

Office, Economic Recovery, Fatherhood and Healthy Families, Inter-religious Dialogue and Cooperation, Environment and Climate Change and Global Poverty and Development.

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Special Assistant.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10237, CMS-10137, CMS-10285, CMS-R-38, CMS-R-70, CMS-10287, CMS-10080 and CMS-846-849, 854, 10125, 10126, and 10269]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage Applications—Part C; *Use:* Under section 1851(a)(1) of the Social Security Act, every individual entitled to Medicare Part A and enrolled under Part B, except for most individuals with end-stage renal disease (ESRD), could elect to receive benefits either through the Original Medicare Program or an M+C plan, if one was offered where he or she lived. The Medicare Prescription Drug, Improvement, and Modernization

Act of 2003 (MMA) Pub. L. 108-173 was enacted on December 8, 2003. The MMA established the Medicare Prescription Drug Benefit Program (Part D) and made revisions to the provisions of Medicare Part C, governing what is now called the Medicare Advantage (MA) program (formerly Medicare+Choice).

Coverage for the prescription drug benefit is provided through contracted prescription drug plans or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost plans that are required under section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the MA and MA-PD plans must complete an application, negotiate rates and receive final approval from CMS. Certain existing MA plans may also expand their contracted area by completing the Service Area Expansion (SAE) application. Health plans must meet regulatory requirements to enter into a contract with CMS in order to provide health benefits to Medicare beneficiaries. The revised MA applications are the collection receptacles required. Refer to the supporting document “High-Level Summary of All Part C Application Revisions from 2010 Version of Part C Application to 2011 Version” for a list of changes: *Form Number:* CMS-10237 (OMB#: 0938-0935); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 291; *Total Annual Responses:* 291; *Total Annual Hours:* 9,547. (For policy questions regarding this collection contact Letticia Ramsey at 410-786-5262. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Application for Prescription Drug Plans (PDP); Application for Medicare Advantage Prescription Drug (MA-PD); Application for Cost Plans to Offer Qualified Prescription Drug Coverage; Application for Employer Group Waiver Plans to Offer Prescription Drug Coverage; Service Area Expansion Application for Prescription Drug Coverage; *Use:* The Medicare Prescription Drug Benefit program was established by section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and is codified in section 1860D of the Social Security Act (the

Act). Section 101 of the MMA amended Title XVIII of the Social Security Act by redesignating Part D as Part E and inserting a new Part D, which establishes the voluntary Prescription Drug Benefit Program (“Part D”). The MMA was amended on July 15, 2008 by the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates and receive final approval from CMS. Existing Part D sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application. Refer to supporting document “Summary of Substantive and Technical Changes for All Part D Application Revisions from 2010 Version of Part D application to 2011 Draft Version”: *Form Number:* CMS-10137 (OMB#: 0938-0936); *Frequency:* Reporting—Once; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 453; *Total Annual Responses:* 453; *Total Annual Hours:* 11,919. (For policy questions regarding this collection contact Marla Rothhouse at 410-786-8063. For all other issues call 410-786-1326.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Request for Expedited Review of Denial of Premium Assistance; *Use:* The American Recovery and Reinvestment Act of 2009 provides for premium assistance and expanded eligibility for health benefits under both the Consolidated Omnibus Budget Reconciliation Act of 1986, commonly called COBRA, and comparable State continuation coverage programs. This premium assistance is not paid directly to the covered employee or the qualified beneficiary, but instead is in the form of a tax credit for the health plan, the employer, or the insurer. “Assistance eligible individuals” pay only 35% of their continuation coverage premiums to the plan and the remaining 65% is paid through the tax credit.

If an individual requests treatment as an assistance eligible individual and the

employee's group health plan, employer, or insurer denies him or her the reduced premium assistance, the Secretary of Health and Human Services must provide for expedited review of the denial upon application to the Secretary in the form and manner the Secretary provides. The Secretary is required to make a determination within 15 business days after receipt of an individual's application for review.

