DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Evidence-Based Falls Prevention Program; OMB Control Number, 0985–0039

AGENCY: Administration for Community Living (ACL), HHS.

ACTION: Notice.

SUMMARY: The Administration for Community Living is announcing that the proposed collection of information listed above has been submitted to the Office of Management and Budget (OMB) for review and clearance as required under section 506(c)(2)(A) of the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to ACL's Evidence-Based Falls Prevention Program's Proposed Extension with Changes of a Currently Approved Collection.

DATES: Submit written comments on the collection of information by March 5, 2018.

ADDRESSES: Submit written comments on the collection of information by:

(a) *Email to: OIRA_submission@omb.eop.gov,* Attn: OMB Desk Officer for ACL;

(b) fax to 202–395–5806, Attn: OMB Desk Officer for ACL; or

(c) by mail to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW, Rm. 10235, Washington, DC 20503, Attn: OMB Desk Officer for ACL.

FOR FURTHER INFORMATION CONTACT: Shannon Skowronski at *shannon.skowronski@acl.hhs.gov* or 202–795–7438.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor.

The Evidence-Based Falls Prevention Programs is a cooperative agreement financed through the Prevention and Public Health Fund (PPHF), most recently with FY 2017 PPHF funds. The statutory authority for cooperative agreements under the current program announcement is contained in the Public Health Service Act, 42 U.S.C. 300u–2 (Community Programs) and 300u–3 (Information Programs); and Consolidated Appropriations Act, 2017, Public Law 115–31, Title II; and the Patient Protection and Affordable Care Act, 42 U.S.C. 300u–11 (Prevention and Public Health Fund).

The Evidence-Based Falls Prevention Programs support a national resource center and award competitive grants to implement evidence-based community programs that have been proven to reduce the incidence of falls for older adults. The programs also identify sustainable funding mechanisms for these programs via the national resource center, promote the importance of falls prevention strategies, and provide public education about the risks of falls and ways to prevent them.

OMB approval of the existing set of Falls Prevention data collection tools (OMB Control Number, 0985–0039) expires on 01/31/2018. This data collection continues to be necessary for monitoring program operations and outcomes. ACL/AoA proposes to use the following tools: (1) Semi-annual performance reports to monitor grantee progress; (2) a Host Organization Data form to record the location of agencies that sponsor programs that will allow mapping of the delivery infrastructure; and (3) a set of tools used to collect information at each program completed by the program leaders (Program Information Cover Sheet and Attendance Log), a Participant Information Form completed by each participant, and a Post Program Survey to be completed by a random sample of participants. ACL/AoA intends to continue using an online data entry system for the program and participant survey data.

Comments in Response to the 60-Day Federal Register Notice

As required by 5 CFR 1320.8(d), a 60-Day notice was published in the **Federal Register** on October 3, 3017, Volume 82, Number 190, page 46064. Four emails were received with comments. Based on the comments, some minor modifications were made to the proposed survey instruments. In addition to the public comments, feedback on the current forms was sought from the following:

- ACL Performance and Evaluation subject matter experts
- CDC Injury Prevention Center subject matter experts
- National Falls Prevention Resource Center and falls prevention subject matter experts
- Two grantee focus groups (with fewer than 9 participants combined)

Based on this collective feedback, the following modifications to the currently approved forms are being proposed:

- On the Participant Information Form:

1. Question #8 on currently approved and proposed Participant Information Form: Additional chronic conditions have been added to the list of options: Cancer; high blood pressure/hypertension; osteoporosis; and Parkinson's Disease.

2. Question #8 on currently approved and proposed Participant Information Form: None (no chronic conditions) has been removed from the list of options.

3. Question #11 on currently approved and proposed Participant Information Form: Two sub-questions have been added to assess the:

- Frequency of Falls (6b)
- Impact of Falls (6c)

4. Question #15 on the Participant Information Form has been added to examine home modifications

5. Question #16 on the Participant Information Form has been added to examine activity level

On the Post Program Survey:

1. Question #2 on the currently approved and proposed Post Program Survey: Two sub-questions have been added to assess the:

- Frequency of Falls (6b)
- Impact of Falls (6c)

2. Question #4 on the currently approved Post Program Survey (''Has this program reduced your fear of falling?'') has been *removed.*

3. Question #7 on currently approved Post Program Survey and Question #6 on the proposed form: *Removed* ''I plan to continue exercising'' from the list of options. Activity level is now addressed in Question #9.

