

Dated: January 26, 2023.

**Alison Barkoff,**

*Acting Administrator and Assistant Secretary for Aging.*

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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Administration for Community Living**

[OMB Control No. 0985-0030]

#### **Agency Information Collection Activities; Submission for OMB Review; Public Comment Request; of the National Network of University Centers for Excellence in Developmental Disabilities Education, Research, and Service**

**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 the Paperwork Reduction Act of 1995. This 30-day notice collects comments on the information collection requirements related to the National Network of University Centers for Excellence in Developmental Disabilities Education, Research, and Service (UCEDDs) OMB control number 0985-0030.

**DATES:** Submit written comments on the collection of information by March 3, 2023.

**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:** Pamela O'Brien, 202-795-7417 or [pamela.obrien@acl.hhs.gov](mailto:pamela.obrien@acl.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, The Administration for Community Living (ACL) has submitted the following proposed collection of information to OMB for review and clearance. ACL is requesting approval of revisions to the

National Network of University Centers for Excellence in Developmental Disabilities Education, Research, and Service OMB control number 0985-0030. The National Network of University Centers for Excellence in Developmental Disabilities Education, Research, and Service (UCEDDs) is a discretionary grant program that supports the operation and administration of UCEDDs which are interdisciplinary education, research, and public service units of universities or public or not-for-profit entities associated with universities that engage in core functions.

This IC revision adds items to ensure ACL is gathering the necessary and relevant demographic information in support of Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government and the Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals. The National Academies of Science, Engineering, and Medicine (NASEM) recently published a report on Measuring Sex, Gender Identity, and Sexual Orientation for the National Institutes of Health. This report represents the culmination of years of work within HHS to develop sexual orientation and gender identity (SOGI) data collection methodology. This IC includes the recommended NASEM SOGI questions.

This IC revision also includes data elements needed to account for the activities supported by funding from the Centers for Disease Control and Prevention (CDC) to support access to vaccines for people with disabilities as well as the funds awarded under the American Rescue Plan to increase the Public Health Workforce (PHWF). All other elements of the template remain consistent with the currently approved UCEDD annual report.

Section 104(a) (42 U.S.C. 15004) of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (DD Act) directs the Secretary of Health and Human Services to develop and implement a system of program accountability to monitor the grantees funded under the DD Act of 2000. The program accountability system must include UCEDDs authorized under Part D of the DD Act of 2000. Section 154(e) (42 U.S.C. 15064) of the DD Act of 2000 includes requirements for a UCEDD Annual Report. The UCEDD Annual Report should contain information on progress made in achieving the projected goals of the Center for the previous year, including:

(1) The extent to which the goals were achieved;

(2) A description of the strategies that contributed to achieving the goals;

(3) The extent goals were not achieved, a description of factors that impeded the achievement; and

(4) An accounting of the manner in which funds paid to the Center under this subtitle for a fiscal year were expended.

In addition, the DD requires information on proposed revisions to the goals and a description of successful efforts to leverage funds, other than funds made available under the DD Act.

The DD Act also states grantees must report on:

(1) Consumer satisfaction with the advocacy, capacity building, and systemic change activities of the UCEDD;

(2) The extent to which the UCEDD's advocacy, capacity building, and systemic change activities resulted in improvements; and

(3) The extent to which collaboration was achieved in the areas of advocacy, capacity building, and systemic change.

Currently, UCEDDs engage in four broad tasks: conducting interdisciplinary training, promoting exemplary community service programs and providing technical assistance at all levels from local service delivery to community and state governments, conducting research, and disseminating information to the field. There are 67 UCEDDs throughout the United States with at least one or more in every State and Territory, as mandated.

The information derived from data collection activities will be used for multiple purposes:

(1) As a tool for UCEDD grantees to measure and report on progress in reaching goals and identify areas for which revisions are indicated;

(2) To enhance the Federal project officers' monitoring of UCEDD progress in reaching projected outcomes;

(3) To provide a set of standardized performance measures that will yield a national portrait of UCEDD program impact; and

(4) For making funding and appropriation decisions about the UCEDD program.

The information provided in the Annual Reports from the UCEDDs is combined with information reported by the State Developmental Disabilities Councils and Protection and Advocacy agencies to develop a biennial report. The report describes the goals and outcomes of programs supported under the DD Act and is submitted to the President, Congress, and the National Council on Disability. The

Administration on Disabilities (AoD) within ACL collects data via the National Information Reporting System (NIRS) a web-based system developed by the Association for University Centers on Disabilities (AUCD). The instrument guides the development of items to be included in NIRS for reporting purposes.

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

A notice published in the **Federal Register** Vol 87 FR 58354 on September

26, 2022. There were zero public comments were received during the 60-day FRN.

*Estimated Program Burden:* ACL estimates the burden of this collection of information as follows: Based on UCEDD reporting experience, current data and reporting efforts constitute approximately 1,462 burden hours per grantee for a total of 97,954 annual burden hours.

UCEDDs also worked with the technical assistance provider to establish burden reporting estimates for

Centers for Disease Control (CDC) and Public Health Workforce (PHWF) reporting. It should be noted that not all UCEDDs chose to accept CDC and PHWF funds. The CDC and PHWF reporting totals 6,298 annual burden hours. The overall estimated total annual burden hours factoring in all three reports is: 104,252.

*Estimated Total Annual Burden Hours:* 104,252.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
UCEDD Annual Report .....	67	1	1,462	97,954
UCEDD CDC Report .....	67	1	76	5,092
UCEDD PHWF Report .....	67	1	18	1,206
Total .....				104,252

Dated: January 26, 2023.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2022-N-1894]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation B12 Pediatric Device Survey

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by March 3, 2023.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information

collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The title of this information collection is “Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation B12 Pediatric Device Survey.” Also include the FDA docket number found in brackets in the heading of this document.

#### FOR FURTHER INFORMATION CONTACT:

JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Yale-Mayo Clinic Centers of Excellence in Regulatory Science and Innovation (CERSI) B12 Pediatric Device Survey

*OMB Control Number 0910-NEW*

Despite numerous legislative, regulatory, and scientific efforts, there has been little change in the number of devices approved for use in pediatric patients. This has often led to devices being adapted for use in children without an appropriate level of evidence, exposing them to inconsistent benefit risk profiles. This health inequity highlights the need for devices that are designed, evaluated, and labelled for pediatric patients. To address these challenges, this collection is being done to survey industry and other key stakeholders in the medical

device ecosystem to identify the barriers that prevent product developers from entering the pediatric device market as well as the proper incentives that would motivate them to innovate and sustain within this market.

This survey is a followup to the public meeting that FDA held in August 2018, entitled “Pediatric Medical Device Development.” As mandated by section 502(d) of the FDA Reauthorization Act of 2017 (Pub. L. 115-52), the meeting was convened to address several topics, including consideration of ways to: (1) increase FDA assistance to medical device manufacturers in developing devices for pediatric populations that are approved or cleared, and labeled, for their use and (2) identify current barriers to pediatric device development and incentives to address such barriers.

Feedback from this meeting clarified the need to better understand factors influencing suboptimal engagement and participation by diverse innovators in the pediatric medical device space. Information garnered from this survey may help inform strategic plans to optimize existing programs for the needs of pediatric medical device innovators and develop new programs that will support sustained development in this space.

In the **Federal Register** of September 23, 2022 (87 FR 58106), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows: