

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10531]

#### 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 (the 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 August 31, 2021.

**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, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

**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–10531 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 Collection

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Transcatheter Valve Therapy (TVT) Registry; *Use:* The data collection is required by the Centers for Medicare & Medicaid Services (CMS) National Coverage Determination (NCD) entitled, "Transcatheter Edge-to-Edge Repair (TEER) for Mitral Valve Regurgitation" and was previously entitled "Transcatheter Mitral Valve Repair (TMVR)". Effective January 19, 2021, CMS updated this NCD to expand coverage to functional mitral regurgitation (MR). Previously, coverage was limited to degenerative MR. To more precisely define the treatment

addressed in this NCD, we replaced the term TMVR with TEER. The TEER 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. In order to remove the data collection requirement under this coverage with evidence development (CED) NCD or make any other changes to the existing policy, we must formally reopen and reconsider the policy. We are continuing to review and analyze the data collected since the original NCD was effective in 2014 and following the update in 2021.

The data collected and analyzed in the TVT Registry will be used by CMS to determine if TEER 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 MR. *Form Number:* CMS–10531 (OMB control number: 0938–1274); *Frequency:* Annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 8,649; *Total Annual Responses:* 34,596; *Total Annual Hours:* 12,974. (For policy questions regarding this collection contact Sarah Fulton at 410–786–2749.)

Dated: June 28, 2021  
**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2021–14162 Filed 7–1–21; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10769]

#### Agency Information Collection Activities: Submission for OMB Review; 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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by August 2, 2021.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

**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:* New collection (Request for a new OMB control number); *Title of Information Collection:* Evaluation of the Centers for Medicare & Medicaid Services (CMS) Network of Quality Improvement and Innovation Contractors (NQIIC); *Use:* The purpose of this Information Collection Request (ICR) is to collect data using telephone surveys to inform the program evaluation of the CMS NQIIC initiative. The purpose of NQIIC is to support quality improvement efforts across settings and programs for maximum impact to health care and value to taxpayers in a manner that aligns with CMS' and Department of Health and Human Services (HHS) priorities. The NQIIC quality improvement efforts involve the QIN-QIO Program, which is one of the largest federal programs dedicated to improving health quality for Medicare beneficiaries.

CMS evaluates the quality and effectiveness of the QIN-QIO Program as authorized in Part B of Title XI of the Social Security Act. This ICR is to conduct data collection using surveys with administrators or managers of nursing homes and hospitals. Subsequent to publishing the 60-day **Federal Register** notice on March 9, 2021 (86 FR 13566), CMS conducted pre-testing with nursing home and hospital administrators using cognitive interviews, which provided substantive input from the targeted respondents to make sure that questions are clearly stated and understood as intended. We have made the required changes to questions to optimize response validity before fielding the survey. There was a slight decrease in burden hours. *Form Number:* CMS-10769 (OMB control number: 0938-NEW); *Frequency:* Yearly; *Affected Public:* State and Private Sector (Business or other for-profits); *Number of Respondents:* 1,000; *Total Annual Responses:* 1,000; *Total Annual Hours:* 290. (For policy questions regarding this collection, contact Jeff Mokry at 214-767-4021.)

Dated: June 29, 2021.

**William N. Parham, III,**  
*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2021-14227 Filed 7-1-21; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Submission for OMB Review; Assessing the Implementation and Cost of High-Quality Early Care and Education: Field Test, OMB 0970-0499

**AGENCY:** Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

**ACTION:** Request for public comment.

**SUMMARY:** The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval to collect new information to use in testing measures of the implementation and costs of high-quality early care and education as part of the project, Assessing the Implementation and Cost of High-Quality Early Care and Education (ECE-ICHQ). The study received approval for a field test to validate and improve the psychometric properties of these measures in November 2019. This request is to add a measure to the approved field test to help further assess the associations between measures of implementation, cost, and quality.

**DATES:** Comments due within 30 days of publication. OMB must make a decision about the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or using the search function.

#### SUPPLEMENTARY INFORMATION:

*Description:* ACF seeks approval to collect new information to use in testing measures of the implementation and costs of high-quality early care and education as part of the ECE-ICHQ