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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Medicare & Medicaid Services**

**[Document Identifiers: CMS-R-70, CMS-R-72, CMS-R-247, CMS-10062, CMS-10268, CMS-10615 and CMS-10623]**

### **Agency Information Collection Activities: Submission for OMB Review; 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 (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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**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

E-mail: [OIRA\\_submission@omb.eop.gov](mailto: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. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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: Extension of a currently approved collection; Title of Information Collection: Information Collection Requirements in HSQ-110, Acquisition, Protection and Disclosure of Peer review Organization Information and Supporting Regulations; 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 (OMB control number: 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 Winsome Higgins at 410-786-1835.)

2. Type of Information Collection Request: Extension of a currently 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 (OMB control number: 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 Winsome Higgins at 410-786-1835.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Expanded Coverage for Diabetes Outpatient Self-Management Training Services and Supporting Regulations; 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 (OMB control number: 0938-0818); Frequency: Recordkeeping and Reporting – Occasionally; Affected Public: Business or other for-profit institutions; Number of Respondents: 5,327; Total Annual Responses: 63,924; Total Annual Hours: 197,542. (For policy questions regarding this collection contact Kristin Shifflett at 410-786-4133.)

4. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments; Use: CMS requires hospital inpatient, hospital outpatient and physician diagnostic data from Medicare Advantage (MA) organizations to continue making payment under the risk adjustment methodology. CMS will use the data to make risk adjusted payment under Parts C and D. MA and MA-PD plans will use the data to develop their Part C and D bids. As required by law, CMS also annually publishes the risk adjustment factors for plans and other interested entities in the Advance Notice of Methodological Changes for MA Payment Rates (every February) and the Announcement of Medicare Advantage Payment Rates (every April). Lastly, CMS issues monthly reports to each individual plan that contains the CMS Hierarchical Condition Category (HCC) and RxHCC models' output and the risk scores and reimbursements for each beneficiary that is enrolled in their plan. Form Number: CMS-10062 (OMB control number: 0938-0878); Frequency: Quarterly; Affected Public: Private sector (Business or other for profit and Not-for-profit institutions); Number of Respondents: 691; Total Annual Responses: 83,000,000; Total Annual Hours: 40,650. (For policy questions regarding this collection contact Michael P. Massimini at 410-786-1566.)

5. Type of Information Collection Request: Extension 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 (OMB control number: 0938-1052); Frequency: Occasionally; Affected Public: 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 Victoria Schlining at 410-786-6878.)

6. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Healthy Indiana Program (HIP) 2.0 Beneficiaries Survey, Focus Groups, and Informational Interviews; Use: The collected information will be used to make decisions about the renewal of precedent-setting waivers of Medicaid policy that assure important beneficiary protections regarding coverage and access to care; e.g., the State of Indiana’s non-emergency medical transportation waiver which will end or will be extended by no later than December 1, 2016. To support CMS decision making, the collection’s survey effort would provide more detailed information on the Healthy Indiana Program (HIP) 2.0

demonstration's beneficiary understanding and experiences (current and new enrollees as well as disenrollees/lockouts). Additional information on other key policies under the demonstration, such as the 60-day beneficiary lock-out period, is also included in this information collection request.

This request does not propose any new or revised information collection requirements or burden estimates outside of what is currently approved by OMB. Rather, it seeks to extend the collection's current expiration date of September 30, 2016 (approved under the emergency PRA process on March 21, 2016; see 81 FR 17460 dated March 29, 2016, and 81 FR 26798 dated May 4, 2016). Since the collection has already been subject to the public comment process for collection activities taking place through September 30, 2016, this "Extension of a currently approved collection" will only consider comments for activities taking place from October 1, 2016, through the end of the revised expiration date. The revised expiration date will be made available upon OMB approval at [reginfo.gov](http://reginfo.gov). Form Number: CMS-10615 (OMB control number: 0938-1300); Frequency: Once; Affected Public: Individuals and households, Private sector (Business or other for-profits and Not-for-profits institutions), and State, Local, or Tribal Governments; Number of Respondents: 5,240; Total Annual Responses: 5,240; Total Annual Hours: 1,442. (For policy questions regarding this collection contact Teresa DeCaro at 202-384-6309.)

7. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: Testing Experience and Functional Tools Demonstration: Personal Health Record (PHR) User Survey; Use: The PHR user survey is

important to the TEFT Program Evaluation and understanding the impact of the TEFT PHR on Medicaid CB-LTSS beneficiaries. The TEFT evaluation team's approach includes monitoring state PHR implementation efforts and fielding a follow-up questionnaire to CB-LTSS program participants that asks about their experiences using the PHR. The evaluation seeks to measure the degree to which the PHR is implemented in an accessible manner for Medicaid beneficiaries of CB-LTSS. The survey also is designed to assess the user experience of the PHR, including access and usability, as well as some measures of user satisfaction and perceived impacts of PHR use.

The information collection request has been revised subsequent to the publication of the 60-day **Federal Register** notice on June 13, 2016 (81 FR 38187). Details can be found in the package's Supporting Statement. While the June 13 Supporting Statement had set out the correct number of burden hours, the 60-day **Federal Register** notice had inadvertently set out 192,113 hours. This should have been 206 hours. Form Number: CMS-10623 (OMB control number: 0938-New); Frequency: Once; Affected Public: Individuals and households; Number of Respondents: 576; Total Annual Responses: 576; Total Annual Hours: 190. (For policy questions regarding this collection contact Kerry Lida at 410-786-4826.)

Dated: September 21, 2016.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff,*

*Office of Strategic Operations and Regulatory Affairs.*

**BILLING CODE 4120-01-U-P**

