(e) Photodynamic therapy
(f) Irreversible electroporation
(5) Whole gland therapies
(a) Brachytherapy
(b) Cryotherapy
(c) External beam radiation therapy
(i) three-dimensional conformal radiotherapy
(ii) intensity-modulated radiation therapy
(iii) proton beam therapy
(iv) stereotactic body radiation therapy
(d) Radical prostatectomy
(i) open
(ii) laparoscopic
(1) without robotic assistance
(2) with robotic assistance
(6) Combination of above

KQ 2: How do patient characteristics modify comparative effectiveness and harms of CLPC therapies?

(1) Age
(2) Race/ethnicity
(3) Comorbidities
(4) Health status

KQ 3: How do tumor characteristics modify comparative effectiveness and harms of CLPC therapies?

(1) Baseline PSA
(2) Gleason score
(3) Tumor index scores (*e.g.,* Cancer of the Prostate Risk Assessment Score [CAPRA], D'Amico Risk Classification for Prostate Cancer, etc.)
(4) Biomarker Status
(a) Decipher (Genomic Classifier)
(b) Oncotype Dx (Genomic Prostate Score)
(c) Prolaris (Cell Cycle Progression)

KQ 4: How do provider/hospital characteristics modify comparative effectiveness of RP compared to other therapies?

(1) Geographic region
(2) Hospital type
(3) Provider volume
(4) Institutional volume

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

Population(s)

- Treatment naïve men with CLPC (stages T1 to T3)

Interventions

KQ1 to 3

(1) Watchful waiting (WW)
(2) Active surveillance (AS)
(3) Androgen deprivation therapy (ADT)
(4) Focal therapies
(a) Brachytherapy
(b) Cryotherapy
(c) High-intensity focused ultrasound (HIFU)
(d) Laser ablation
(e) Photodynamic therapy
(f) Irreversible electroporation
(5) Whole gland therapies
(a) Brachytherapy
(b) Cryotherapy
(c) External beam radiation therapy
(i) Three-dimensional conformal radiotherapy
(ii) Intensity-modulated radiation therapy
(iii) Proton beam therapy
(iv) Stereotactic body radiation therapy
(d) Radical prostatectomy
(i) Open
(ii) Laparoscopic
(1) Without robotic assistance
(2) With robotic assistance
(6) Combination of above

KQ4

(1) Radical prostatectomy (RP)

Comparators

KQ1 to KQ4

- Any other intervention of listed above except certain within category comparisons (*e.g.,* nerve-sparing vs non-nerve sparing prostatectomy; different dosage/frequency/timing/duration of same therapy)

Outcomes

KQ1 to KQ3

- Overall survival/mortality
- Prostate cancer specific survival/mortality
- Metastatic-progression free survival
- Metastases (lymph nodes/distant)
- Health status
- Quality of life (measured with validated instruments)
- Prostate-cancer related quality of life (measured with validated instruments)

KQ4

- Overall survival/mortality
- Prostate cancer specific survival/mortality
- Metastatic free survival/metastases (lymph nodes/distant)

Harms

KQ1 to KQ3

Common and serious treatment side effects:

- Bowel, bladder, and sexual/erectile dysfunction
- Serious adverse effects associated with ADT such as cognitive impairment, MACE, fractures

Timing

KQ1 to KQ3

Follow up from treatment initiation:

- Mortality/survival outcomes/metastases: 5 years or more
- Health status, quality of life and harms: 1 year or more

KQ4

Follow up from treatment initiation:

- Mortality/survival outcomes/metastases: 5 years or more

Setting

KQ1 to KQ4

- All settings

Study Design

KQ1 to KQ4

(1) RCTs
(2) Non-RCT if:
(a) Comparative
(b) Concurrent
(c) Multicenter (enrolling patients treated at multiple locations)
(d) ≥500 patients
(e) Some method to control for selection bias (propensity scores, instrumental variables, multivariate regression)
(f) Prospective data collection

Dated: September 16, 2019.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2019–20303 Filed 9–18–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review: Assessing Models of Coordinated Services for Low-Income Children and Their Families (AMCS) (New Collection)

AGENCY: Office of Planning, Research, and Evaluation; ACF; HHS

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new study, Assessing Models of Coordinated Services for Low-Income Children and Their Families (AMCS).

DATES: *Comments due within 30 days of publication.* OMB is required to make a decision concerning 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 directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@acf.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Description: Through AMCS, ACF seeks to learn more about how states and communities coordinate early care and education, family economic security, and/or other health and human services to most efficiently and effectively serve the needs of low-income children and their families. ACF aims to understand strategies used to support partnerships, including the federal barriers to agency collaboration. In support of achieving these goals, the study team will conduct site visits to six programs that offer coordinated services. The study team will gather information through interviews with program staff members, such as agency leaders or frontline staff, and focus groups with parents.

Data collection activities will include up to six program site visits. Programs will be identified through a scan of publicly available information about programs, recommendations from stakeholders, and proposed telephone interviews (the information collection request for these interviews will be submitted under the generic clearance: Formative Data Collections for ACF Research, OMB #0970–0356)). Once potential programs are identified, agency leaders will be invited to participate in the site visit. Site visits will include semi-structured interviews with up to 30 total staff at each site. Staff invited will include lead program and partner staff to include agency leaders (including program directors, executive directors, or CEOs), directors of programs within the site, frontline staff (including service navigators or coordinators), and focus groups with 8–10 parents at each site. Semi-structured interviews with program and partner staff will obtain in-depth information about the goals and objectives of programs, the services provided, how the coordinated services are implemented, how staffing is managed, data use, and any facilitators and barriers to coordination. Focus groups with parents participating in the program will provide the opportunity to learn about how parents perceive the program, how it meets their needs, what benefits they gain from the program, and how they enroll, participate, and progress through the program.

Respondents: Lead program and partner program staff members working in six programs across the United States that coordinate early care and education services with family economic security services and/or other health and human services, as well as parents receiving services from these programs. Staff respondents will be selected with the goal of having staff represent each level of the organization. Parents who have participated in the program for at least six months and who received early childhood services and at least one other program service will be invited to participate in focus groups.

ANNUAL BURDEN ESTIMATES

Instrument	Total/annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Master Interview Protocol	180	1	2	360
Parent Focus-Group Protocol	60	1	1	60

Estimated Total Annual Burden Hours: 420.

Authority: 42 U.S.C. 9858(a)(5).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–20307 Filed 9–18–19; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–4048]

Safer Technologies Program for Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; 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 the draft guidance entitled ''Safer Technologies Program for Medical Devices.'' This draft guidance describes a new, voluntary program for certain medical devices and device-led combination products that are reasonably expected to significantly improve the safety of currently available treatments or diagnostics that target an underlying disease or condition associated with morbidities and mortalities less serious than those eligible for the Breakthrough Devices Program. Devices and device-led combination products are eligible for this program if they are subject to review under a premarket approval application (PMA), De Novo classification request (''De Novo request''), or premarket notification (510(k)). Consistent with the Agency's statutory mission to protect and promote public health, FDA believes that this ''Safer Technologies Program'' or ''STeP'' will help patients have more timely access to these medical devices and device-led combination products by expediting their development, assessment, and review, while preserving the statutory standards for premarket approval, De Novo marketing authorization, and 510(k) clearance. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by November 18, 2019 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