Appendix P. Federal Register Notice

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)—Continued

Picots element	Inclusion criteria
	Noninvasive nonpharmacological therapy: Noninvasive nonpharmacological therapies used for acute pain (exercise [and related therapies], cognitive behavioral therapy, meditation, relaxation, music therapy, virtual reality, acupuncture, massage, manipulation/mobilization, physical modalities [transcutaneous electrical nerve stimulation, ultrasound, braces, traction, heat, cold]).
Comparators	Opioid therapy: a–d. Usual care, another opioid, nonopioid drug, or noninvasive, nonpharmacological therapy. e. Usual care, another opioid, nonopioid drug, or noninvasive, nonpharmacological therapy, no opioid/nothing prescribed. f. Reference standard for misuse, opioid use disorder, or overdose; or other benchmarks. g. Usual care. h. Not utilizing the factors specified in interventions (h) above. Nonopioid pharmacological therapy: Other nonopioid pharmacological therapy or noninvasive nonpharmacological therapy. Noninvasive nonpharmacological therapy: Sham treatment, waitlist, usual care, attention control, and no treatment; or other noninvasive nonpharmacological therapy.
Outcomes	Opioid therapy: a–d, g, i. Pain, function, pain relief satisfaction, and quality of life, harms, adverse events (including withdrawal, risk of misuse, opioid, opioid use disorder, overdose). e. Persistent opioid use. f. Measures of diagnostic accuracy. h. Opioid prescribing rates. Nonopioid therapy: Pain, function, pain relief satisfaction, quality of life and quality of life, harms, adverse events, opioid use. Noninvasive nonpharmacological therapy: Pain, function, pain relief satisfaction, quality of life and quality of life, harms, adverse events, opioid use.
Time of followup	<1 day; 1 day to <1 week; 1 week to <2 weeks; 2 weeks to <4 weeks; ≥4 weeks.
Setting	Emergency department (initiation of therapy and following discharge), physician's office, outpatient or inpatient surgical center, dental clinic or oral surgery center, inpatient (sickle cell only).
Study design	All KQs: RCTs; in addition: e. Cohort studies (for long-term opioid use). f. studies assessing diagnostic accuracy. h. cohort studies and before-after studies assessing effects on prescribing rates.

Abbreviations: RCT = randomized controlled trial.

Dated: January 3, 2020.

Virginia Mackay-Smith,

Associate Director, Office of the Director, AHRQ.

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BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Data Collection for the Next Generation of Enhanced Employment Strategies Project (New Collection)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Office of Planning, Research, and Evaluation (OPRE) within the Administration for Children and Families (ACF) is proposing data collection activities conducted for the Next Generation of Enhanced Employment Strategies (NextGen) Project. The objective of this project is to identify and rigorously evaluate innovative interventions designed to promote employment and economic security among low-income individuals with complex challenges to employment. The project will include an experimental impact study, descriptive study, and cost study.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *OPREinfocollection@acf.hhs.gov*. Alternatively, copies can also 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, emailed or written should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION: To further build the evidence around effective strategies for helping low-income individuals find and sustain employment, OPRE is conducting the NextGen Project. This project will identify and test up to 10 innovative, promising employment interventions designed to help individuals facing complex challenges secure a pathway toward economic independence. These challenges may be physical and mental health conditions, a criminal history, or limited work skills and experience. The project is actively coordinating with the Building Evidence on Employment Strategies for Low-Income Families Project (0970–0537), another OPRE project focused on strengthening ACF's understanding of effective interventions aimed at supporting low-income individuals to find jobs, advance in the labor market, and improve their economic security. Additionally, the project is working closely with the Social Security Administration (SSA) to incorporate a focus on employment-related early interventions for individuals with current or foreseeable disabilities who have limited work

history and are potential applicants for Supplemental Security Income (SSI).

The NextGen Project will use a two-phased approach for approval of this proposed information collection activity. In Phase 1 (current request) the research team seeks approval to formally recruit programs, to administer the informed consent form and baseline participant survey, and to collect identifying and contact information for study participants. The project intends for these data collections to be uniform across programs selected for evaluation and it does not anticipate that they will require revisions.

Under Phase 2 of the request, the project will update the information collection request for the remaining instruments to tailor to each program selected for the evaluation, as needed.

The proposed information collection activities cover an experimental impact study, descriptive study, and cost study. Data collection activities for the impact study include: (1) Baseline survey and identifying and contact information data collection, (2) a first follow-up survey, and (3) a second follow-up survey. Data collection activities for the descriptive study include: (1) Service receipt tracking; (2) staff characteristics survey; (3) program leadership survey; (4) semi-structured program discussion guide (conducted with program leaders, supervisors, partners, staff, and providers); (5) semi-structured employer discussion guide (for those interventions that include an employer component); and (6) in-depth participant interviews. Data collection activities for the cost study include an Excel-based cost workbook.

Respondents: Program staff, program partners, employer staff, and individuals enrolled in the NextGen Project. Program staff and partners may include case managers, health professionals, workshop instructors, job developers, supervisors, managers, and administrators. Employers may include administrators, human resources staff, and worksite supervisors.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
PHASE 1					
Baseline survey & identifying and contact information—participants	10,000	3,333	1	0.42	1,400
Baseline survey & identifying and contact information—staff	200	67	50	0.42	1,407
Estimated Total Annual Burden Hours, Phase 1:					2,807
PHASE 2 ESTIMATES					
First follow-up survey—participants	8,000	2,667	1	0.83	2,214
Second follow-up survey—participants	8,000	2,667	1	0.83	2,214
Service receipt tracking—program staff	200	67	250	0.08	1,340
Staff characteristics survey—program staff	200	67	1	0.42	28
Program leadership survey—program leaders	50	17	1	0.25	4
Semi-structured program discussion guide—program leaders	40	13	1	1.5	20
Semi-structured program discussion guide—program supervisors and partners	80	27	1	1.0	27
Semi-structured program discussion guide—program staff, providers	80	27	1	0.75	20
Semi-structured employer discussion guide—employers	50	17	1	1.0	17
In-depth participant interview guide—participants	200	67	1	2.0	134
Cost workbook—program staff	40	13	1	32.0	416
Estimated Total Annual Burden Hours, Phase 2:					6,434

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: Section 413 of the Social Security Act, as amended by the FY 2017 Consolidated Appropriations Act, 2017 (Public Law 115–31).

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0764]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Feed Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing