

FOR FURTHER INFORMATION CONTACT:

William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. The term “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 publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title:* Medicare Program: Procedures for Making National Coverage Decisions; *Use:* This collection is required by a notice (78 FR 48164-69) published on August 7, 2013 which delineates the process for making a national coverage determination (NCD) including information for external parties to submit a formal request for a new NCD or a reconsideration of an existing NCD. An NCD is defined in 1862(l) of the Social Security Act (the Act) as “a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this title.” This information collection will assist us in obtaining the information we require to make a national coverage determination in a timely manner and ensuring that the Medicare program continues to meet the needs of its beneficiaries. *Form Number:* CMS-R-290 (OMB control number: 0938-0776); *Frequency:* Annual; *Affected Public:* Private Sector: Business or other for-profits; *Number of Respondents:* 30; *Total Annual Responses:* 30; *Total Annual Hours:* 1,200. (For policy questions regarding this collection contact Lori M. Ashby at 410-786-6322.)

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Transcatheter Valve Therapy (TVT) Registry; *Use:* The data collection is

required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, “Transcatheter Aortic Valve Replacement (TAVR)”. The TAVR device is only covered when specific conditions are met including that the heart team and hospital are submitting data in a prospective, national, audited registry. The data includes patient, practitioner and facility level variables that predict outcomes such as all cause mortality and quality of life. CMS finds that the Society of Thoracic Surgery/American College of Cardiology Transcatheter Valve Therapy (STS/ACC TVT) Registry, one registry overseen by the National Cardiovascular Data Registry, meets the requirements specified in the NCD on TAVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TAVR technologies for the treatment of aortic stenosis.

The data will also include the variables on the eight item Kansas City Cardiomyopathy Questionnaire (KCCQ-10) to assess health status, functioning and quality of life. In the KCCQ, an overall summary score can be derived from the physical function, symptoms (frequency and severity), social function and quality of life domains. For each domain, the validity, reproducibility, responsiveness and interpretability have been independently established. Scores are transformed to a range of 0-100, in which higher scores reflect better health status.

The conduct of the STS/ACC TVT Registry and the KCCQ-10 is in accordance with Section 1142 of the Social Security Act (the Act) that describes the authority of the Agency for Healthcare Research and Quality (AHRQ). Under section 1142, research may be conducted and supported on the outcomes, effectiveness, and appropriateness of health care services and procedures to identify the manner in which disease, disorders, and other health conditions can be prevented, diagnosed, treated, and managed clinically. Section 1862(a)(1)(E) of the Act allows Medicare to cover under coverage with evidence development (CED) certain items or services for which the evidence is not adequate to support coverage under section 1862(a)(1)(A) and where additional data gathered in the context of a clinical setting would further clarify the impact of these items and services on the health of beneficiaries.

The data collected and analyzed in the TVT Registry will be used by CMS to determine if the TAVR is reasonable and necessary (e.g., improves health

outcomes) for Medicare beneficiaries under Section 1862(a)(1)(A) of the Act. Furthermore, data from the Registry will assist the medical device industry and the Food and Drug Administration (FDA) in surveillance of the quality, safety and efficacy of new medical devices to treat aortic stenosis. For purposes of the TAVR NCD, the TVT Registry has contracted with the Data Analytic Centers to conduct the analyses. In addition, data will be made available for research purposes under the terms of a data use agreement that only provides de-identified datasets. *Form Number:* CMS-10443 (OMB control number: 0938-1202); *Frequency:* Annual; *Affected Public:* Individuals, Households and Private Sector; *Number of Respondents:* 49,704; *Total Annual Responses:* 198,816; *Total Annual Hours:* 63,790. (For policy questions regarding this collection contact Nina Arya at 667-290-9456).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-28077 Filed 11-27-24; 8:45 am]

BILLING CODE 4120-01-P

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, 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 revision of a currently approved information collection request (ICR Rev) solicits comments on the information collection requirements related to the Centers for Independent Living (CILs) under the Rehabilitation Act of 1973, 29 U.S.C. 701, *et seq.* (the Act).

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (ET) or postmarked by January 28, 2025.

ADDRESSES: Submit electronic comments on the collection of information to: Peter Nye at 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.

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 Office of Management and Budget 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.

Independent living (IL) programs, including CILs, are authorized by the Act 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" (Title VII, chapter 1). This request is for the CIL Program Performance Report (PPR), which is submitted annually by all CILs receiving IL Subchapter C funds. The PPRs are used by ACL to assess grantees' compliance with title VII of the Act, with 45 CFR part 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 is also used by ACL to design CIL and Statewide Independent Living Council training and technical assistance programs authorized by sections 711A and 721 of the Act.

This revision adds the collection of sexual-orientation and gender-identity (SOGI) data elements consistent with

Executive Orders: 13985 *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government*; 13988 *Preventing and Combating Discrimination on the Basis of Gender Identity and Sexual Orientation* and 14075 *Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals*. ACL will adhere to best practices for collection of all demographic information in accordance with Office of Management and Budget (OMB) guidance—including, but not limited to guidance specific to the collection of SOGI. In addition, measures were added around the nature of CIL board governance and number of full-time equivalent positions filled by individuals with significant disabilities to affirm adherence to statutory requirements. Additional measures were also added to allow CILs to report carryover funding and to count the total number of services provided by consumer, as well as to describe their collaborations. These measures were added based on the request of stakeholders to yield more precise data that show impact. With the addition of these four measures, eleven other measures are suggested to be removed to increase efficiency and remove redundancy and unnecessary information. The revised CIL PPR instrument is expected to take less time than the prior instrument.

The proposed data collection tool 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 for new measures added as follows: 351 CILs completing one CIL PPR annually, taking an estimated time of 36 hours per CIL for total of 12,708 annual burden hours. This burden estimate is based partly on OILP's estimates of how long CILs take to complete the PPRs as well as feedback gathered from CILs to ACL.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
CIL	351	1	36	12,636

Dated: November 25, 2024.

Maura Calsyn,

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

[FR Doc. 2024–28052 Filed 11–27–24; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4731]

Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Detention and Banned Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish 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 notice solicits comments on information collection associated with administrative detention and banned medical devices.

DATES: Either electronic or written comments on the collection of information must be submitted by January 28, 2025

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 28, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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://](https://www.regulations.gov)

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 comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2024–N–4731 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Administrative Detention and Banned Medical Devices." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance