respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

Legal authority for the State Plan for Independent Living (SPIL) is contained in Chapter 1 of Title VII of the Rehabilitation Act of 1973, as amended by the Workforce Innovation and Opportunity Act ([the Act], Pub. L. 113–128). Section 704 of the Rehabilitation Act requires that, to be eligible to receive financial assistance under Chapter 1, ''a State shall submit to the Department, and obtain approval of, a State plan containing such provisions as the Department may require.'' ACL approval of the SPIL is required for states to receive federal funding for both the Independent Living Services State grants and Centers for Independent Living (CIL) programs. Federal statute and regulations require the collection of this information every three years. The current three-year approval period for the SPIL expires March 31, 2023. The SPIL Instrument is the template for SPILs; the SPIL Instructions explain the Instrument and give tips about how to draft SPILs.

The Office of Independent Living Programs (OILP) is proposing minor revisions based on OILP and the technical assistance provider revising the Instrument and Instructions to resolve issues that SILCs have reported having with their SPILs, and to increase the Instrument's and Instructions' clarity, conciseness, and precision. For example,

- The revised Instrument and Instructions correct grammatical and punctuation errors.
- The revised Instructions add lines for each core service.
- The revised Instrument and Instructions clarify the definition, and example, of state match.

These updates were recommended by the technical assistance provider and analyzed by all the independent living project officers who work directly with SPILs and the issues that they plan for. The SPIL is jointly developed by the chairperson of the Statewide Independent Living Council and the directors of the CILs in the state, after receiving public input from individuals throughout the State, and signed by the chairperson of the SILC, acting on behalf of—and at the direction of—the SILC, the director of the designated State entity, and not less than 51 percent of the directors of the CILs in the State. ACL reviews the SPIL for compliance with the Rehabilitation Act and 45 CFR part 1329 and approves the SPIL. The SPIL serves as a primary planning document for continuous monitoring of, and technical assistance to, the state independent living (IL) programs to ensure appropriate planning, financial support and coordination, and other assistance to appropriately address, statewide, needs for the provision of IL services in the state.

The proposed data collection tools may be found on the ACL website for review at *https://www.acl.gov/about-acl/public-input.*

Estimated Program Burden: ACL estimates the burden associated with this collection of information as follows: 56 Statewide Independent Living Councils (SILCs) will respond to the requirement for a SPIL every three years. Each state's SILC will take approximately 60 hours to develop the SPIL for a total of approximately 3,360 hours. This estimate is based on amounts of time SILCs have reported previously spending to complete the SPIL. ACL does not expect the change in Instrument and Instructions to take more or less time than the currently approved information collection. Therefore, there is no change to the estimated reporting burden.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Statewide Independent Living Councils	56	1	60	3,360
Total	56	1	60	3,360

Dated: November 19, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2022–25691 Filed 11–23–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; Prevention and Public Health Fund Evidence-Based Chronic Disease Self-Management Education Program Information Collection; OMB# 0985–0036

AGENCY: Administration for Community Living, 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 requirements related to the Prevention and Public Health Fund Evidence-Based Chronic Disease Self-Management Education Program Information Collection OMB# 0985–0036.

DATES: Submit written comments on the collection of information by December 27, 2022.

ADDRESSES: Submit written comments and recommendations for the proposed information collection within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* Find the information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. 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 (*Shannon.skowronski@acl.hhs.gov*). Administration for Community Living, Washington, DC 20201, Attention: Shannon Skowronski.

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 Administration for Community Living (ACL) is requesting approval to collect data for the Prevention and Public Health Fund Evidence-Based Chronic Disease Self-Management Education Program Information Collection OMB# 0985–0036. The Evidence-Based

Chronic Disease Self-Management Education (CDSME) Grant Program is financed through the Prevention and Public Health Fund (PPHF). The statutory authority for cooperative agreements under the most recent program announcement (FY 2022) is contained in the Older Americans Act, Title IV; and the Patient Protection and Affordable Care Act, 42 U.S.C. 300u–11 (Prevention and Public Health Fund). The CDSME Grant Program supports a National CDSME Resource Center that provides technical assistance, education, and resources for the national CDSME network of partners, and awards competitive grants to implement and promote the sustainability of evidence-based CDSME programs that have been proven to provide older adults and adults with disabilities with education and tools to help them better manage chronic conditions such as diabetes, heart disease, arthritis, chronic pain, and depression. OMB approval of the existing set of CDSME data collection tools (OMB Control Number, 0985–0036) expires on 11/30/2022. This data collection continues to be necessary for the monitoring of program operations and outcomes. ACL currently uses and proposes to continue to use a set of tools to collect information for each program including: (1) Program Information Cover Sheet and Attendance Log, to be completed by the program leaders; and a (2) Participant Information Survey to be completed by participants on a voluntary basis before or at the beginning of the first program session and at the last session or post program to document their demographic and health characteristics. ACL/AoA intends to continue using an online data entry system for the program and participant survey data.

ACL collected public comments for analysis, conducted focus groups that included a sub-set of current CDSME grantees, as well as consulted with subject-matter experts to gather feedback and determine if changes to the data collection tools are warranted.

Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** *Vol. 87, No. 137 on July 19, 2022.* Five (5) public comments were received during the 60-day FRN. ACL's responses to these comments, along with feedback from grantee focus groups, National CDSME Resource Center and ACL's Center for Policy and Evaluation, are included below.

PARTICIPANT INFORMATION SURVEY

Topic/issue	Comment	ACL response
Survey Purpose	Suggestion to add a purpose statement to the forms to better inform participants of why this specific data collection is pertinent.	ACL will not adopt this suggestion. The purpose of this data collection is multi-fold—with different benefits and potential uses of the data by federal, state, and local stakeholders.
Survey Format	Multiple comments were received as detailed below: (a) Suggestion to change the type of bullet used for the response options from a circle to a text box. (b) Suggestion to group the disability-related questions and present in a table/grid format.	(a) ACL will incorporate this suggested revision. (b) ACL will incorporate this suggested revision.
Sexual Orientation and Gender Identity (SOGI).	Multiple respondents suggested the incorporation of inclusive sexual orientation and gender identity question(s).	HHS, and ACL as an operating division of HHS, recognize the importance of collecting SOGI data to better assess diversity and equity in evidence-based program scaling and participation. ACL intends to update this question to incorporate more inclusive questions and responses.
Race/Ethnicity	Multiple comments were received as detailed below: Suggestion to combine the race and ethnicity questions into one item. Suggestion to ''Include Middle Eastern/North African (MENA) as a response option. This race does not roll up to the current categories (maybe white) and could be a cause for not answering the question''.	ACL works to align data collection with what is currently collected across the Federal Government, specifically the U.S. Census. The questions as presented reflect how race/ethnicity is asked. ACL will not incorporate the suggestion to combine the race and ethnicity questions. Similarly, ACL will not incorporate the suggestion to include the MENA group for the reason mentioned above. However, ACL will incorporate the ''some other race'' option to allow for inclusion of additional responses.
Chronic Conditions List.	Multiple comments were received as detailed below: (a) Suggestion to expand the list of conditions to include post-traumatic stress disorder (PTSD), substance use disorder, urinary incontinence, malnutrition and Alzheimer's Disease or other dementia. (b) Suggestion to alphabetize the list to facilitate data entry	(a) ACL will incorporate these conditions based on the growing prevalence of these conditions in the aging population. For example, an estimated 6.5 million older adults are living with Alzheimer's dementia in 2022, 73% of which are 75 years and older; 50% of older adults are at risk for becoming malnourished; and nearly 1 million adults aged 65 and older live with a substance use disorder. (b) ACL will incorporate this suggested revision.
Social Isolation/Loneliness.	Multiple respondents suggested that this question be revised as it is asking about two different constructs—isolation and loneliness. Many respondents suggested ''replacing the question with the UCLA loneliness questions''—a three part question.	ACL appreciates the suggestion to collect more data around social isolation and loneliness but has decided in the interest of balancing data collection and burden to not include these specific questions in the survey. Instead, the constructs will be separated into their own questions in efforts to better analyze and report the information collected.
Participant Outcomes Questions.	(a) Multiple suggestions to add outcomes questions to better understand the impact of participating in a program and what participants might have done since the program to manage their chronic condition. (b) Suggestions to add elements from the Patient Activation Measure, Healthy Days Measures and RAPID3.	(a) ACL is interested in assessing impact of the program as well as activities that participants may be using to manage their condition as a result of their participation. ACL will therefore include a question that will assess what participants have done as it relates to talking with their healthcare provider, reviewing medications with appreciate healthcare personnel, increasing physical activity, eating healthy foods, participating in other health and wellness programming, and talking to their friends and family about their health. (b) ACL will not incorporate these suggestions at this time as these measures are: too general; lack direct applicability to assessing impact of participating in a CDSME program; or are too specific to particular chronic conditions or symptom.

PARTICIPANT INFORMATION SURVEY—Continued

Topic/issue	Comment	ACL response
Satisfaction Question	Request to add satisfaction question into the post-survey. Summary of respondents justification include ''Many organizations may be offering multiple programs, or just getting their programs off the ground. Measuring participants' satisfaction and overall experience with the program can help identify strengths and challenges across programs and implementation sites, including satisfaction with the leaders, time the program was offered, location, and other factors that impact delivery and sustainability''.	Although a satisfaction question has not been part of the required data collection elements, ACL agrees with this suggestion and will include a satisfaction question in the survey to assess the extent to which a program is meeting the needs of the participant, as well as overall program delivery.
Additional Questions	Suggestion to incorporate questions specific to language other than English spoken at home, language preference for reading or speaking about health/medical information, how well someone speaks English.	ACL appreciates the suggestion to collect more data but has decided in the interest of balancing data collection and burden to not include these additional elements on the survey.

PROGRAM INFORMATION COVER SHEET

Topic/issue	Comment	ACL response
Size of Implementation Site.	Suggestion to include the question ''How many older adults does your organization serve on an annual basis?'' as this would be helpful in analyzing the differences in how small and large sites implement programs.	ACL will not be incorporating this element at this time. Being able to scale and sustain programs depend on a variety of factors. The number of older adults served is not an adequate measure of success in program implementation.
Consent to Receive Information from National CDSME Resources Center.	A comment was received that this question seems unnecessary to have as a standard question, since it should only be asked once of each leader.	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.
Facilitator Demographics.	Suggestion to include demographic questions such as age, race/ethnicity as facilitator demographics can have a large impact on the effectiveness of program implementation. Knowing some demographic characteristics about the leaders could inform equity, diversity, and inclusion initiatives and add value to understanding program adoption and sustainability.	ACL agrees and will incorporate this suggestion by including the same questions as outlined in the participant information survey.
Facilitator Status	Suggestion to include a question to better understand how facilitators are compensated as organizations use a mix of paid and volunteer staff. It would be helpful to analyze whether a certain model is used more frequently depending on the program or whether the leader's employment status has an impact on completion of the workshop.	ACL agrees and will incorporate this suggestion.
Program Delivery Format.	Suggestion to include a question that asks about the delivery format for a program— ''With many programs now offered in multiple formats, it is important to know how program format impacts the demographic of participants who elect one format vs another, completion rates, and mapping the growth of these alternate program formats''.	ACL agrees and will incorporate this suggestion.
Network Status	A suggestion was made to ask a question about network status—''Is this workshop implemented as a part of a centralized, coordinated Community-Integrated Health Network? Yes/No. If yes, provide the name of the Community—Integrated Network: (open-ended)''.	Although Community Care Hubs/Community Integrated Health Network are increasing across the country, ACL will not incorporate this suggestion at this time. This may cause undue burden on a program facilitator or implementation site coordinator and possibly delay the return of data.

ATTENDANCE LOG

Topic/issue	Comment	ACL response
Format	Suggestions to: (a) Modify format to add the following: survey completion, liability form completion, attendance to other programs at site, and an example row. (b) Make participant ID column smaller so participants do not write their names.	(a) This form is to be completed by the program facilitator who should clearly print the program information and participant IDs. As a part of their training, facilitators should be instructed to not put participant name or other identifying information in the participant ID column. (b) ACL will not incorporate this suggestion to reduce burden on the program facilitator. If a grantee would like to collect additional information, they may choose to do so independently.

Estimated Program Burden: ACL estimates the burden associated with 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).	680	Twice per year (one set per program).	.34	462.40
Program participants (Participant Information Survey)	14,000	1	.20	2,800.00

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Data entry staff (Program Information Cover Sheet, Attendance Log, Participant Information Survey).	70	Once per program times 1,360 programs.	.20	272.0
Total Burden Hours				** 3,534

** Rounded to the nearest hour.

Dated: November 18, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2022–25698 Filed 11–23–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1262]

Notice of Approval of Product Under Voucher: Rare Pediatric Disease Priority Review Voucher

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of approval of a product redeeming a priority review voucher. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA), authorizes FDA to award priority review vouchers to sponsors of approved rare pediatric disease product applications that meet certain criteria. FDA is required to publish notice of the issuance of priority review vouchers as well as the approval of products redeeming a priority review voucher. FDA has determined that the supplemental application for SKYRIZI (risankizumab-rzaa), approved June 16, 2022, meets the criteria for redeeming a priority review voucher.

FOR FURTHER INFORMATION CONTACT: Cathryn Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1394, email: *Cathryn.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is announcing the approval of a product redeeming a rare pediatric disease priority review voucher. Under section 529 of the FD&C Act (21 U.S.C. 360ff), which was added by FDASIA, FDA will report the issuance of rare pediatric disease priority review vouchers and the approval of products for which a voucher was redeemed. FDA has determined that the supplemental application for SKYRIZI (risankizumab-rzaa), approved June 16, 2022, meets the redemption criteria.

For further information about the Rare Pediatric Disease Priority Review Voucher Program and for a link to the full text of section 529 of the FD&C Act, go to *https://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/RarePediatricDiseasePriorityVoucherProgram/default.htm.* For further information about SKYRIZI (risankizumab-rzaa), approved June 16, 2022, go to the ''Drugs@FDA'' website at *https://www.accessdata.fda.gov/scripts/cder/daf/.*

Dated: November 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–25644 Filed 11–23–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2782]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

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

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on January 24, 2023, from 9 a.m. to 4:30 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of the COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2022–N–2782. Please note that late, untimely filed comments will not be considered. The docket will close on January 23, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 23, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Comments received on or before January 9, 2023, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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