

Appropriations Act, 2021 (Pub. L. 116–260).

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities; Proposed Collection; Comment Request; ACL Program Performance Report Generic Information Collection, OMB 0985–NEW

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 (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.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by February 5, 2024.

ADDRESSES: Submit electronic comments on the collection of information to: Shannon Skowronski to the ACL Office of Performance and Evaluation public comment inbox at evaluation@acl.hhs.gov. Submit written comments on the collection of information to Administration for Community Living, 330 C Street SW, Washington, DC 20201, Attention: Shannon Skowronski Office of Performance and Evaluation.

FOR FURTHER INFORMATION CONTACT: Shannon Skowronski at the ACL Office of Performance and Evaluation public comment inbox evaluation@acl.hhs.gov or at 202–795–7438 or shannon.skowronski@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: This announcement solicits comments on the ACL Program Performance Report Generic Information Collection, a mechanism to collect program performance reports for programs authorized by the Older Americans Act (Pub. L. 89–27 of 1965, as amended through Pub. L. 116–131 of 2020), and the Elder Justice Act (title XX of the Social Security Act, subtitle B, the Elder Justice Act of 2009).

Under the PRA, 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 as 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.

ACL invites comments on burden estimates or other aspects 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.

ACL will adhere to best practices for collection of all demographic information when this information is collected for the programs listed below in accordance with OMB guidance. This includes, but is not limited to, guidance specific to the collection of sexual orientation and gender identity (SOGI) items that align with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, Executive Order 14075 on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals and Executive Order 13988 on Preventing and Combating Discrimination on the Basis of Gender Identity and Sexual Orientation. Understanding these disparities can and should lead to improved service delivery for ACL’s programs and populations served.

Authorizing Legislation

In 1965, the Older Americans Act (OAA) was passed in response to

concerns by policymakers about a lack of community social services for older adults. The original legislation established authority for grants for community planning and social services, research and development projects, and personnel training in the field of aging. The OAA was last amended in 2020 (Pub. L. 116–131) and authorizes a variety of social and health services programs for older adults, families, and caregivers. The Elder Justice Act (EJA), passed in 2010, is the first comprehensive legislation to address the abuse, neglect, and exploitation of older adults at the federal level. The law authorized programs and initiatives that coordinate federal responses to elder abuse, promote elder justice research and innovation, support Adult Protective Services systems, and provide additional protections for residents of long-term care facilities. OAA and EJA programs help advance ACL’s mission of supporting the independence, well-being, and health of older adults, older adults with disabilities, and their families and caregivers.

The OAA, EJA, 45 CFR 75.342 (monitoring and reporting program performance), 45 CFR 75.301 (performance measurement), and the GPRA Modernization Act of 2010 (Pub. L. 111–352, Sec 12) require grantee program performance monitoring and reporting. Grantee program performance reporting serves several functions, enabling ACL to: (1) monitor program achievement of performance objectives; (2) identify areas of performance that may benefit from technical assistance and/or corrective action; (3) establish program policy and direction; and (4) prepare responses and reports for Congress, the OMB, other federal departments, and public and private agencies, including legislatively required reports.

In order to streamline the collection of performance data and enhance efficacy, ACL is requesting approval of a generic IC for performance reporting for programs authorized under the OAA and EJA.

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

Estimated Program Burden: ACL estimated total annual burden for this generic IC is 50,335.60 hours. This estimate is based on the current number of grantees for these programs, their number of program performance indicators, and previous ACL experience with program performance reporting.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
State Formula Grantees, SPR Generic	112	1	70.3	7,873.60
State Competitive Grants, PPR Generic	56	2	1.0	112
Tribal Formula Grantees, PPR Generic	282	1	60	16,920
Competitive Grantees, PPR Generic	1,189	2	10	23,780
Veteran Organization Competitive Grantees, PPR Generic	275	12	0.5	1,650
Total Annual Hours				50,335.60

Dated: November 30, 2023.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the delegable duties of the Administrator and the Assistant Secretary for Aging.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration’s (FDA), Center for Biologics Evaluation and Research (CBER), Office of Blood Research and Review (OBRR) and the Office of Vaccines Research and Review (OVRR) have modified organizational structures.

