ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Parents/Guardians	Web Survey	900	1	10/60
Parents/Guardians	Follow-up web survey	900	1	1/60
Parents/Guardians	Focus Group Screener	60	1	5/60
Parents/Guardians	Focus Group Informed Consent	54	1	5/60
Parents/Guardians	Focus Group Moderator	54	1	1

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10268, CMS–10287, CMS–R–70, CMS–R–72, CMS–R–247, CMS–10151, CMS–10380, CMS–10286, and CMS–10339]

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 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 August 23, 2013.

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) 395–6974, 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:* Reinstatement of a currently approved collection; *Title of Information Collection:* Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-party Submission Authorization Form; *Use:* The Consolidated Renal Operations in a Web Enabled Network (CROWNWeb) Third-Party Submission Authorization form (CWTPSA) is to be completed by ''Facility Administrators'' (administrators of CMS-certified dialysis facilities) if they intend to authorize a third party (a business with which the facility is associated, or an independent vendor) to submit data to us to comply with the recently-revised Conditions for Coverage of dialysis facilities. The CROWNWeb system is the system used as the collection point of data necessary for entitlement of ESRD patients to Medicare benefits and for Federal Government monitoring and assessing of the quality and types of care provided to renal patients. The information collected through the CWTPSA form will allow us along with our contractors to receive data from authorized parties acting on behalf of CMS-certified dialysis facilities. Since February 2009, we have received 4,160 CWTPSA forms and anticipates that they will continue to receive no more than 400 new CWTPSA forms annually to address the creation of new facilities under the current participating ''third party submitters.'' *Form Number:* CMS–10268 (OCN: 0938–1052); *Frequency:* Occasionally; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 400; *Total Annual Responses:* 400; *Total Annual Hours:* 34. (For policy questions regarding this collection contact Michelle Tucker at 410–786–0736.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Quality of Care Complaint Form; *Use:* In

accordance with Section 1154(a)(14) of the Social Security Act, Quality Improvement Organizations (QIOs) are required to conduct appropriate reviews of all written complaints submitted by beneficiaries concerning the quality of care received. The Medicare Quality of Care Complaint Form will be used by Medicare beneficiaries to submit quality of care complaints. This form will establish a standard form for all beneficiaries to utilize and ensure pertinent information is obtained by QIOs to effectively process these complaints. *Form Number:* CMS–10287 (OCN: 0938–1102); *Frequency:* Reporting—Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 3,500; *Total Annual Responses:* 3,500; *Total Annual Hours:* 583. (For policy questions regarding this collection contact Coles Mercier at 410–786–2112.)

3. *Type of Information Collection Request:* Reinstatement with a change of a previously approved collection; *Title of Information Collection:* Information Collection Requirements in HSQ–110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations in 42 CFR, Sections 480.104, 480.105, 480.116, and 480.134; *Use:* The Peer Review Improvement Act of 1982 authorizes quality improvement organizations (QIOs), formally known as peer review organizations (PROs), to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. The QIOs are required to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties. The information provided in these notices is used by the patients, practitioners and providers to: obtain access to the data maintained and collected on them by the QIOs; add additional data or make changes to existing QIO data; and reflect in the QIO's record the reasons for the QIO's disagreeing with an individual's or provider's request for amendment.: *Form Number:* CMS–R–70 (OCN: 0938–0426); *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profits; *Number of Respondents:* 400; *Total Annual Responses:* 21,200; *Total Annual Hours:* 42,400. (For policy questions regarding this collection contact Coles Mercier at 410–786–2112.)

4. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Information Collection Requirements in 42 CFR 478.18, 478.34, 478.36, 478.42, QIO Reconsiderations and Appeals; *Use:* In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a Quality Improvement Organization (QIO) or a QIO subcontractor, it is within that party's rights to request reconsideration. The information collection requirements 42 CFR 478.18, 478.34, 478.36, and 478.42, contain procedures for QIOs to use in reconsideration of initial determinations. The information requirements contained in these regulations are on QIOs to provide information to parties requesting the reconsideration. These parties will use the information as guidelines for appeal rights in instances where issues are actively being disputed. *Form Number:* CMS–R–72 (OCN: 0938–0443); *Frequency:* Reporting—On occasion; *Affected Public:* Individuals or Households and Business or other for-profit institutions; *Number of Respondents:* 2,590; *Total Annual Responses:* 5,228; *Total Annual Hours:* 2,822. (For policy questions regarding this collection contact Coles Mercier at 410–786–2112.)

5. *Type of Information Collection Request:* Reinstatement with a change of a previously approved collection; *Title of Information Collection:* Expanded Coverage for Diabetes Outpatient Self-Management Training Services and Supporting Regulations Contained in 42 CFR 410.141, 410.142, 410.143, 410.144, 410.145, 410.146, 414.63; *Use:* According to the National Health and Nutrition Examination Survey (NHANES), as many as 18.7 percent of Americans over age 65 are at risk for developing diabetes. The goals in the management of diabetes are to achieve normal metabolic control and reduce the risk of micro- and macro-vascular complications. Numerous epidemiologic and interventional studies point to the necessity of maintaining good glycemic control to reduce the risk of the complications of diabetes. Despite this knowledge, diabetes remains the leading cause of blindness, lower extremity amputations and kidney disease requiring dialysis. Diabetes and its complications are primary or secondary factors in an estimated 9 percent of hospitalizations (Aubert, RE, et al., Diabetes-related hospitalizations and hospital utilization. In: Diabetes in America. 2nd ed. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Disease, NIH, Pub. No 95–1468–1995: 553–570). Overall, beneficiaries with diabetes are hospitalized 1.5 times more often than beneficiaries without diabetes. HCFA–3002–F provided for uniform coverage of diabetes outpatient self-management training services. These services include educational and training services furnished to a beneficiary with diabetes by an entity approved to furnish the services. The physician or qualified non-physician practitioner treating the beneficiary's diabetes would certify that these services are needed as part of a comprehensive plan of care. This rule established the quality standards that an entity would be required to meet in order to participate in furnishing diabetes outpatient self-management training services. It set forth payment amounts that have been established in consultation with appropriate diabetes organizations. It implements section 4105 of the Balanced Budget Act of 1997. *Form Number:* CMS–R–247 (OCN: 0938–0818); *Frequency:* Recordkeeping and Reporting—Occasionally; *Affected Public:* Business or other for-profit institutions; *Number of Respondents:* 5327; *Total Annual Responses:* 63,924; *Total Annual Hours:* 197,542. (For policy questions regarding this collection contact Kristin Shifflett at 410–786–4133.)

6. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Data Collection for Medicare Beneficiaries Receiving Implantable Cardioverter-Defibrillators for Primary Prevention of Sudden Cardiac Death; *Use:* We provide coverage for implantable cardioverter-defibrillators (ICDs) for secondary prevention of sudden cardiac death based on extensive evidence showing that use of ICDs among patients with a certain set of physiologic conditions are effective. Accordingly, we consider coverage for ICDs reasonable and necessary under Section 1862 (a) (1) (A) of the Social Security Act. However, evidence for use of ICDs for primary prevention of sudden cardiac death is less compelling for certain patients.

To encourage responsible and appropriate use of ICDs, we issued a ''Decision Memo for Implantable Defibrillators'' on January 27, 2005, indicating that ICDs will be covered for primary prevention of sudden cardiac death if the beneficiary is enrolled in either an FDA-approved category B IDE clinical trial (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1) or a qualifying prospective data collection system (either a practical clinical trial or prospective systematic data collection, which is sometimes referred to as a registry). *Form Number:* CMS–10151 (OMB#: 0938–0967); *Frequency:* Occasionally; *Affected Public:* Private

Sector; Business or other for-profits, Not-for-profit institutions; *Number of Respondents:* 1,702; *Total Annual Responses:* 82; *Total Annual Hours:* 139,356. (For policy questions regarding this collection contact JoAnna Baldwin at 410–786–7205.)

7. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Reporting Requirements for Grants to Support States in Health Insurance Rate Review and Pricing Transparency—Cycles I, II, and III; *Use:* Under the Section 1003 of the Affordable Care Act (ACA) (Section 2794 of the Public Health Service Act), the Secretary, in conjunction with the states and territories, is required to establish a process for the annual review, beginning with the 2010 plan year, of unreasonable increases in premiums for health insurance coverage. Section 2794(c) requires the Secretary to establish the Rate Review Grant Program to States to assist states to implement this provision. In addition, Section 2794(c) requires the Rate Review Grant Program to assist states in the establishment and enhancement of ''Data Centers'' that collect, analyze, and disseminate health care pricing data to the public.

