Estimated Total Annual Burden Hours: 630,960.

Authority: 42 U.S.C. 601, 607, 609, 611, 613, and 1302.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–19304 Filed 8–28–20; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Cost Study of Trauma-Specific Evidence-Based Programs Used in the Regional Partnership Grants Program (New Collection)

AGENCY: Children's Bureau, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Children's Bureau (CB), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is proposing to collect data for a new descriptive study—the Cost Study of Trauma-Specific Evidence-Based Programs used in the Regional Partnership Grants (RPG) Program.

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: Since 2006, CB has awarded multiple rounds of competitive grants to state and local agencies and service providers under the RPG Program. Grants are awarded to organizations such as child welfare agencies, substance abuse treatment providers, or family court systems to develop interagency collaborations and provide services designed to increase well-being, improve permanency, and enhance the safety of children who are in or are at risk of being placed in out-of-home care as a result of a parent's or caretaker's substance abuse. Thirty-five grantees are participating in the ongoing RPG national cross-site evaluation, which examines implementation, partnerships, outcomes, and impacts. All grantees collect data on a uniform set of performance measures and report them to CB on a semi-annual basis through a web-based system. These ongoing data collection activities are approved under OMB #0970–0527. All grantees are also required to use a portion of their funding to conduct their own ''local'' program impact evaluation.

This proposed cost study adds a new and unique contribution to CB's portfolio of evaluation activities. Although the RPG cross-site evaluation will provide evidence for the effectiveness of some interventions to address the emotional effects of trauma, more information is needed about the cost of implementing these Evidence-Based Programs (EBPs).

The cost study has the key objective to determine the cost of implementing three select Trauma-Specific EBPs: Parent-Child Interaction Therapy, Seeking Safety, and Trauma-Focused Cognitive Behavioral Therapy. To carry out this objective, the study team will collect detailed cost information from nine RPG round four and five grantees who are implementing these selected EBPs. For each grantee, the study team will administer two data collection instruments: (1) A Cost Workbook used to collect comprehensive information on the cost of implementing each select program (Instrument #1), and (2) a Staff Survey and Time Log used to collect information on how program staff allocate their time (Instrument #2).

Respondents: Grantee staff.

Annual Burden Estimates: Data collection will take place within a one year period.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total/annual burden hours
Cost Workbook	9	1	8	72
Staff Survey and Time Log	90	1	3.6	330

Estimated Total Annual Burden Hours: 402.

Authority: The Child and Family Services Improvement and Innovation Act (Pub. L. 112–34).

Emily Ball Jabbour,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–19066 Filed 8–28–20; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1564]

Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation; Draft Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders; Availability

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation.'' The FDA encourages the collection, analysis, and integration of patient perspectives in the development, evaluation, and surveillance of medical devices, including digital health technologies. Patient-reported outcome (PRO) instruments facilitate the systematic collection of patient perspectives as scientific evidence to support the regulatory and healthcare decision-making process. This draft guidance describes principles that should be considered when using PRO

instruments in the evaluation of medical devices and provides recommendations about the importance of ensuring the measures are ''fit-for-purpose.'' 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 October 30, 2020 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 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–2020–D–1564 for ''Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation.'' 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 and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Michelle Tarver, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5608, Silver Spring, MD 20993–0002, 301–796–6884 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

A PRO instrument can be used in a clinical investigation to measure the effects of a medical intervention or changes in the health status of a patient. PRO instruments allow for collection of certain data as evidence of safety and effectiveness which is complementary to other clinical outcomes and/or biomarkers. Information from well-defined and reliable PRO instruments can provide valuable evidence for benefit-risk assessments and can be used in medical device labeling to communicate the effect of a treatment on patient symptoms, functioning, or quality of life when the labeling is consistent with the PRO instrument's documented measurement capability. PRO instruments may be used to inform a patient's eligibility for inclusion within a study, to capture safety or effectiveness outcomes, and may be aligned as primary or secondary endpoints or used as a stand-alone outcome assessment or component of a composite endpoint. FDA determines the validity evidence needed to support use of a PRO instrument for a particular regulatory purpose informed by the way it is used in the clinical investigation. FDA uses the term ''fit-for-purpose'' to describe this flexible approach. In addition to providing evidence to assess the safety and effectiveness of medical devices, PRO instruments can measure the impact of medical devices on patient well-being and other concepts that may influence payers, healthcare providers, and patients when making decisions about potential treatments or management options.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115).

The draft guidance, when finalized, will represent the current thinking of FDA on ''Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* This guidance document is also available at *https://www.regulations.gov* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.* Persons unable to download an electronic copy of ''Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 18042 to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in the following FDA regulations and guidance have been approved by OMB as listed in the following table:

21 CFR part or guidance	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485

Dated: August 21, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2020–19094 Filed 8–28–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–N–3657; FDA–2019–N–6085; FDA–2017–N–6381; FDA–2017–N–0084; FDA–2013–N–0731; FDA–2019–N–5971; FDA–2014–N–1021; and FDA–2019–N–3018]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control number	Date approval expires
Accreditation Scheme for Conformity Assessment Pilot Program	0910–0889	6/30/2023
General Administrative Practice and Procedures	0910–0191	7/31/2023
Records and Reports Concerning Experience With Approved New Animal Drugs	0910–0284	7/31/2023
Adverse Event Program for Medical Devices (Medical Product Safety Network	0910–0471	7/31/2023
Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Eligibility Determination for Donors; and Current Good Tissue Practice	0910–0543	7/31/2023
Recommendations to Reduce the Risk of Transfusion-Transmitted of Infection in Whole Blood and Blood Components; Agency Guidance	0910–0681	7/31/2023
Food Labeling; Gluten-Free Labeling of Fermented or Hydrolyzed Foods	0910–0817	8/31/2023