

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10060, CMS-37, and CMS-10117, 10118, 10119, 10135, 10136]

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:* Quality Assessment and Performance Improvement (QAPI) Project Completion Report and Supporting Regulations in 42 CFR 422.152; *Use:* This project completion report derives from the Quality Improvement System for Managed Care (QISMC) Standards and Guidelines as required by the Balanced Budget Act of 1997 (as amended by Balanced Budget Refinement Act of 1999) and the related regulations, 42 CFR 422.152. These regulations established QISMC as a requirement for Medicare Advantage Organizations (MAOs) by requiring improved health outcomes for enrolled beneficiaries. The provisions of QISMC specify that MAOs will implement and evaluate quality improvement projects. The form submitted herein will permit MAOs to report their completed projects to CMS in a standardized fashion for evaluation by CMS of the MAO's compliance with regulatory provisions. This form will improve consistency and reliability in the CMS evaluation

process, as well as provide a standardized structure for public use and review; *Form Number:* CMS-10060 (OMB No.: 0938-0873); *Frequency:* Annually; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 155; *Total Annual Responses:* 155; *Total Annual Hours:* 620.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Program Budget Report; *Form Nos.:* CMS-37 (OMB No. 0938-0101); *Use:* The Medicaid Program Budget Report is prepared by the State Medicaid Agencies and is used by the Centers for Medicare & Medicaid Services (CMS) for (1) developing National Medicaid Budget estimates, (2) qualification of Budget Estimate Changes, and (3) the issuance of quarterly Medicaid Grant Awards. The structure of the currently approved CMS-37 was revised based on CMS experience with budget information provided by the States. (Note: Details are outlined in the Addendum which can be found on the CMS Web site address below.)

Frequency: Quarterly; *Affected Public:* State, local or tribal government; *Number of Respondents:* 56; *Total Annual Responses:* 224; *Total Annual Hours:* 7,616.

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicare Advantage Application for Coordinated Care, Private Fee-for-Service, Regional Preferred Provider Organization, Service Area Expansion for Coordinated Care and Private Fee-for-Service Plans, Medical Savings Account Plans; *Form Nos.:* CMS-10117, 10118, 10119, 10135, 10136 (OMB No. 0938-0935); *Use:* Health plans must meet certain regulatory requirements to enter into a contract with CMS to provide health benefits to Medicare beneficiaries. These applications are the collection forms to obtain the information from a health plan that will allow CMS staff to determine compliance with the regulations; *Frequency:* Other—one-time submission; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; *Number of Respondents:* 370; *Total Annual Responses:* 520; *Total Annual Hours:* 20,100.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at <http://www.cms.hhs.gov/regulations/pa/>, 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.

Written comments and recommendations for the proposed information collections will be considered if they are mailed within 30 days of this notice directly to the OMB desk officer:

OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 15, 2005.

Michelle Shortt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS-10167]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

AGENCY: Center for Medicare and Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and 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 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have

submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR 1320.13(a)(2)(iii). This is necessary to ensure compliance with an initiative of the Administration. The use of normal clearance procedures is reasonably likely to cause a statutory deadline to be missed.

The Competitive Acquisition Program (CAP) is required by Section 303(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and amends Title XVIII of the Social Security Act (the Act) by adding a new section 1847(B), which establishes a competitive acquisition program for the payment for Part B covered drugs and biologicals furnished on or after January 1, 2006. Physicians will be given a choice between buying and billing these drugs under the average sales price (ASP) system, or obtaining these drugs from vendors selected in a competitive bidding process.

A physician is provided an election process for the selection of an approved CAP vendor on an annual basis. The CAP election agreement will initiate physician participation and designation of their approved CAP vendor and agreement to abide by the CAP program requirements. The Physician Election Agreement will be used annually by physicians to elect to participate in the CAP or to make changes to the previous year's selections.

CMS is requesting OMB review and approval of this collection by August 12, 2005, with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by August 8, 2005.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site address at <http://www.cms.hhs.gov/regulations/pra> 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.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be

mailed and/or faxed to the designees referenced below by August 8, 2005:

Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C5-13-27, 7500 Security Boulevard, Baltimore, MD 21244-1850, Fax Number: (410) 786-0262, Attn: William N. Parham, III, CMS-10167 and
OMB Human Resources and Housing Branch, Attention: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: July 15, 2005.

Michelle Shortt,

Acting 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

[CMS-3158-N]

Medicare Program; Request for Nominations for Members for the Medicare Coverage Advisory Committee

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice requests nominations for consideration for membership on the Medicare Coverage Advisory Committee (MCAC).

DATES: Nominations will be considered if received at the designated address, as provided in the **ADDRESSES** section of this notice, no later than 5 p.m. on August 25, 2005.

ADDRESSES: Mail nominations for membership to the following address: Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Attention: Kimberly Long, 7500 Security Blvd., Mail Stop: Central Building 1-09-06, Baltimore, MD 21244.

A copy of the Secretary's Charter for the Medicare Coverage Advisory Committee can be obtained from Maria Ellis, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, 7500 Security Blvd., Mail Stop: Central Building 1-09-06, Baltimore, MD 21244, or by e-mail to Maria.Ellis@cms.hhs.gov. The Charter is also posted on the Web at <http://www.cms.hhs.gov/mcac/8b1-1.asp>.

FOR FURTHER INFORMATION CONTACT:

Kimberly Long, 410-786-5702.

SUPPLEMENTARY INFORMATION:

I. Background

On December 14, 1998, we published a notice in the **Federal Register** (63 FR 68780) announcing establishment of the Medicare Coverage Advisory Committee (MCAC). The Secretary signed the initial Medicare Coverage Advisory Committee Charter on November 24, 1998. The charter was renewed by the Secretary and will terminate on November 24, 2006, unless renewed again by the Secretary.

The Medicare Coverage Advisory Committee is governed by provisions of the Federal Advisory Committee Act (Pub. L. 92-463), as amended (5 U.S.C. App. 2), which sets forth standards for the formulation and use of advisory committees, and is authorized by section 222 of the Public Health Service Act, as amended (42 U.S.C. 217A).

The MCAC consists of a pool of 100 appointed members. Members are selected from among authorities in clinical medicine of all specialties, administrative medicine, public health, biologic and physical sciences, health care data and information management and analysis, patient advocacy, the economics of health care, medical ethics, and other related professions (for example, epidemiology and biostatistics), and methodology of trial design. A maximum of 88 members are standard voting members, and 12 are nonvoting members (6 of whom are representatives of consumer interests, and 6 of whom are representatives of industry interests).

The MCAC functions on a committee basis. The committee reviews and evaluates medical literature, reviews technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered or are eligible for coverage under Medicare. The Committee works from an agenda provided by the Designated Federal Official that lists specific issues and develops technical advice to assist us in determining reasonable and necessary applications of medical services and technology when making national coverage decisions for Medicare.

As of November 2005, there will be 15 terms of membership expiring, one of which is a non-voting industry representative. Accordingly, we are requesting nominations for both voting and nonvoting members to serve on the MCAC. Nominees are selected based upon their individual qualifications, and not as representatives of