The U.S. Department of Health and Human Services (HHS) released the Rate Review Grants Cycle I funding opportunity twice—first to states (and the District of Columbia) in June 2010 and then to the territories and the five states that did not apply during the first release, (*http://www.hhs.gov/ociio/initiative/final_premium_review_grant_solicitation.pdf*). The second release was due to the decision that the territories were subject to provisions of the ACA and hence eligible for the Rate Review Grants. Forty-five (45) states, 5 U.S. territories, and the District of Columbia were awarded grants. On February 24, 2011, HHS released the Funding Opportunity Award (FOA) for Cycle II Rate Review Grants. On December 21, 2012, Cycle II of the Rate Review Grant Program was amended in order to include an additional application date. Thirty (30) states, the District of Columbia, and three territories were awarded grants in Cycle II.

On May 8, 2013, CMS published the Cycle III Funding Opportunity Announcement, ''Grants to Support States in Health Insurance Rate Review and Pricing Transparency''. On July 12, 2013, the Funding Opportunity Announcement for Cycle III of the Rate Review Grants Program was amended in order to extend the deadline for submission of Letters of Intent. Concurrent with the publication of the Funding Opportunity Announcement for Cycle III, CMS published associated grantee reporting requirements consisting of: (4) quarterly reports, (5) rate review transaction data reports (quarterly and annual), (1) annual report, and (1) final report from all grantees. This information collection is required for effective monitoring of grantees and to fulfill statutory requirements under section 2794(b)(1)(A) of the ACA that requires grantees, as a condition of receiving a grant authorized under section 2794(c) of the ACA, to report to the Secretary information about premium increases. *Form Number:* CMS–10380 (OCN: 0938–1121); *Frequency:* Annually; On Occasion; *Affected Public:* Public Sector—State and Territory Governments; *Number of Respondents:* 56; *Total Annual Responses:* 1,001; *Total Annual Hours:* 31,378; (For policy questions regarding this collection contact Sarah Norman at 301–492–4185.)

8. *Type of Information Collection Request:* Reinstatement with change of a previously approved information collection; *Title of Information Collection:* Notice of Research Exception under the Genetic Information Nondiscrimination Act; *Use:* Under the Genetic Information Nondiscrimination Act of 2008 (GINA), a plan or issuer may request (but not require) a genetic test in connection with certain research activities so long as such activities comply with specific requirements, including: (i) The research complies with 45 CFR part 46 or equivalent Federal regulations and applicable State or local law or regulations for the protection of human subjects in research; (ii) the request for the participant or beneficiary (or in the case of a minor child, the legal guardian of such beneficiary) is made in writing and clearly indicates that compliance with the request is voluntary and that non-compliance will have no effect on eligibility for benefits or premium or contribution amounts; and (iii) no genetic information collected or acquired will be used for underwriting purposes. The Secretary of Labor or the Secretary of Health and Human Services is required to be notified if a group health plan or health insurance issuer intends to claim the research exception permitted under Title I of GINA. Nonfederal governmental group health plans and issuers solely in the individual health insurance market or Medigap market will be required to file with the Centers for Medicare & Medicaid Services (CMS). The Notice of Research Exception under the Genetic Information Nondiscrimination Act is a model notice that can be completed by group health plans and health insurance issuers and filed with either the Department of Labor or CMS to comply with the notification requirement. *Form Number:* CMS–10286 (OCN: 0938–1077); *Frequency:* On Occasion; *Affected Public:* State, Local, or Tribal Governments, Private Sector; *Number of Respondents:* 2; *Total Annual Responses:* 2; *Total Annual Hours:* 1; (For policy questions regarding this collection contact Usree Bandyopadhyay at 410–786–6650.)

9. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Pre-Existing Health Insurance Plan and Supporting Regulations; *Use:* On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111–148. Section 1101 of the law establishes a ''temporary high risk health insurance pool program'' (which has been named the Pre-Existing Condition Insurance Plan, or PCIP) to provide health insurance coverage to currently uninsured individuals with pre-existing conditions. The law authorizes HHS to carry out the program directly or through contracts with states or private, non-profit entities.

We are requesting an extension of this package because this information is needed to assure that PCIP programs are established timely and effectively. This request is being made based on regulations and guidance that have been issued and contracts which have been executed by HHS with states or an entity on their behalf participating in the PCIP program. PCIP is also referred to as the temporary qualified high risk insurance pool program, as it is called in the Affordable Care Act, but we have adopted the term PCIP to better describe the program and avoid confusion with the existing state high risk pool programs. *Form Number:* CMS–10339 (OMB#: 0938–1100); *Frequency:* Reporting—On occasion; *Affected Public:* state governments; *Number of Respondents:* 51; *Total Annual Responses:* 2,652; *Total Annual Hours:* 36,924. (For policy questions regarding this collection contact William Brice at 410–786–1777.)

Dated: July 19, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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