4. Question #8 on currently approved Post Program Survey and Question #7 on the proposed form: *Removed* ''Did exercises I learned in this program at home'' from the list of options. Activity level is now addressed in Question #9 on the revised form.

5. Question #8 on currently approved Post Program Survey and Question #7 on the proposed form: *Removed* ''Made changes in my home to reduce my risk of falling (for example, secured rugs or improved lighting)'' from the list of options. Home modifications are now addressed in Question #8 in the revised form.

6. Question #8 on the Participant Information Form has been added to examine home modifications

7. Question #9 on the Participant Information Form has been added to examine activity level

On the Program Information Cover Sheet:

1. Question #6 has been revised to improve clarity to read ''Session 0/Introductory Session''.

2. Question #7 has been revised to change wording to ''Name of program offered.''

Estimated Annualized Burden Hours

The proposed Falls Prevention Data Collection Tools can be found at ACL's Website at: *https://www.acl.gov/about-acl/public-input.*

The total estimated burden is 4,345 hours per year. ACL/AoA estimates the burden of this collection of information as 288 hours for project staff, 1,435 hours for local agency staff, and 2,622 hours for individuals.

Type of respondent	Form name	Estimated number of respondents	Number of responses per respondent	Average time per response (in hours)	Total burden hours (annual)
Project staff	Semi-annual Performance Report.	18	Twice a year	8	288
Local agency leaders	Program Information Cover Sheet/Participant Information Form/Attendance Log/Post Program Survey.	700 leaders	Twice a year (one set per program).	.50	700
Local data entry staff		36 data entry staff	Once per program × 1,400 programs.	.50	700
Local organization staff and local database entry staff.	Host Organization Data Form.	700 staff	1	.05	35
Program participants	Participant Information Form.	16,390	1	.10	1,639
Program participants	Post Program Survey	9,834	1	.10	983
Total Burden Hours					4,345

Dated: January 26, 2018.

Mary Lazare,

Principal Deputy Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0001]

Best Practices in Modeling and Simulation for Oncology Products; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration's (FDA, the Agency, or we) Center for Drug Evaluation and Research (CDER), in co-sponsorship with the International Society of Pharmacometrics (ISoP), is announcing a public workshop entitled ''Best Practices in Modeling and Simulation for Oncology Products.'' The purpose of the meeting is to discuss ''best practices'' in integrating pharmacokinetic, pharmacodynamic, efficacy, and safety data into models to best inform oncology drug development, evaluate disease- and mechanism-specific early endpoints to predict long-term efficacy, and discuss potential regulatory implications of model-informed decisions in drug development. This workshop is also being conducted to satisfy one of FDA's performance goals included in the sixth reauthorization of the Prescription Drug User Fee Act (PDUFA VI), part of the FDA Reauthorization Act of 2017 (FDARA), to hold a series of workshops related to model-informed drug development (MIDD).

DATES: The public workshop will be held on February 1, 2018, from 8 a.m. to 5 p.m., Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503, B and C), Silver Spring, MD 20993–0002. Entrance for public workshop participants (non-FDA employees) is through Building 1 where routine security procedures will be performed. For parking and security information, please refer to: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

FOR FURTHER INFORMATION CONTACT: Jeannette Dinin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2108, Silver Spring, MD 20993–0002, 240–402–4978, email: *Jeannette.Dinin@fda.hhs.gov*; or Yvonne Knight, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2142, Silver Spring, MD 20993–0002, 301–796–2133, email: *Yvonne.Knight@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under FDARA, FDA agreed, in accordance with section I of the PDUFA VI Performance Goals, Ensuring the Effectiveness of the Human Drug Review, part J, Enhancing Regulatory Decision Tools to Support Drug Development and Review, to convene a series of workshops to identify best practices for MIDD (*https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*). FDA is conducting this workshop as part of the MIDD workshop series.

Over the past few decades, there has been extensive investment in oncology drug discovery and development. Despite greater understanding of disease biology and drug mechanisms of action, further progress in model-informed strategies is needed to continue advancements in oncology drug development. Innovations in clinical trial design utilizing more informative endpoints could help bring more effective treatment options to cancer patients faster by accelerating development of effective new drugs and reducing failure rates in expensive late-phase development.

As more effective and complex combination strategies and novel targets for cancer treatment evolve, exploring more informative and predictive endpoints to assess treatment response