Average Minutes per Response: 56 minutes.

Annual Burden Hours: 4,030 hours.

Frequency: On occasion.

Request for Comments: Public comment is invited specifically on the need for and practical utility of this Generic Clearance, the accuracy of OGE's burden estimate, the enhancement of quality, utility and clarity of the information collected, and the minimization of burden (including the use of information technology). The comments will become a matter of public record.

Approved: September 4, 2024.

Shelley K. Finlayson,

Acting Director, U.S. Office of Government Ethics.

[FR Doc. 2024–20352 Filed 9–9–24; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10141, CMS–10913, CMS–R–290 and CMS–10443]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. 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 or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by November 12, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number:___, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–10141 Medicare Prescription Drug Benefit Program

CMS–10913 Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data Request

CMS–R–290 Medicare Program: Procedures for Making National Coverage Decisions

CMS–10443 Transcatheter Valve Therapy (TVT) Registry

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. 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 requires Federal agencies to publish a 60-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.

Information Collections

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Medicare Prescription Drug Benefit Program; *Use:* CMS will use this information from plan sponsors and States to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and ensure that correct information is disclosed to potential and current enrollees. *Form Number:* CMS–10141 (OMB control number: 0938–0964); *Frequency:* Annually; *Affected Public:* Private Sector, State, Local, or Tribal Governments; *Number of Respondents:* 4,633,032; *Total Annual Responses:* 87,014,803; *Total Annual Hours:* 25,409,037. (For policy questions regarding this collection contact Chad Buskirk at 410–786–1630 or *chad.buskirk@cms.hhs.gov*).

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Part C Utilization Management Annual Data Submission and Audit Protocol Data Request; *Use:* Section 1857(d) of the Act, added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR 422.503 and 422.504 state that CMS must oversee an MA organization's continued compliance with the requirements for a MA organization. Additionally, per § 422.516(a), MA organizations are required to compile and report to CMS information related to the utilization of services, and other matters as CMS may require.

The information gathered during this annual data collection and audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM) to assess Sponsoring organizations' compliance with Medicare UM requirements. CMS will utilize the data submitted during the annual data submission to assess the number of items and services that have associated internal coverage criteria, and to develop a landscape of items and services across the nation to assess

trends related to the development and utilization of internal coverage criteria. Additionally, CMS will use the annual submission to select a number of Sponsoring organizations to undergo UM audits each year, and to select specific items and services to audit. Annual UM data submissions, for all Sponsoring organizations, will be due to CMS by January 31 of each calendar year. *Form Number:* CMS–10913 (OMB control number: 0938–new); *Frequency:* Yearly*; Affected Public:* Private Sector, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 179; *Total Annual Responses:* 179; *Total Annual Hours:* 19,180. (For policy questions regarding this collection contact Caroline Zeman at 410–786–1564).

3. *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.)

4. *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 heath 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. 2024–20400 Filed 9–9–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Oncology 1-Basic Translational Integrated Review Group; Cancer Cell Biology Study Section.

Date: October 8–9, 2024.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria Old Town, 1900 Diagonal Road, Alexandria, VA 22314.

Contact Person: Charles Morrow, Ph.D., M.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, 301–408–9850, *morrowcs@csr.nih.gov.*

Name of Committee: Interdisciplinary Molecular Sciences and Training Integrated Review Group; Enabling Bioanalytical and Imaging Technologies Study Section.

Date: October 9–10, 2024.

Time: 8:00 a.m. to 6:00 p.m.