

detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10463 Cooperative Agreement To Support Navigators in Federally-Facilitated Exchanges

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 term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Cooperative Agreement to Support Navigators in Federally-facilitated Exchanges; *Use*: Section 1311(i) of the PPACA requires Exchanges to establish a Navigator grant program under which it awards grants to eligible individuals and entities (as described in Section 1311(i)(2) of the PPACA and 45 CFR 155.210(a) and (c)) applying to serve consumers in States with a FFE. Navigators assist consumers by providing education about and facilitating selection of qualified health plans (QHPs) within the Exchanges, as well as other required duties. Entities and individuals cannot serve as federally certified Navigators and carry out the required duties without receiving federal cooperative agreement funding.

As a condition of award, Navigator awardees must agree to cooperate with any Federal evaluation of the program and must provide required weekly, monthly, quarterly, annual, and final (at the end of the cooperative agreement period) reports in a form prescribed by CMS, as well as any additional reports as required. *Form Number*: CMS-10463 (OMB control number: 0938-1215); *Frequency*: Annually, Monthly, Quarterly, Weekly; *Affected Public*: Private sector; *Number of Respondents*: 50; *Total Annual Responses*: 50; *Total*

Annual Hours: 20,850. (For questions regarding this collection contact Gian Johnson at 301-492-4323.)

Dated: October 17, 2019.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Chronic Disease Self-Management Education Program; OMB# 0985-0036

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 the Paperwork Reduction Act of 1995. This 30-Day notice collects comments on the information collection requirements related to ACL's Chronic Disease Self-Management Education grant program (Proposed Extension with Changes of a Currently Approved Collection [ICR Rev]).

DATES: Submit written comments on the collection of information by November 22, 2019.

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:

Kristie Kulinski (kristie.kulinski@acl.hhs.gov) or (202) 795-7379.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, ACL has submitted the following proposed collection of information to OMB for review and clearance. The “Empowering Older Adults and Adults with Disabilities through Chronic

Disease Self-Management Education (CDSME) Programs” cooperative agreement program has been financed through the Prevention and Public Health Fund (PPHF). The statutory authority for cooperative agreements under the most recent program announcement (FY 2019) is contained in the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2019 and Continuing Appropriations Act, 2019, Public Law 115-245; Public Health Service Act, 42 U.S.C. 300u-2 (Community Programs) and 300u-3 (Information Programs); and the Patient Protection and Affordable Care Act, 42 U.S.C. 300u-11 (Prevention and Public Health Fund). The Empowering Older Adults and Adults with Disabilities through CDSME Programs initiative supports a national resource center and awards competitive grants to deliver and sustain evidence-based CDSME interventions.

OMB approval of the existing set of data collection tools expires on October 31, 2019 (OMB Control Number 0985-0036). This data collection continues to be necessary for monitoring program operations and outcomes. ACL proposes to use the following tools: (1) Semi-annual program reports to monitor grantee progress; and (2) a set of tools used to collect information at each program completed by the program facilitators (Program Information Cover Sheet and Attendance Log) and a Participant Information Survey completed by each participant to document their demographic and health characteristics. ACL is not requesting renewal of Host/Implementation Organization Information Form. ACL intends to continue using an online data entry system for the program and participant survey data. In addition to non-substantive formatting edits, minor changes are being proposed to two of the four currently approved tools, as indicated below. All changes proposed are based on feedback from a focus group that included a sub-set of current grantees, as well as consultation with subject matter experts.

Comments in Response to the 60-Day Federal Register Notice

A notice was published in the **Federal Register** on July 9, 2019 (Vol. 84, Number 131; pp. 32746-32747). Thirteen 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
- National Chronic Disease Self-Management Education Resource Center

- One grantee focus group (fewer than nine participants)

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

PARTICIPANT INFORMATION SURVEY

Topic/issue	Comment	ACL response
Participant ID	More than one respondent indicated that the unique identifier is cumbersome and presents an opportunity for mistakes due to its length. Also a comment that the change may make it difficult to evaluate at the individual level across years.	Compared to previous versions, the Participant ID is now to be completed by onsite staff and/or program leaders. The National CDSME Resource Center will be providing training and technical assistance on the best strategies for documenting the Participant ID. The change is primarily driven by increased attention to the application of the highest standards for safeguarding data collected by our grantees. After extensive review of evidence-based program data collection processes, ACL and the Resource Center are working to elevate standards to ensure the privacy and security of all data collected from participants. As such, the use of the existing Participant ID, which includes components of the participants' names and year of birth, could potentially provide clues into the person's identity, especially if coupled with other demographic data.
Provider Referral	Specific to Question #1 (Did your health care provider suggest that you take this program?), replace the word "take" with "attend."	ACL will incorporate this suggested revision.
Sex/Gender	More than one respondent suggested the incorporation of a non-binary response option, in addition to male/female.	As a federal agency, ACL references the American Community Survey (implemented by the Census Bureau) as a benchmark for demographic questions. To remain consistent with the U.S. Census/American Community Survey, ACL will continue to use male/female response options.
	Suggestion to delineate either sex or gender (question currently reads, "Are you . . . male/female?")	This wording has been used for the past 6 years without issue and preserves data collection continuity.
LGBTQ Identification	Suggestion to incorporate a question to allow individuals to self-identify their sexual orientation.	As noted previously, ACL works to align our data collection with what is collected by the U.S. Census around demographic information. Census does not currently collect information on sexual orientation.
Chronic Conditions List	Suggestion to add HIV to chronic conditions list.	Collection of HIV/AIDS data requires additional special care in the collection and sharing of this data because persons with HIV/AIDS can face discrimination. In some states, added protections require providers to request additional permission from the patient to share information related to HIV/AIDS status. HIV/AIDS has not been asked in prior iterations of this survey. Centers for Medicare & Medicaid Services (CMS) data from 2017 shows that across all beneficiaries (age 65+), HIV/AIDS accounted for .1% of cases nationally. The goal is not to capture an exhaustive list of chronic conditions; rather, the most common based the public data and the experience of current/prior grantees. This question also allows participants to select 'Other' (without an open-ended response).
Social Isolation	Multiple comments received, as detailed below: Truncate Question #16 (How often do you feel lonely or isolated from those around you?) to remove "from those around you" at end. Question #16 (and corresponding post-test Question #3) adds to the survey length and may be perceived by some as intrusive. Additionally, wording may be off-putting for participants who are expecting a positive, strengths-based experience. Specific to post-test Question #3, comment that item is not likely to show change from pre- to post-, especially given the negative direction. Suggestion to ask at post-test only and frame as "After taking this class, how much more connected to others do you feel?" or something similar.	The item stems from validated tools in the National Institutes of Health's PROMIS item bank (v2.0)—Social Isolation. The original version is written in the first person. Loneliness was added to improve literacy (reduce grade level) It is also an adaptation from the UCLA Loneliness Scale (v3, #14). "How often do you feel isolated from others?" (Never to Always), which has been extensively used for decades (Russell, 1996). It continues to be validated with older adults (Ausin et al, 2019; Domenech-Abella, et al, 2017). The item has also been used successfully by CMS in social screening efforts (Accountable Health Communities Health-Related Social Needs Screening), as well as Kaiser Permanente.

PARTICIPANT INFORMATION SURVEY—Continued

Topic/issue	Comment	ACL response
Chronic Conditions Language.	Comment that a single social isolation question may not provide useful information. Suggestion to include sub-questions specific to companionship, worry about being alone, shared interests and ideas, and participation in social clubs or religious groups. Suggestion to replace “chronic” health condition(s) with “ongoing” health condition(s).	ACL appreciates the suggestion to collect more data but has decided in the interest of balancing data collection and burden to not include additional elements on the survey. ACL appreciates that “ongoing” may be considered synonymous with “chronic”; however, we will continue to use the term chronic, as this is the vernacular generally used within the U.S. Department of Health and Human Services (<i>e.g.</i>, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, <i>etc.</i>).
For Whom Attending Program.	Comment that Question #12 (For whom are you attending this program?) lengthens the questionnaire without substantial benefit (purpose is unclear).	ACL agrees with this comment; we will remove the question from the survey.
Disability Status	Proposed revision to Question #15 includes three sub-parts to independently assess various facets of disability status; the current version combines all three parts into a single item. Suggestion to keep question as is (single item). A comment was received that suggested using the Behavior Risk Factor Surveillance System (BRFSS) questions to assess disability.	The six-item set of questions used in the American Community Survey (ACS) are the minimum standard for disability survey questions. Questions and answers in this set cannot be changed. The six questions define disability from a functional perspective and are collectively a meaningful measure of disability for data collection and reporting. Edits initially proposed by ACL utilize five of the six BRFSS questions specific to disability status (hearing, vision, mobility, self-care, and independent living). ACL will add the question related to cognition (Because of a physical, mental, or emotional condition, do you have difficulty concentrating, remembering, or making decisions?).
Confidence Managing Chronic Conditions.	Suggestion to revise wording in Question #17 (How confident are you that you can manage your chronic conditions?) to reference both physical and emotional concerns. Positive comment received regarding inclusion of question at post-test (Question #2) to assist with evaluating change over time.	ACL appreciates this comment and proposes revising the language to read, “How sure are you that you can manage your condition so you can do the things you need and want to do?” to be inclusive of both physical and emotional health concerns.
Health Status	Specific to post-test Question #1 (In general, would you say that your health is), comment that this question seems unnecessary unless the underlying assumption is that CDSME changes self-perceived health. Positive comment received regarding inclusion of self-rated health at post-test (Question #1) to assist with evaluating change over time.	ACL is interested in utilizing this question to assess changes in self-rated health at pre/post intervention. If changes are not detected, we will consider removal of this item during the next data collection renewal.
Satisfaction Question	Request to add satisfaction question back into the post-survey.	A satisfaction question has not been part of the required data collection elements, though some grantees choose to collect this information voluntarily.
Additional Questions	Suggestion to incorporate questions specific to: Formal referral by physician, weight, exercise, medications, and health care utilization.	ACL appreciates the suggestion to collect more data but has decided in the interest of balancing data collection and burden to not include additional elements on the survey.

PROGRAM INFORMATION COVER SHEET

Topic/issue	Comment	ACL response
Funding Source	Specific to Question #7, program facilitators may not know the funding source (determined by other program staff). Another comment was received suggesting that ACL clarify that the intent of question is to capture direct sources of funding support (vs. indirect/global support). Another comment was received that it would be helpful to have a description of funding sources.	ACL suggests that local program coordinators complete this question prior to submitting form for data entry. ACL will incorporate this revision. ACL will work with the National CDSME Resource Center to develop a brief overview of the various funding sources listed. Grantee can distribute this information to their partners.

PROGRAM INFORMATION COVER SHEET—Continued

Topic/issue	Comment	ACL response
National Resource Center and National Database Language.	Suggestion to use a term other than “chronic disease”, as there are many programs in the menu of health promotion programs.	ACL awarded a five-year cooperative agreement in 2016 that specifically designates a National Chronic Disease Self-Management Education (CDSME) Resource Center. This resource center houses the National CDSME Database. ACL may consider modifying the name of the National CDSME Resource Center if/when it is re-competed in 2021; however, such a change is not appropriate at this time.
Consent to Receive Information from National CDSME Resources Center.	A comment was received that the addition of this question seems unnecessary to have as a standard question, since it should only be asked once of each leader. A suggestion was made to ask this question at leader trainings instead.	Requesting this consent through a standard data collection form is the most direct manner ACL can use to ensure that program facilitators can opt in to receiving technical assistance communications from our National CDSME Resource Center. ACL is unable to require grantees to share information collected via facilitator trainings.

ATTENDANCE LOG

Topic/issue	Comment	ACL response
Format	Suggestion to modify format from portrait to landscape to accommodate participant signature.	Participant signatures are not required by ACL with respect to this data collection effort (and ACL does not retain the names of CDSME participants). If other partners/funders require participant signature, grantee should modify the format accordingly.
Program Name	Suggestion to add program name to form	The very top of the form has an editable field (Your Program Name) that can be customized by the grantee.
Participant Phone/Email Address.	Suggestion to collect participant phone number and email address for facilitators to use for reminder follow-up.	ACL does not collect any personally identifiable information from participants. Grantees can independently request this information from participants as needed for programmatic reminders.

The proposed data collection forms may be found on the ACL website at

<https://www.acl.gov/about-acl/public-input>.

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Program facilitators (Program Information Cover Sheet, Attendance Log).	1,350	Once per program	.33	445.5
Program participants (Participant Information Survey)	13,500	1	.20	2,700
Data entry staff (Program Information Cover Sheet, Attendance Log, Participant Information Survey).	65	Once per program times 1,350 programs.	.17	229.5
Total				3,375

Dated: October 16, 2019.

Mary Lazare,
Principal Deputy Administrator.

[FR Doc. 2019–23121 Filed 10–22–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors of the NIH Clinical Center.

The meeting will be closed to the public as indicated below in accordance

with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual grant applications conducted by the CLINICAL CENTER, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors of the NIH Clinical Center.

Date: October 28–29, 2019.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 10 Rockville Pike, Bethesda, MD 20892.

Contact Person: Ronald Neumann, MD, Deputy Scientific Director, Office of Clinical

Research, NIH–Clinical Center, 10 Center Drive, Room 1C453, Bethesda, MD 20892, 301–496–6455.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Dated: October 17, 2019.

Ronald J. Livingston, Jr.,
Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23042 Filed 10–22–19; 8:45 am]

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