

Semistandard Supplies; and FAR 52.216-4, Economic Price Adjustment—Labor and Material. These clauses require contractors on contracts that provide for economic price adjustments to promptly notify the contracting officer of any increases or decreases to established prices or labor rates (including fringe) because of certain contingencies, such as increases or decreases to established catalog or market prices or changes to cost indexes for labor or materials.

The contracting officer uses the information provided by the contractor to negotiate price adjustments under the contract due to the contingency specified in the contract.

- *FAR 52.216-5, Price*

Redetermination-Prospective. Paragraph (c) of this clause requires a contractor on a fixed-price contract with prospective price redetermination to submit to the Government (within an agreed upon timeframe) a statement of costs incurred for the most recent period of performance, the proposed prices for the upcoming contract period, and any supporting or relevant documentation. Per paragraph (h) of this clause, during periods where firm prices have not been established, the contractor must also submit quarterly statements that includes a breakdown of total contract prices, costs, and profit incurred and all invoices accepted for delivered items or services for which final prices have not been established.

The contracting officer uses the information to negotiate/redetermine fair and reasonable prices for supplies and services that may be delivered or performed under the contract in the period following the effective date of price redetermination.

- *FAR 52.216-6, Price*

Redetermination—Retroactive. Paragraph (c) of this clause requires a contractor on a fixed-ceiling-price contract with retroactive price redetermination to submit to the Government (within an agreed upon timeframe after completion of the contract) the proposed prices, all costs incurred in performing the contract, and any supporting or relevant documentation. Per paragraph (g) of this clause, until final price redetermination has been completed, the contractor must also submit a quarterly statement that includes a breakdown of total contract prices, costs, and interim profit incurred and all invoices accepted for delivered items.

The contracting officer uses the information provided by the contractor to negotiate/redetermine fair and reasonable prices for supplies and services that have already been

delivered or performed under the contract.

- *FAR 52.216-16, Incentive Price Revision—Firm Target; and FAR 52.216-17, Incentive Price Revision—Successive Targets.* These clauses require contractors on fixed price incentive (firm or successive target) contracts to submit to the Government on a quarterly basis a statement regarding total contract prices, costs, portions of interim profit, and amounts of invoices or vouchers for completed work that is cumulative from the beginning of the contract (see 52.216-16(g) and 52.216-17(i)). Upon final delivery of supplies or completion of services for covered line items, the contractor is required to submit a detailed statement of all costs incurred up to the end of that month in performing all work under the items; an estimate of costs of further performance, if any, that may be necessary to complete performance of all work under the items; a list of all residual inventory and an estimate of its value; and any other relevant data that the Contracting Officer may reasonably require (see 52.216-16(c) and 52.216-17(e)). Paragraph (c) of 52.216-17 also requires submission of data for establishing the firm fixed price or a final profit adjustment formula.

The contracting officer uses the information provided by the contractor to evaluate the contractor's performance in meeting the incentive target and to negotiate the final prices of incentive-related items and services.

C. Annual Burden

Respondents: 2,710.

Total Annual Responses: 45,260.

Total Burden Hours: 71,192.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202-501-4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 9000-0067, Certain Federal Acquisition Regulation Part 16 Contract Pricing Requirements.

William Clark,

Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-290 and CMS-10443]

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 December 30, 2024.

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. 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, 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 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.

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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).