

“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. The PRA 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.

This is a revision to a currently approved information collection (IC), the Department replaced four existing

Protection and Advocacy Program Performance Reports under one IC in March 2019. This is termed One-PPR. The four annual reports included the following: (1) Developmental Disabilities Protection and Advocacy Systems Program Performance Report, (2) Protection and Advocacy for Assistive Technology (PAAT) Program Performance Report; (3) Protection and Advocacy Voting Access Annual Report (Help America Vote Act) (HAVA); and (4) Protection and Advocacy for Traumatic Brain Injury (PATBI) Program Performance Report. This revision includes data elements based on funding from the Centers for Disease Control and Prevention to increase access to COVID-19 vaccines (ACCESS), and expand the Public Health Workforce (PHWF), provided under Section 2501 of the American Rescue Plan Act of 2021 (Pub. L. 117-2). Each P&A submits one report (One-PPR) for four funding sources, administered by ACL. As with each funding source, there is a reporting requirement. In an effort to reduce the burden of the P&As, each will continue to submit one report for all funding sources; however, as of FY2022, the report will incorporate the activities undertaken for the ACCESS and PHWF funding, by creating a new goal or priority in Part 2C, and adding the narrative in Part 2.C.4 (Rationale for Adding/Changing Goal) or 2.C.5 (Rationale for Adding/Changing Priority). The guidance document provides a description of the data elements to be included in this section of the One-PPR template.

State Protection and Advocacy (P&A) Systems in each State and Territory provide individual legal advocacy,

systemic advocacy, monitoring and investigations to protect and advance the rights of people with developmental disabilities, using funding administered by the Administration on Disabilities (AoD), Administration for Community Living, HHS. To meet statutory reporting requirements, P&As use these forms for submitting annual reports.

The PPRs are reviewed by federal staff for compliance and outcomes. Information in the reports is analyzed to create a national profile of programmatic compliance, outcomes, and goals and priorities for P&A Systems for tracking accomplishments against goals and to formulate areas of technical assistance related to compliance with Federal requirements. Information collected informs AoD of trends in P&A advocacy, facilitate collaboration with other federally funded entities, and identify best practices for the efficient use of federal funds. Additionally, the information is used to provide a national perspective on where the program is going (prospective view), and to provide a gauge for program accomplishments against program objectives for purposes of identifying continuing challenges and formulating technical assistance and management support provided to P&A systems.

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

The following table summarizes the burden hour estimate for this information collection:

| Number of states | Number of responses per state | Average burden hours per state | Total hours |
|------------------|-------------------------------|--------------------------------|-------------|
| 57 .....         | 1                             | 144                            | 8208        |

The estimates of annual burden to the States vary in accordance with the size, program complexity, and technological capacity of the States. The annual burden on this form is estimated to be 144 hours, which is an increase of 16 hours from the previous instrument.

| PPR           | Annual hours estimate (based on previous OMB burden estimates) |
|---------------|----------------------------------------------------------------|
| PADD .....    | 90                                                             |
| PAAT .....    | 16                                                             |
| PATBI .....   | 16                                                             |
| HAVA .....    | 20                                                             |
| ACCESS .....  | 10                                                             |
| PHWF .....    | 6                                                              |
| ONE PPR ..... | 144                                                            |

Dated: February 3, 2022.

**Alison Barkoff,**

*Principal Deputy Administrator.*

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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; Process Evaluation of the Aging Network and Its Return on Investment; OMB #0985-New**

**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 information collection requirements related to the information collection requirements for the Process Evaluation of the Aging Network and its Return on Investment [OMB #0985–New].

**DATES:** Submit written comments on the collection of information by March 10, 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](http://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:** Caryn Bruyere, Office of Performance and Evaluation, Administration for Community Living Telephone: 202–795–7393 Email: [caryn.bruyere@acl.hhs.gov](mailto:caryn.bruyere@acl.hhs.gov).

**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 Process Evaluation of the Aging Network and its Return on Investment [OMB #0985–New]. Many older adults have unmet health care and social service needs, which require coordinated care across a range of services, including access to nutritious meals, transportation, preventive health care, home and community-based care, social interaction, support for family caregivers, and advocacy to help maintain older adults’ safety, dignity, and legal rights. This proposed data collection for the Process Evaluation of the Aging Network and its Return on Investment is intended to provide timely information on, (1) how agencies in the Aging Network collaborate to serve older adults and family caregivers, and (2) how agencies measure the effectiveness of their efforts with the goal of strengthening their reach and impact. Through this data collection ACL will investigate how states differ in their network structure, how agencies work together, and potential strategies for evaluating return on investments (ROI) of ACL programs.

The Process Evaluation of the Aging Network and its Return on Investment will include: (1) A census of agencies in the Aging Network, and (2) key informant interviews with agencies that are evaluating ROI. The survey seeks to collect data from all State Units on Aging (SUAs), Area Agencies on Aging (AAAs) (including some Aging and Disability Resource Centers), and Older

Americans Act Title VI Native American tribal organizations. Surveying these organizations will help ACL understand how and with whom agencies in the network collaborate to address the needs of older adults and family caregivers, partnerships that have formed or expanded because of COVID–19, and how agencies measure the effectiveness and ROI of their various programs. The study will also include key informant interviews with a subset of 10 agencies that responded to the survey whose responses indicate that their agency is evaluating ROI. The data collection team will ask in-depth questions about the costs and benefits included in ROI calculations, successes and challenges to evaluating ROI, and lessons learned that could benefit other agencies seeking to conduct their own assessment of ROI.

#### Comments in Response to the 60-Day Federal Register Notice

A notice published in the **Federal Register** on, August 30, 2021 in 86 FR 48428. There were no substantive public comments received during the 60-day FRN.

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

The proposed data collection estimates the average burden per response to be 0.17 hours for the Aging Network survey. The average burden per response for the key informant interviews estimated as 1 hour.

| Data collection activity            | Annual number of respondents | Number of responses per respondent | Total number of responses | Average burden per response (in hours) | Annual estimated burden hours |
|-------------------------------------|------------------------------|------------------------------------|---------------------------|----------------------------------------|-------------------------------|
| Aging Network survey .....          | 864                          | 1 .....                            | 864                       | 0.25 .....                             | 216                           |
| Key informant interview guide ..... | 10                           | 1 .....                            | 10                        | 1 .....                                | 10                            |
| Total .....                         | 874                          | Varies .....                       | 874                       | 0.26 (weighted mean).                  | 226                           |

Dated: February 3, 2022.

**Alison Barkoff,**

*Principal Deputy Administrator.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

[Docket No. FDA–2021–D–1051]

##### Clinical Pharmacology Considerations for Antibody-Drug Conjugates; Draft Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft

guidance for industry entitled “Clinical Pharmacology Considerations for Antibody-Drug Conjugates,” which provides recommendations for the development of antibody-drug conjugates (ADCs). Specifically, this guidance addresses the FDA’s current thinking regarding clinical pharmacology considerations and recommendations for ADC development programs, including bioanalytical methods, dose selection and adjustment, dose- and exposure-response analysis, intrinsic factors, QTc assessments, immunogenicity, and drug-drug interactions (DDIs). Currently, there are