DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10377, CMS–10338, CMS–10465, CMS–10443, and CMS–10379]

Agency Information Collection Activities: Submission for OMB Review; Comment Request.

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 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 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 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 on the collection(s) of information must be received by the OMB desk officer by July 18, 2016.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *or* Email: *OIRA_submission@omb.eop.gov*.

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. Email 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: 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:* Revision of a currently approved collection; *Title of Information Collection:* Student Health Insurance Coverage; *Use:* Under the Student Health Insurance Coverage Final Rule published March 21, 2012 (77 FR 16453), an issuer that provides student health insurance coverage that does not meet the annual dollar limits requirements under Public Health Service Act (PHS Act) section 2711 must provide notice in the insurance policy or certificate and in any other written materials informing students that the policy being issued does not meet the annual limits requirements under the Affordable Care Act. The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule removed outdated provisions in § 147.145(b)(2) and (d) allowing student health insurance issuers to impose restricted annual dollar limits on policies started before January 1, 2014, with an accompanying requirement that student health issuers must provide notice to students. Those provisions, by their own terms, no longer apply and student health insurance issuers are subject to the prohibition on annual dollar limits under PHS Act section 2711 and § 147.126 for policy years beginning on or after January 1, 2014. Therefore, the annual limit notification requirement is being discontinued.

The Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2017 Final Rule further provides that, for policy years beginning on or after July 1, 2016, student health insurance coverage is exempt from the actuarial value (AV) requirements under section 1302(d) of the Affordable Care Act, but must provide coverage with an AV of at least 60 percent. This provision also requires issuers of student health insurance coverage to specify in any plan materials summarizing the terms of the coverage the AV of the coverage and the metal level (or the next lowest metal level) the coverage would otherwise satisfy under § 156.140. This disclosure will provide students with information that allows them to compare the student health coverage with other available coverage options. *Form Number:* CMS–10377 (OMB Control Number: 0938–1157); *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 49; *Total Annual Responses:* 1,255,000; *Total Annual Hours:* 49. (For policy questions regarding this collection contact Russell Tipps at 301–492–4371.)

2. *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information Collection:* Affordable Care Act Internal Claims and Appeals and External Review Procedures for Non-grandfathered Group Health Plans and Issuers and Individual Market Issuers; *Use:* The PHS Act section 2719 and paragraph (b)(2)(i) of the Appeals regulations provide that group health plans and health insurance issuers offering group health insurance coverage must comply with the internal claims and appeals processes set forth in 29 CFR 2560.503–1, the Department of Labor (DOL) claims procedure regulation, and update such processes in accordance with standards established by the Secretary of Labor in paragraph (b)(2)(ii) of the regulations. Paragraph (b)(3)(i) requires issuers offering coverage in the individual health insurance market to also comply with the DOL claims procedure regulation as updated by the Secretary of Health and Human Services (HHS) in paragraph (b)(3)(ii) of the Appeals regulation for their internal claims and appeals processes.

The PHS Act section 2719 and the Appeals regulation also provide that health insurance issuers and self-funded nonfederal governmental health plans must comply either with a State external review process or a Federal review process. The IFR provides a basis for

determining when health insurance issuers and self-funded non-federal governmental health plans must comply with an applicable State external review process and when they must comply with the Federal external review process.

The PRA coverage and any burdens contained herein recognize requirements that the Department identified in the NAIC Uniform Health Carrier External Review Model Act that must be met or exceeded. The claims procedure regulation imposes information collection requirements as part of the reasonable procedures that an employee benefit plan must establish regarding the handling of a benefit claim. *Form Number:* CMS–10338 (OMB control number: 0938–1099); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits and not-for-profit institutions); *Number of Respondents:* 95,500; *Number of Responses:* 399,000,000; *Total Annual Hours:* 2,322,500. (For policy questions regarding this collection contact Leslie Wagstaffe at (301) 492–4251.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Minimum Essential Coverage; *Use:* The final rule titled ''Patient Protection and Affordable Care Act; Exchange Functions: Eligibility for Exemptions; Miscellaneous Minimum Essential Coverage Provisions,'' published July 1, 2013 (78 FR 39494) designates certain types of health coverage as minimum essential coverage. Other types of coverage, not statutorily designated and not designated as minimum essential coverage in regulation, may be recognized by the Secretary of Health and Human Services (HHS) as minimum essential coverage if certain substantive and procedural requirements are met. To be recognized as minimum essential coverage, the coverage must offer substantially the same consumer protections as those enumerated in the Title I of Affordable Care Act relating to non-grandfathered, individual health insurance coverage to ensure consumers are receiving adequate coverage. The final rule requires sponsors of other coverage that seek to have such coverage recognized as minimum essential coverage to adhere to certain procedures. Sponsoring organizations must submit to HHS certain information about their coverage and an attestation that the plan substantially complies with the provisions of Title I of the Affordable Care Act applicable to non-grandfathered individual health insurance coverage. Sponsors must also provide notice to enrollees informing them that the plan has been recognized as minimum essential coverage for the purposes of the individual coverage requirement. *Form Number:* CMS–10465 (OMB control number 0938–1189); *Frequency:* Occasionally; *Affected Public:* Public and Private Sector; *Number of Respondents:* 10; *Total Annual Responses:* 10; *Total Annual Hours:* 53. (For policy questions regarding this collection contact Russell Tipps at 301–492–4371.)

4. *Type of Information Collection Request:* Extension of a previously approved collection. *Title of Information Collection:* Transcatheter Valve Therapy Registry and KCCQ–10; *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:* 14,871; *Total Annual Responses:* 59,484; *Total Annual Hours:* 19,184. (For policy questions regarding this collection contact Sarah Fulton at 410–786–2749.)

5. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Rate Increase Disclosure and Review Reporting Requirements; *Use:* Section 1003 of the Affordable Care Act adds a new section 2794 of the PHS Act which directs the Secretary of the Department of Health and Human Services (the Secretary), in conjunction with the states, to establish a process for the annual review of ''unreasonable increases in premiums for health insurance coverage.'' The statute provides that health insurance issuers must submit to the Secretary and the applicable state justifications for unreasonable premium increases prior to the implementation of the increases. Section 2794 also specifies that beginning with plan years beginning in 2014, the Secretary, in conjunction with the states, shall monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange.

Section 2794 directs the Secretary to ensure the public disclosure of information and justification relating to unreasonable rate increases. Section 2794 requires that health insurance issuers submit justification for an unreasonable rate increase to CMS and the relevant state prior to its implementation. Additionally, section 2794 requires that rate increases effective in 2014 (submitted for review in 2013) be monitored by the Secretary, in conjunction with the states.

To those ends, section 154 of the CFR establishes various reporting requirements for health insurance issuers, including a Preliminary Justification for a proposed rate increase, a Final Justification for any rate increase determined by a state or CMS to be unreasonable, and a notification requirement for unreasonable rate increases which the issuer will not implement.

In order to obtain the information necessary to monitor premium increases of health insurance coverage offered through an Exchange and outside of an Exchange, 45 CFR 154.215 would require health insurance issuers to submit the Unified Rate Review Template for all single risk pool coverage products in the individual or small group (or merged) market, regardless of whether any plan within a product is subject to a rate increase. That regulation would also require health insurance issuers to submit an Actuarial Memorandum (in addition to the Unified Rate Review Template) when a plan within a product is subject to a rate increase. Although the two required documents are submitted at the risk pool level, the requirement to submit is based on increases at the plan level. To conduct a review to assess reasonableness when a plan within a product has a rate increase that is subject to review, health insurance issuers would be required to submit a written description justifying the increase (in addition to the Unified Rate Review Template and Actuarial Memorandum). Although the required documents are submitted at the risk pool level, the requirement to submit is based on increases at the plan level. *Form Number:* CMS–10379 (OMB control number: 0938–1141); *Frequency:* Yearly; *Affected Public:* Private sector (Business or other for-profits and Not-for-profit institutions) and State agencies; *Number of Respondents:* 1,081; *Total Annual Responses:* 1,621; *Total Annual Hours:* 17,837. (For policy questions regarding this collection contact Lisa Cuozzo at 410–786–1746.)

Dated: June 14, 2016.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Information Collection and Record Keeping for the Timely Placement and Release of Unaccompanied Children in ORR Care.

OMB No.:

Description: The ORR Unaccompanied Children Program provides placement, care, custody and mandated services for UC until such time as they can be successfully released to a sponsor, repatriated to their home country, or obtain legal status.

Through cooperative agreements and contracts, ORR funds residential care providers that provide temporary housing and other services to unaccompanied children in ORR custody. These care provider facilities are State licensed and must meet ORR requirements to ensure a high level quality of care. They provide a continuum of care for children, including placements in ORR foster care, group homes, shelter, staff secure, secure, and residential treatment centers. The care providers provide children with classroom education, health care, socialization/recreation, vocational training, mental health services, access to legal services, and case management.

In order to monitor performance and ensure compliance with statutory and regulatory requirements and standards, ORR:

- Collects information from its network of care providers to show evidence that care providers' standards of care, family reunification methods, internal policies and procedures, personnel, training, and other components meet minimum standards and ensure the safety and security of children in ORR care.
- Requires care providers to track the timely release process and delivery of services for individual children and youth to ensure compliance and allow ORR to conduct formal monitoring and performance review.

The tasks described in this supporting statement are mainly conducted through the ORR online database (The UC Portal), which provides a central location for case records and the documentation of other activities (for example, when a child or youth is transferred to another facility). Many of these records are ''auto-populated'' on the UC Portal once the original data points are completed (such as DOB, ''A'' number, date of initial placement). The UC Portal is a secure limited access database that requires two factor authentication. The use of electronic records also allows ORR Project Officers to more easily monitor grantee compliance with standards of care and record keeping compared with hard copy case files that are only available onsite. The database also allows ORR to more easily calculate bed capacity throughout the network so that resources are efficiently distributed, particularly during an influx when large numbers of unaccompanied children are crossing the border.

Respondents:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
UC Portal Capacity Report	50	1	.16/hour	8
Further Assessment Swift Track (FAST) Placement Tool	2,320	1	.25/hour	580
Placement Authorization Form	58,000	1	.1/hour	5,800
Notice of Placement in Secure or Staff Secure Facility	2,320	1	.1/hour	232
Initial Intakes Form	58,000	1	.25/hour	14,500
UC Assessment	58,000	1	.50/hour	29,000
Individual Service Plan	58,000	1	.25	14,500
UC Case Review Form	58,000	1	.50/hour	29,000