The *Request for Review If You Have Been Denied Premium Assistance* (the "application") is the form that will be used by individuals to file their expedited review appeals. Each individual must complete all information requested on the application in order for CMS to begin reviewing his or her case. An application cannot be reviewed if sufficient information is not provided. Refer to the supporting document "Crosswalk of Changes Between Request for Expedited Review of Denial of Premium Assistance (4/09) and Request for Review if You Have Been Denied Premium Assistance (6/09)" for a list of changes: *Form Number*: CMS-10285 (OMB#: 0938-1062); *Frequency*: Reporting—Once; *Affected Public*: Individuals and households; *Number of Respondents*: 12,000; *Total Annual Responses*: 12,000; *Total Annual Hours*: 12,000. (For policy questions regarding this collection contact Jim Mayhew at 410-786-9244. For all other issues call 410-786-1326.)

4. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Conditions of Certification for Rural Health Clinics and Supporting Regulations in 42 CFR 491.9, 491.10, 491.11; *Use*: The Rural Health Clinic (RHC) conditions of certification are based on criteria prescribed in law and are designed to ensure that each facility has a properly trained staff to provide appropriate care and to assure a safe physical environment for patients. The Centers for Medicare and Medicaid Services (CMS) uses these conditions of participation to certify RHCs wishing to participate in the Medicare program. These requirements are similar in intent to standards developed by industry organizations such as the Joint Commission on Accreditation of Hospitals, and the National League of Nursing/American Public Association and merely reflect accepted standards of management and care to which rural health clinics must adhere. *Form Number*: CMS-R-38 (OMB#: 0938-0334); *Frequency*: Recordkeeping and Reporting—Annually and upon initial application for Medicare approval;

Affected Public: Business or other for-profits; *Number of Respondents*: 3,937; *Total Annual Responses*: 3,937; *Total Annual Hours*: 18,932. (For policy questions regarding this collection contact Mary Collins at 410-786-3189. For all other issues call 410-786-1326.)

5. *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 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 (OMB#: 0938-0426); *Frequency*: Reporting—On occasion; *Affected Public*: Business or other for-profits; *Number of Respondents*: 362; *Total Annual Responses*: 3729; *Total Annual Hours*: 60,919. (For policy questions regarding this collection contact Tom Kessler at 410-786-1991. For all other issues call 410-786-1326.)

6. *Type of Information Collection Request*: New 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 (OMB#: 0938-New); *Frequency*: Reporting—On occasion; *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 Tom Kessler at 410-786-1991. For all other issues call 410-786-1326.)

7. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Publication Usage Survey; *Use*: The Publication Usage survey was developed to gather information from people who request or access Medicare publications, to ensure comprehension, usability, and use of the publications. CMS is seeking understanding about whether publications have been effective in informing members of the Medicare audience regarding policy and benefits. Included in the survey are questions regarding the satisfaction of publication users with specific publications and whether the information they received informed them about the Medicare program. Information gathered in this survey will be used only for purposes of targeting and improving communications with Medicare beneficiaries, caregivers, partners, and community organizations. *Form Number*: CMS-10080 (OMB#: 0938-0892); *Frequency*: Reporting—On occasion; *Affected Public*: Individuals or Households; *Number of Respondents*: 3,800; *Total Annual Responses*: 3,800; *Total Annual Hours*: 950. (For policy questions regarding this collection contact Renee Clarke at 410-786-0006. For all other issues call 410-786-1326.)

8. *Type of Information Collection Request*: Revision of a currently approved collection; *Title of Information Collection*: Durable Medical Equipment Medicare Administrative Contractors (MAC), Certificates of Medical Necessity; *Use*: The certificate of medical necessity (CMN) collects information required to help determine the medical necessity of certain items. CMS requires CMNs where there may be a vulnerability to the Medicare program. Each initial claim for these items must have an associated CMN for the beneficiary. Suppliers (those who bill for the items) complete the administrative information (e.g., patient's name and address, items ordered, etc.) on each CMN. The 1994 Amendments to the Social Security Act require that the supplier also provide a narrative description of the items ordered and all related accessories, their charge for each of these items, and the Medicare fee schedule allowance (where applicable). The supplier then sends the CMN to the treating physician or other clinicians (e.g., physician assistant,

LPN, etc.) who completes questions pertaining to the beneficiary's medical condition and signs the CMN. The physician or other clinician returns the CMN to the supplier who has the option to maintain a copy and then submits the CMN (paper or electronic) to CMS, along with a claim for reimbursement.

