

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier CMS–10147, CMS–10396 and CMS–R–246]

#### 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:* Standardized Pharmacy Notice: Your Prescription Cannot be Filled (f/k/a Medicare Prescription Drug Coverage and Your Rights) *Use:* This is a request for approval of changes to a currently approved collection under 42 CFR 423.562(a)(3). This regulatory provision has recently been modified to eliminate the previously available option of posting the standardized notice at the pharmacy. Revised 423.562(a)(3) and an associated regulatory provision at § 423.128(b)(7)(iii) require the pharmacy to provide the Part D enrollee with a printed copy of this standardized notice if the prescription cannot be filled.

The purpose of this notice is to provide enrollees with information about how to contact their Part D plans to request a coverage determination, including a request for an exception to the Part D plan's formulary. The notice reminds enrollees about certain rights and protections related to their Medicare prescription drug benefits, including the right to receive a written explanation from the drug plan about why a prescription drug is not covered.

A Part D plan sponsor's network pharmacies are in the best position to notify enrollees about how to contact their Part D plan if the prescription cannot be filled.

As noted in a final rule published April 15, 2011 (76 FR 21432), the option of posting this notice at the pharmacy has been eliminated. If a prescription cannot be filled, the pharmacy must provide the enrollee with a printed copy of this notice. *Form Number:* CMS–10147 (OCN: 0938–0975) *Frequency:* Yearly; *Affected Public:* Private Sector—Business or other For-profits; *Number of Respondents:* 42,000; *Number of Responses:* 37,087,402; *Total Annual Hours:* 617,876. (For policy questions regarding this collection, contact Kathryn McCann Smith at 410–786–7623. For all other issues call (410) 786–1326.)

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Medication Therapy Management Program Improvements—Standardized Format. *Use:* The Medicare Modernization Act of 2003 (MMA) under title 42 CFR part 423, subpart D, established the requirements that Part D sponsors must meet with regard to medication therapy management (MTM) programs. Beginning in 2010, sponsors must offer an interactive, person-to-person comprehensive medication review (CMR) by a pharmacist or other qualified provider at least annually. A CMR is a review of a beneficiary's medications, including prescription and over-the-counter (OTC) medications, herbal therapies, and dietary supplements, which is intended to aid in assessing medication therapy and optimizing patient outcomes. Sponsors must summarize the CMR and provide an individualized written or printed summary to the beneficiary. The burden associated with the time and effort necessary for Part D sponsors to conduct CMRs with written summaries was estimated previously under OMB Control Number 0938–0964 as 937,500 hours with total labor cost of \$112.5 million.

The Affordable Care Act (ACA) under Section 10328 specifies that the Secretary, in consultation with relevant stakeholders, develop a standardized format for the action plan and written or printed summary that are given to beneficiaries as a result of their CMRs. The standardized format will replace whatever formats Part D sponsors are using for their written CMR summaries and action plans prior to 2013. Beginning in January, 2013, Part D sponsors will collect information required by the new standardized

format, and provide that information to Medicare beneficiaries after their CMRs on forms that comply with the requirements specified by CMS for the standardized format. The use of the standardized format will increase the burden associated with providing the CMRs with written summaries and action plans as described in this submission. The use of the standardized format will support a uniform and consistent level of MTMP communications with beneficiaries, improve the ability of beneficiaries to understand and manage their medications safely and effectively, and support improved healthcare outcomes and lower overall healthcare costs. The final standardized format will be posted in the 2013 Call Letter for implementation by Part D sponsors in January 2013. *Form Number:* CMS–10396 (OCN: 0938–New) *Frequency:* Yearly; *Affected Public:* Private sector—business or other for-profits; *Number of Respondents:* 673; *Number of Responses:* 1,875,000; *Total Annual Hours:* 1,179,894. (For policy questions regarding this collection, contact Gary Wirth at 410–786–3997. For all other issues call (410) 786–1326.)

