DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS-10341, CMS-R-246 and CMS-10531]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

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 a 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 any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). 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' Web Site address at http://www.cms.hhs.gov/PaperworkReductionActof1995.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

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-10341 Affordable Care Act Information and Collection Requirements for Section 1115 Demonstration Projects

CMS-R-246 Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey

CMS-10531 Transcatheter Mitral Valve Repair (TMVR) National Coverage Decision (NCD)

Under the Paperwork Reduction Act (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: Extension of a currently approved collection; Title of Information Collection: Affordable Care Act Information and Collection Requirements for Section 1115 Demonstration Projects; Use: This collection is necessary to ensure that states comply with regulatory and statutory requirements related to the development, implementation and evaluation of demonstration projects. States seeking waiver authority under Section 1115 are required to meet certain requirements for public notice, the evaluation of demonstration projects, and reports to the Secretary on the implementation of approved demonstrations. Form Number: CMS-10341 (OMB control number 0938-1162); Frequency: Yearly; Affected Public:

State, Local, or Tribal Governments; Number of Respondents: 37; Total Annual Responses: 130; Total Annual Hours: 13,910. (For policy questions regarding this collection contact Lane Terwilliger at 410-786-2059).

2. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Medicare Advantage, Medicare Part D, and Medicare Fee-For-Service Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey; Use: The primary purpose of the Medicare consumer assessment of healthcare providers and systems (CAHPS) surveys is to provide information to Medicare beneficiaries to help them make more informed choices among health and prescription drug plans available to them. The surveys also provides data to help CMS and others monitor the quality and performance of Medicare health and prescription drug plans and identify areas to improve the quality of care and services provided to enrollees of these plans. Form Number: CMS-R-246 (OMB control number: 0938-0732; Frequency: Yearly; Affected Public: Individuals and households; Number of Respondents: 799,650; Total Annual Responses: 799,650; Total Annual Hours: 277,740 (For policy questions regarding this collection contact Sarah Gaillot at 410-786-4637).

3. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Transcatheter Mitral Valve Repair (TMVR) National Coverage Decision (NCD); Use: The data collection is required by the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) entitled, "Transcatheter Mitral Valve Repair (TMVR)". The TMVR 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.

We find 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 TMVR. The TVT Registry will support a national surveillance system to monitor the safety and efficacy of the TMVR technologies for the treatment of mitral regurgitation (MR). 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 pursuant to 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 to determine if TMVR 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 mitral regurgitation. For purposes of the TMVR 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-10531(OMB Control Number: 0938-NEW); Frequency: Annually; Affected Public: Business or other for-profits; Number of Respondents: 4,000; Total Annual Responses: 16,000 Total Annual Hours: 5,600. (For policy questions regarding this collection contact Roya Lotfi at 410-786-4072.)

Dated: December 9, 2014. _____

Martique Jones,

Director, Regulations Development Group,

Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

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