Due to a technical oversight on the part of CMS, an important question on CMN Form 10269 was omitted from the last OMB submission that would allow claims with an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) greater than or equal to 5 without symptoms for Criterion 2 be paid for by the Medicare program. The omission of the following question "Does the patient have documented evidence of at least one of the following: Excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, hypertension, ischemic heart disease or history of stroke" could cause improper payment of claims without regards as to whether the patient has signs or symptoms in support of meeting the applicable coverage criteria for PAP devices. We are resubmitting this information collection request to have the revised CMN Form 10269 approved. None of the other CMN forms have changed.

Form Number: CMS-846-849, 854, 10125, 10126, 10269 (OMB# 0938-0679); *Frequency:* Occasionally; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 59,200; *Total Annual Responses:* 6,480,000; *Total Annual Hours:* 1,296,000. (For policy questions regarding this collection contact Doris Jackson at (410) 786-4459. For all other issues call (410) 786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by August 25, 2009:

1. *Electronically.* You may submit 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) 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.

Dated: June 18, 2009.

Michelle Shortt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS-R-205 and CMS-R-206]

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

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this 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 function; (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.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements Referenced in HIPAA title I for the Individual Market, Supporting Regulations at 45 CFR 148 (148.120, 148.122, 148.124, 148.126, and 148.128), Forms and Instructions; *Use:* The provisions of title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) amend the Public Health Service Act

(PHS Act) and are designed to make it easier for people to get access to health care coverage; to reduce the limitations that can be put on the coverage; and to make it more difficult for issuers to terminate the coverage. The information collection requirements will ensure that issuers in the individual market comply with HIPAA title I, provide individuals with certificates of creditable coverage necessary to demonstrate prior creditable coverage and file documentation with CMS for review in a Federal direct enforcement state. Requirements must also ensure states' flexibility to implement state alternative mechanisms. *Form Number:* CMS-R-205 (OMB#: 0938-0703); *Frequency:* Reporting—Yearly and Occasionally; *Affected Public:* Business or other For-profit and Not-for-profit institutions; *Number of Respondents:* 2,042; *Total Annual Responses:* 2,979,801; *Total Annual Hours:* 856,384. (For policy questions regarding this collection contact Louis Blank at 410-786-5511. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements in HIPAA title I for the Group Market, Supporting Regulations 45 CFR 146 (146.111, 146.115, 146.117, 146.150, 146.152, 146.160 and 146.180) Forms and Instructions; *Use:* The provisions of title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are designed to make it easier for people to get access to health care coverage and to reduce the limitations that can be put on the coverage. This collection pertains to notices issued by group health insurance issuers and self-funded non-Federal governmental plans as required by 45 CFR 146. These notices are triggered by the issuance of certificates of creditable coverage; notification of preexisting condition exclusions; notification of special enrollment rights; and State review of issuers' filings of group market products or similar Federal review in cases in which a State is not enforcing a HIPAA group market provision. *Form Number:* CMS-R-206 (OMB#: 0938-0702); *Frequency:* Reporting—Yearly; *Affected Public:* Private Sector; Business or other For-profit and Not-for-profit institutions, and State, Local, or Tribal Governments; *Number of Respondents:* 8,050; *Total Annual Responses:* 37,002,217; *Total Annual Hours:* 2,920,012. (For policy questions regarding this collection contact Louis Blank at 410-786-5511. For all other issues call 410-786-1326.)

To be assured consideration, comments and recommendations for the