DATES: These new organizational structures were approved by the Secretary of Health and Human Services on June 27, 2023.

FOR FURTHER INFORMATION CONTACT: Yashika Rahaman, Director, Office of Planning, Evaluation and Risk Management, Office of Finance, Budget, Acquisitions and Planning, FDA, 4041 Powder Mill Road, Beltsville, MD 20705-4304, 301-796-3843.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D–B, (Food and Drug Administration), the Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, 60 FR 56606, November 9, 1995, 64 FR 36361, July 6, 1999, 72 FR 50112, August 30, 2007, 74 FR 41713, August 18, 2009, 76 FR 45270, July 28, 2011, and 84 FR 22854, May 20, 2019) is revised to reflect FDA’s reorganization of CBER, OBRR and OVRR.

CBER’s mission is to protect and enhance public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. With substantial growth in innovative, novel products, as well as a need to address an ever-changing landscape of potential public health threats, CBER is currently facing scientific, medical, and regulatory challenges that require changes to its structure.

In OBRR, the establishment of a Laboratory of Pathogen Reduction will address Center-level initiatives focusing on the optimization of new pathogen inactivation technologies. These technologies can dramatically help the American public and potentially reduce or eliminate donor deferral and/or testing requirements. Additionally, the proposed structural changes, keeping OBRR’s functioning state of two divisions instead of three, will maintain operational consistency and enable the divisions to build on processes and efficiencies gained in the last 2 years.

In OVRR, the Division of Vaccines and Related Product Applications will split into the Division of Review Management and Regulatory Review and the Division of Clinical and Toxicology Review to allow for improved operational efficiency, appropriate supervisory ratios, and a better balance of workload within an area of increased demand.

Under Part D, FDA’s CBER, Office of Blood Research and Review, has been restructured as follows:

DCB. ORGANIZATION. CBER is headed by the Center Director, Center for Biologics Evaluation and Research.

Center for Biologics Evaluation and Research (DCB)

Office of Blood Research and Review (DCBE)

Administrative Staff (DCBE1)

Regulatory Project Management Staff (DCBE2)

Laboratory of Pathogen Reduction (DCBE3)

Division of Emerging and Transfusion Transmitted Diseases (DCBEA)

Laboratory of Molecular Virology

(DCBEA1)

Laboratory of Emerging Pathogens

(DCBEA2)

Product Review Branch (DCBEA4)

Laboratory of Emerging Pathogens (DCBEA2)

Product Review Branch (DCBEA4)

Division of Blood Components and Devices (DCBEB)

Devices Review Branch (DCBEB2)

Blood and Plasma Branch (DCBEB6)

Laboratory of Cellular Hematology (DCBEB7)

Laboratory of Biochemistry and Vascular Biology (DCBEB8)

Under Part D, FDA’s CBER, Office of Vaccines Research and Review, has been restructured as follows:

DCB. ORGANIZATION. CBER is headed by the Center Director, Center for Biologics Evaluation and Research.

Center for Biologics Evaluation and Research (DCB)

Office of Vaccines Research and Review (DCBF)

Program Operations Staff (DCBF1)

Division of Bacterial Parasitic and Allergenic Products (DCBFA)

Laboratory of ImmunoBiochemistry (DCBFA1)

Laboratory of Respiratory and Special Pathogens (DCBFA2)

Laboratory of Bacterial

Polysaccharides (DCBFA3)

Laboratory of Mucosal Pathogens and Cellular Immunology (DCBFA4)

Division of Viral Products (DCBFB)

Laboratory of Pediatric and Respiratory Viral Diseases (DCBFB1)

Laboratory of Hepatitis Viruses (DCBFB2)

Laboratory of Retroviruses (DCBFB3)

Laboratory of DNA Viruses (DCBFB4)

Laboratory of Vector Borne Diseases (DCBFB5)

Laboratory of Method Development (DCBFB6)

Laboratory of Immunoregulation (DCBFB7)

Division of Review Management and Regulatory Review (DCBFD)

Regulatory Review Branch 1

(DCBFD1)

Regulatory Review Branch 2