

functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. NIOSH implements this responsibility for CDC.

The Advisory Board's charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 13889 on March 22, 2020, and will terminate on March 22, 2022.

**Purpose:** The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. SDRR was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

**Matters To Be Considered:** The agenda will include discussions on the following dose reconstruction program quality management and assurance activities: Dose reconstruction cases under review from Set 29, possibly including cases involving: Albuquerque Operations Office, Area IV of the Santa Susana Field Laboratory, Argonne National Laboratory-East, Argonne National Laboratory-West, Battelle Laboratories-King Avenue, Clarksville Modification Center, Feed Materials Production Center (FMPC), Fermi National Accelerator Laboratory, General Atomics, Hanford, Idaho National Laboratory, Lawrence Berkeley National Laboratory, Lawrence Livermore National Laboratory, Los Alamos National Laboratory, Mound

Plant, Nevada Test Site, Oak Ridge Gaseous Diffusion Plant (K-25), Oak Ridge Institute for Science and Education, Oak Ridge National Laboratory (X-10), Pacific Northwest National Laboratory, Paducah Gaseous Diffusion Plant, Pantex Plant, Portsmouth Gaseous Diffusion Plant, Rocky Flats Plant, Savannah River Site, and/or Y-12 Plant. If time permits, there may also be discussion on professional judgement in response to the April 12, 2021 SDRR report to the Advisory Board. Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

**Kalwant Smagh,**

*Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Community Living**

**Agency Information Collection Activities; Proposed Collection; Public Comment Request; Centers for Independent Living Program Performance Report (0985-0061)**

**AGENCY:** Administration for Community Living, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This Proposed Extension without Revision of a Currently Approved Collection (ICR Ext) solicits comments on the information collection requirements relating to the Centers for

Independent Living *under* the Rehabilitation Act of 1973.

**DATES:** Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by October 8, 2021.

**ADDRESSES:** Submit electronic comments on the collection of information to: Peter Nye at [OILPPRAComments@acl.hhs.gov](mailto:OILPPRAComments@acl.hhs.gov). Submit written comments on the collection of information to Administration for Community Living, Washington, DC 20201, Attention: Peter Nye.

**FOR FURTHER INFORMATION CONTACT:**

Peter Nye, Administration for Community Living, Washington, DC 20024, (202) 795-7606 or [OILPPRAComments@acl.hhs.gov](mailto:OILPPRAComments@acl.hhs.gov).

**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. "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 (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) Whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

In the context of ACL, IL programs are supported through funding authorized by the Rehabilitation Act of 1973, as amended (The Act). Title VII, chapter 1 of the Act states the current purpose of the program is to “promote a philosophy of independent living including a philosophy of consumer control, peer support, self-help, self-determination, equal access, and individual and system advocacy, in order to maximize the leadership, empowerment, independence, and productivity of individuals with disabilities, and the integration and full inclusion of individuals with disabilities into the mainstream of American society.”

ILS PPR and CIL PPR are being submitted separately because they are separate collections of different information from different parties. Separating these PRA processes reduces confusion and increases the Office of Independent Living Programs’s (OILP’s) ability to identify issues specific to CILs. This request is for CIL PPR, which is submitted annually by all CILs receiving IL Part C funds. The PPRs are used by

ACL to assess grantees’ compliance with title VII of the Act, and with 45 CFR 1329 of the Code of Federal Regulations and with applicable provisions of the HHS Regulations at 45 CFR part 75. The PPR serves as the primary basis for ACL’s monitoring activities in fulfillment of its responsibilities under sections 706 and 722 of the Act. The PPR also enables ACL to track performance outcomes and efficiency measures of the Centers for Independent Living (CIL) programs with respect to the annual and long-term performance targets established in compliance with GPRA. The PPR is also used by ACL to design CIL and SILC training and technical assistance programs authorized by section 711A and section 721 of the Act.

ACL published a **Federal Register** Notice regarding the independent living programs information collection on February 23, 2017. Two-hundred and twenty-one individual comments were received. The responses indicated a need to make substantial changes to the collection. The current version of the CIL PPR that OILP is requesting an

extension for was approved by OMB; the approval was extended and will expire on January 31, 2022. Further deliberation is needed to ensure that we appropriately address all of the concerns. OILP is proposing to extend the currently approved forms for one year while we work on a revision that addresses all the suggested changes. 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 of this collection of information as follows: 353 Centers for Independent Living will each complete one CIL PPR annually, and it will take an estimated 35 hours per CIL for an estimated total of 12,355 hours. This burden estimate is based partly on OILP’s estimates of how long CILs probably take to find the information that PPRs ask for and partly on what CILs have told OILP about how long filling out the PPRs took.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Centers for Independent Living .....	353	1	35	12,355

Dated: July 29, 2021.  
**Alison Barkoff**,  
*Acting Administrator and Assistant Secretary for Aging.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2015-N-0030]

**Extension of the Period Before the Food and Drug Administration Intends To Begin Enforcing the Statutory 5 Percent Limit on Out of State Distribution of Compounded Human Drug Products**

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).  
**ACTION:** Notice; extension of the period before FDA intends to begin enforcing the statutory 5 percent limit on out of state distribution of compounded human drug products.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the period for States to decide

whether to sign the final standard memorandum of understanding (MOU) entitled “Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration” (final standard MOU) before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that do not sign the final standard MOU. FDA is extending the period, which was scheduled to end on October 27, 2021, to October 27, 2022. States may sign the final standard MOU at any time, including after the period is scheduled to end on October 27, 2022.

**DATES:** FDA is extending the period before FDA intends to begin enforcing the statutory 5 percent limit on distribution of compounded human drug products out of the State in which they are compounded in States that do not sign the final standard MOU as of August 9, 2021.

**FOR FURTHER INFORMATION CONTACT:** Alexandria Fujisaki, Center for Drug Evaluation and Research, Food and

Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5169, Silver Spring, MD 20993-0002, 240-402-4078.

**SUPPLEMENTARY INFORMATION:** Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a) describes the conditions that must be satisfied for drug products compounded by a licensed pharmacist or licensed physician in a State licensed pharmacy or a Federal facility, to be exempt from the following sections of the FD&C Act: (1) Section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice (CGMP) requirements), (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use), and (3) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications).

One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that (1) the drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate