the U.S. Department of Health and Human Services (HHS), upon receipt of credible information that a foreign national minor may have been subjected to a severe form of trafficking in persons and is seeking assistance available to victims of trafficking, to promptly determine if the child is eligible for benefits and services to the same extent as refugees. HHS delegated this authority to OTIP.

OTIP developed a RFA form for case managers, attorneys, law enforcement officers, child welfare workers, and other representatives to report these trafficking concerns to HHS in accordance with the TVPA of 2000, as amended, and allow for OTIP to review the concerns and determine eligibility for benefits.

Specifically, the RFA form asks the requester for their identifying information, identifying information for the child, and information describing the potential trafficking concerns. The RFA form takes into consideration the need to compile information regarding a child's experiences in a trauma-informed and child-centered manner and assists the requester in assessing whether the child may have been subjected to a severe form of trafficking in persons.

The information provided through the completion of a RFA form enables OTIP to make prompt determinations regarding a foreign national minor's eligibility for assistance, facilitate the required consultation process should the minor receive interim assistance, and enable OTIP to assess and address potential child protection issues. OTIP also uses the information provided to respond to congressional inquiries, fulfill Federal reporting requirements, and inform policy and program development that is responsive to the needs of victims.

In 2019, OTIP launched Shepherd, an online case management system, to process requests for assistance and certification on behalf of foreign

national minor and adult victims of trafficking. If a requester encounters issues submitting a request through Shepherd, they may submit the RFA form to OTIP as a password protected PDF to *childtrafficking@acf.hhs.gov*.

Respondents: Representatives of governmental entities, members of the community, and nongovernmental entities providing social, legal, or protective services to foreign national minors in the United States who may have been subjected to severe forms of trafficking in persons. Furthermore, representatives within the community with a concern that a foreign national minor may have been subjected to severe forms of trafficking in persons may also use the RFA form.

Annual Burden Estimates

Increased awareness of reporting requirements under the TVPA of 2000, as amended among providers who serve foreign national children and youth has resulted in sustained, year-over-year increases in the number of RFA forms received by OTIP since fiscal year 2021. While the number of RFA forms received by OTIP each year largely reflects OTIP's efforts to engage case managers, attorneys, law enforcement officers, child welfare workers, and other representatives who serve foreign national children and youth, the number of RFA forms received is also impacted by a variety of social, political, and environmental factors that impact migration trends, including natural disasters and other climate-mediated events, that fluctuate each year. In fiscal year 2021, a record number of unique individuals (2,178) were referred to OTIP through 2,650 total RFA forms. In fiscal year 2022, 3,150 unique individuals were referred to OTIP through 3,709 total RFA forms. In fiscal year 2023, 3,612 unique individuals were referred to OTIP through 4,052 total RFA forms. There are no changes proposed to the RFA form but based on the increased need for trafficking-specific case management services among foreign national children and youth, as evidenced through sustained increases in the volume of RFA forms received by OTIP each year since fiscal year 2021, burden estimates for this collection have been revised.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Request for Assistance for Child Victims of Human Trafficking	10,500	1	1	10,500	3,500

Authority: 22 U.S.C. 7105 (b)

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2024–15789 Filed 7–17–24; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0113]

Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies; 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 ''Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies.'' This guidance describes FDA's recommendations regarding clinical pharmacology considerations for conducting human radiolabeled mass balance studies, including deciding whether and when to conduct the study, designing the study, and reporting results.

DATES: The announcement of the guidance is published in the **Federal Register** on July 18, 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–0113 for ''Clinical Pharmacology Considerations for Human Radiolabeled Mass Balance Studies.'' 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