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage, Medicare Part D and Medicare Fee For Service Consumer Assessment of Healthcare Providers and Systems Survey. *Use:* CMS has fielded the MA Consumer Assessment of Health Care Providers and Systems (CAHPS) Survey annually since 1998, the Medicare FFS CAHPS Survey annually since 2000, and the MA DP and Stand Alone PDP CAHPS survey annually since 2006. The Medicare CAHPS is a national survey of health and prescription drug plans conducted at the contract level for MA, MA PD and Stand Alone PDP plans and at the state level for Medicare fee-for-service. Medicare CAHPS provides data to permit preparation of plan performance measures to assist Medicare beneficiaries in their selection of a health plan, prescription drug plan or both, and help policymakers and others assist the Medicare program and Medicare plans design and monitor patient-centered quality improvement initiatives. The 2009 Call letter for MA and MA PD plans requires these plans to contract with private vendors from a list selected by CMS to conduct the 2011 Medicare CAHPS survey for their plan at the contract level and provide the collected data to CMS for analyses and preparation of CAHPS measures for

use in consumer and plan reports and for quality improvement purposes for MA, MA PD, and Stand Alone PDP plans. CMS will continue to collect the Medicare FFS CAHPS data from surveys at the state and some sub-state levels. This revision to a currently approved collection is to add questions focusing on care coordination. *Form Number:* CMS-R-246 (OCN: 0938-0732) *Frequency:* Yearly; *Affected Public:* Private sector—business or other for-profits; *Number of Respondents:* 598,200; *Number of Responses:* 598,200; *Total Annual Hours:* 216,555. (For policy questions regarding this collection, contact Sarah Gaillot at 410-786-4637. 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.gov/PaperworkReductionActof1995/PRAL/list.asp#TopOfPage> or 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), or call the Reports Clearance Office at 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 1, 2011*:

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: May 25, 2011.

**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-10136 and CMS-10303]

#### 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:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Demonstration Ambulatory Care Quality Measure Performance Assessment Tool ("PAT"); *Use:* This request is to cover a modification of an existing, approved data collection effort with a new secure web based system. This system will also provide a platform for developing tools to collect clinical quality data for future demonstrations and programs. There is no increase in burden. In fact, because all of the practices submitting data will have Electronic Health Records (EHRs), it is likely that the originally estimated burden will decrease over the coming years of the demonstration. CMS is requesting an extension of the currently approved tool for the collection of ambulatory care clinical performance measure data.

The data will be used to continue implementation of two Congressionally mandated demonstration projects (the Physician Group Practice (PGP) Demonstration and the Medicare Care Management Performance (MCMP) Demonstration); also the support data collection under the new EHR

Demonstration. Each of these demonstrations, test new payment methods for improving the quality and efficiency of health care services delivered to Medicare fee-for-service beneficiaries, especially those with chronic conditions that account for a disproportionate share of Medicare expenditures. In addition, the MCMP and EHR demonstration specifically encourage the adoption of electronic health records systems as a vehicle for improving how health care is delivered. *Form Number:* CMS-10136 (OMB# 0938-0941); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and not-for-profit institutions; *Number of Respondents:* 400; *Total Annual Responses:* 400; *Total Annual Hours:* 9600. (For policy questions regarding this collection contact Jodie Blatt at 410-786-6921. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Revision of currently approved collection; *Title of Information:* Medicare Gainsharing Demonstration Evaluation: Physician Focus Groups; *Use:* The proposed physician focus groups are part of the evaluation of the Centers for Medicare and Medicaid Services (CMS)'s Medicare Physician Hospital Collaboration Demonstration. The Congress, under Section 646 of the Medicare Modernization Act (MMA) of 2003 permitted CMS to conduct demonstrations to test methods for the provision of incentives for improving the quality and safety of care and achieving the efficient allocation of resources. The primary goal of the demonstration is to evaluate gainsharing as means to align physician and hospital incentives to improve quality and efficiency. This demonstration plans to use the physician focus group protocols approved by OMB for the DRA 5007 Gainsharing Demonstration. *Form Number:* CMS-10303 (OMB#: 0938-1103); *Frequency:* Once; *Affected Public:* Private sector, business or other for profits; *Number of Respondents:* 288; *Total Annual Responses:* 144; *Total Annual Hours:* 144 (For policy questions regarding this collection contact William Buczko at 410-786-6593. For all other issues call 410-786-1326.)

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on *June 30, 2011*. OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395-6974, *E-mail:* [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).