CQ4. What survivorship care resources are available to providers who care for adult survivors of childhood cancer?

a. What are the intended outcomes of the different resources available to care providers?

b. What is the evidence of effectiveness of the different resources available to care providers?

c. What are the monetary costs to access these resources?

Key Questions (KQs) for the Realist Review

KQ1. For whom and under what circumstances could different survivorship care models for adult survivors of childhood cancer that include primary care be effective?

a. What are the key mechanisms by which these models could be effective?

b. What are important contexts that determine whether different mechanisms could be effective?

KQ2. For whom and under what circumstances could different survivorship care resources for adult survivors of childhood cancer be effective in achieving their intended outcomes?

a. For survivors and their families

i. What are the key mechanisms by which these resources could lead to their intended outcome?

ii. What are important contexts that determine whether different mechanisms could lead to outcomes?

b. For care providers

i. What are the key mechanisms by which these resources could lead to their intended outcome?

ii. What are important contexts that determine whether different mechanisms could lead to outcomes?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

We will adapt the PICOTS framework (populations, interventions, comparators, outcomes, timing, and setting) to inform our realist review. The PICOTS include but are not limited to the following.

Population(s)

- Adult survivors of childhood cancer (cancer diagnosed prior to age 21years old) with no evidence of clinical disease; and their families
- Care providers of adult survivors of childhood cancer

Interventions

- Models of childhood cancer survivorship care for use in adult survivors
  - Models of childhood cancer survivorship care for use in adult survivors that include primary care
- Survivorship resources available to adult survivors of childhood cancer and their families
- Survivorship resources available to care providers of adult survivors of childhood cancer

Comparators

- Optional (will not require a comparison)

Outcomes

List of outcomes will be informed by contextual questions but may include:

- Intermediate patient health outcomes
- Morbidity
- Mortality
- Relapse
- Quality of life
- Psychosocial outcomes
- Mental health outcomes
- Caregiver burden
- Satisfaction with care
- Educational attainment
- Adherence with care
- Cost and resource utilization
- Unintended consequences
- Additional burdens
- Late effects—new cancers, cardiac or respiratory issues, etc. from original treatment

Timing

- After the transition from childhood cancer care

Settings

- All care settings

Dated: November 19, 2020.

Marquita Cullom,

Associate Director.

[FR Doc. 2020–26041 Filed 11–24–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; ORR Serious Medical Procedure Request (SMR) Form (New Collection)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new data collection, *the Serious Medical Procedure Request (SMR) Form.*

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.

SUPPLEMENTARY INFORMATION:

Description: Children with complex medical/dental conditions may require surgical intervention or procedures in order to maintain and promote their health while in ORR custody. Procedures requiring general anesthesia, surgeries, and invasive diagnostic procedures (*e.g.,* cardiac catheterization, invasive biopsy, amniocentesis) require advance ORR approval. Before a decision can be rendered by ORR, data on clinical indications, risks and benefits of the surgery/procedure, potential adverse outcomes if services are not rendered, timeframe for recovery, follow-up care, and points of contact must be collected and submitted to ORR. The form is not required for emergency procedures, procedures performed during hospitalization, or procedures resulting from complication of a previously approved procedure.

Respondents: Healthcare providers, ORR grantee staff.

Annual Burden Estimates:

ESTIMATED OPPORTUNITY BURDEN FOR RESPONDENTS

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Healthcare providers: Serious Medical Procedure Request (SMR) Form	195	1	.22	128.7	42.9

Estimated Total Annual Burden Hours: 42.9.

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
ORR Grantee Staff: Serious Medical Procedure Request (SMR) Form	195	1	.08	46.8	15.6

Estimated Total Annual Burden Hours: 15.6.

ESTIMATED RECORDKEEPING BURDEN FOR RESPONDENTS

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
ORR Grantee Staff: Serious Medical Procedure Request (SMR) Form	195	1	.08	46.8	15.6

Estimated Total Annual Burden Hours: 15.6.

Authority: 6 U.S.C. Section 279: Exhibit 1, part A.2 of the Flores Settlement Agreement (Jenny Lisette Flores, et al., v. Janet Reno, Attorney General of the United States, et al., Case No. CV 85–4544–RJK [C.D. Cal. 1996]).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–26121 Filed 11–24–20; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3077]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by December 28, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0883. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Obtaining Information To Understand Challenges and Opportunities Encountered by Compounding Outsourcing Facilities

OMB Control Number 0910–0883—Extension

This information collection supports Agency-sponsored research. Drug compounding is generally the practice of combining, mixing, or altering ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients when an approved drug is not medically appropriate, they also present a risk to patients. Compounded drugs are not FDA-approved. Therefore, they do not undergo premarket review by FDA for safety, effectiveness, and quality. Since compounded drugs are subject to a lower regulatory standard than approved drugs, Federal law places conditions on compounding that are designed to protect the public health.

The Drug Quality and Security Act of 2013 (Pub. L. 113–54) created ''outsourcing facilities''—a new industry sector of drug compounders held to