Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: November 15, 2011.

Martique Jones,

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

[FR Doc. 2011–29840 Filed 11–17–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10373]

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

AGENCY: Centers for Medicare & 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 & 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:* Medical Loss Ratio (MLR) Quarterly Reporting for Mini-Med Plans and Expatriate Plans; *Use:* Under Section 2718 of the Affordable Care Act and implementing regulations at 45 CFR part 158 (75 FR 74865, December 1, 2010) as modified by technical corrections on December 30, 2010 (75 FR 82277), a health insurance issuer (issuer) offering group or individual health insurance coverage must submit a report to the Secretary concerning the amount the issuer spends each year on claims, quality improvement expenses, non-claims costs, Federal and State taxes and licensing or regulatory fees, and the amount of earned premium. An issuer must provide an annual rebate to enrollees if the amount it spends on certain costs compared to its premium revenue (excluding Federal and States taxes and licensing or regulatory fees) does not meet a certain ratio, referred to as the medical loss ratio (MLR). An interim final rule (IFR) implementing the MLR was published on December 1, 2010 (75 FR 74865) and modified by technical corrections on December 30, 2010 (75 FR 82277), which added part 158 to Title 45 of the Code of Federal Regulations. The IFR is effective January 1, 2011. Issuers are required to submit annual MLR reporting data for each large group market, small group market, and individual market within each State in which the issuer conducts business. For policies that have a total annual limit of $250,000 or less (sometimes referred to as ''mini-med plans'') and for group policies that primarily cover employees working outside the United States (referred to as ''expatriate plans''), the IFR applies a special circumstance adjustment to the MLR data for the 2011 MLR reporting year. In order to evaluate the appropriateness of this special circumstance adjustment for years 2012 and beyond, issuers that provide such policies are required to submit quarterly MLR data to the Secretary for the 2011 MLR reporting year. We received two comment letters in response to the 60-day comment period that was associated with CMS–10373. We have taken into consideration all of the proposed suggestions, and as result, have not made any changes to the quarterly reporting form or to the estimated burden that correlates with the form. *Form Number:* CMS–10373 (OCN: 0938–1132); *Frequency:* Quarterly; *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 75; *Total Annual Responses:* 825; *Total Annual Hours:* 3,700. (For policy questions regarding this collection contact Carol Jimenez at (301) 492–4109. 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 address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*, or Email 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.

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 *December 19, 2011.*

OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *Email: OIRA_submission@omb.eop.gov*.

Dated: November 15, 2011.

Martique Jones,

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

[FR Doc. 2011–29838 Filed 11–17–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3253–N]

Medicare Program; Meeting of the Medicare Evidence Development and Coverage Advisory Committee—January 25, 2012

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

ACTION: Notice of meeting.

SUMMARY: This notice announces that a public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) (''Committee'') will be held on Wednesday, January 25, 2012. The Committee generally provides advice and recommendations concerning the adequacy of scientific evidence needed to determine whether certain medical items and services can be covered under the Medicare statute. This meeting will focus on the currently available evidence regarding the management of carotid atherosclerosis. This meeting is open to the public in accordance with the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)).

DATES: *Meeting Date:* The public meeting will be held on Wednesday, January 25, 2012 from 7:30 a.m. until 4:30 p.m., Eastern Standard Time (EST).

Deadline for Submission of Written Comments: Written comments must be received at the address specified in the **ADDRESSES** section of this notice by 5 p.m. EST, Monday, December 19, 2011. Once submitted, all comments are final.

Deadlines for Speaker Registration and Presentation Materials: The

deadline to register to be a speaker and to submit PowerPoint presentation materials and writings that will be used in support of an oral presentation is 5 p.m., EST on Monday, December 19, 2011. Speakers may register by phone or via email by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentation materials must be received at the address specified in the **ADDRESSES** section of this notice.

Deadline for All Other Attendees Registration: Individuals may register online at *http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3* or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m. EST, Friday, January 20, 2012.

We will be broadcasting the meeting live via Webcast at *http://www.cms.gov/live/.*

Deadline for Submitting a Request for Special Accommodations: Persons attending the meeting who are hearing or visually impaired, or have a condition that requires special assistance or accommodations, are asked to contact the Executive Secretary as specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice no later than 5 p.m., EST Friday, January 6, 2012.

ADDRESSES: *Meeting Location:* The meeting will be held in the main auditorium of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

Submission of Presentations and Comments: Presentation materials and written comments that will be presented at the meeting must be submitted via email to *MedCACpresentations@cms.hhs.gov* or by regular mail to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

FOR FURTHER INFORMATION CONTACT: Maria Ellis, Executive Secretary for MEDCAC, Centers for Medicare & Medicaid Services, Office of Clinical Standards and Quality, Coverage and Analysis Group, S3–02–01, 7500 Security Boulevard, Baltimore, MD 21244 or contact Ms. Ellis by phone (410) 786–0309 or via email at *Maria.Ellis@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

MEDCAC, formerly known as the Medicare Coverage Advisory Committee (MCAC), provides advice and recommendations to CMS regarding clinical issues. (For more information on MCAC, see the December 14, 1998 **Federal Register** (63 FR 68780). This notice announces the Wednesday, January 25, 2012, public meeting of the Committee. During this meeting, the Committee will discuss the currently available evidence regarding the management of carotid atherosclerosis.

Background information about this topic, including panel materials, is available at *http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&.* CMS will no longer be providing paper copies of the handouts for the meeting. Electronic copies of all the meeting materials will be on the CMS Web site no later than 2 business days before the meeting. We encourage the participation of appropriate organizations with expertise in the management of carotid atherosclerosis.

II. Meeting Format

This meeting is open to the public. The Committee will hear oral presentations from the public for approximately 45 minutes. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, CMS may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 22, 2011. Your comments should focus on issues specific to the list of topics that we have proposed to the Committee. The list of research topics to be discussed at the meeting will be available on the following web site prior to the meeting: *http://www.cms.gov/medicare-coverage-database/indexes/medcac-meetings-index.aspx?bc=BAAAAAAAAAAA&.* We require that you declare at the meeting whether you have any financial involvement with manufacturers (or their competitors) of any items or services being discussed.

The Committee will deliberate openly on the topics under consideration. Interested persons may observe the deliberations, but the Committee will not hear further comments during this time except at the request of the chairperson. The Committee will also allow a 15-minute unscheduled open public session for any attendee to address issues specific to the topics under consideration. At the conclusion of the day, the members will vote and the Committee will make its recommendation(s) to CMS.

III. Registration Instructions

CMS' Coverage and Analysis Group is coordinating meeting registration. While there is no registration fee, individuals must register to attend. You may register online at *http://www.cms.gov/apps/events/upcomingevents.asp?strOrderBy=1&type=3* or by phone by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the deadline listed in the **DATES** section of this notice. Please provide your full name (as it appears on your state-issued driver's license), address, organization, telephone, fax number(s), and email address. You will receive a registration confirmation with instructions for your arrival at the CMS complex or you will be notified that the seating capacity has been reached.

IV. Security, Building, and Parking Guidelines

This meeting will be held in a Federal government building; therefore, Federal security measures are applicable. We recommend that confirmed registrants arrive reasonably early, but no earlier than 45 minutes prior to the start of the meeting, to allow additional time to clear security. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Inspection of vehicle's interior and exterior (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Inspection, via metal detector or other applicable means of all persons brought entering the building. We note that all items brought into CMS, whether personal or for the purpose of presentation or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for presentation or to support a presentation.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building.

Authority: 5 U.S.C. App. 2, section 10(a).

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774,

Medicare—Supplementary Medical Insurance Program)

Dated: October 18, 2011.

Patrick Conway,

CMS Chief Medical Officer and Director, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–29782 Filed 11–17–11; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–1431–N]

Medicare Program; Town Hall Meeting on FY 2013 Applications for New Medical Services and Technology Add-On Payments Under the Hospital Inpatient Prospective Payment System

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a town hall meeting in accordance with to discuss fiscal year (FY) 2013 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2013 new medical services and technologies applications meet the substantial clinical improvement criterion.

DATES: *Meeting Date:* The town hall Meeting will be held on Tuesday, February 14, 2012. The town hall meeting will begin at 9 a.m. eastern standard time (e.s.t.) and check-in will begin at 8:30 a.m. e.s.t.

Deadline for Registration of Presenters of the Town Hall Meeting: All presenters for the town hall meeting, whether attending in person or by phone, must register and submit their agenda item(s) by Monday, January 23, 2012.

Deadline for Registration of All Other Participants for the Town Hall Meeting and Submitting Requests for Special Accommodations: All other participants must register by Tuesday, January 24, 2012. Requests for special accommodations must be received no later than 5 p.m., e.s.t. on Tuesday, January 31, 2012.

Deadline for Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Written comments and agenda items for discussion at the town hall meeting must be received by January 23, 2012. In addition to materials submitted for discussion at the town hall meeting, individuals may submit other written comments, as specified in the **ADDRESSES** section of this notice, on whether the service or technology represents a substantial clinical improvement. These comments must be received by March 6, 2012, for consideration before publication of the FY 2013 IPPS proposed rule.

ADDRESSES: *Meeting Location:* The town hall meeting will be held in the main Auditorium in the central building of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Registration and Special Accommodations: Individuals wishing to participate in the meeting must register by following the on-line registration instructions located in section III. of this notice or by contacting staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individuals who need special accommodations should contact staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Registration information and special accommodation requests may also be mailed to the address listed in the **ADDRESSES** section of this notice.

Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Each presenter must submit an agenda item(s) regarding whether a FY 2013 application meets the substantial clinical improvement criterion. Agenda items, written comments, questions or other statements must not exceed three single-spaced typed pages and may be sent via email to *newtech@cms.hhs.gov* or sent via regular mail to: Division of Acute Care, New Technology Team, Mailstop C4–08–06, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244–1850, *Attention:* Michael Treitel or Celeste Beauregard.

FOR FURTHER INFORMATION CONTACT: Michael Treitel, (410) 786–4552, *michael.treitel@cms.hhs.gov*, or Celeste Beauregard, (410) 786–8102, *celeste.beauregard@cms.hhs.gov*.

Alternatively, you may forward your requests via email to *newtech@cms.hhs.gov* or regular mail as specified in the **ADDRESSES** section of this notice.

SUPPLEMENTARY INFORMATION:

I. Background on the Add-On Payments for New Medical Services and Technologies Under the Hospital Inpatient Prospective Payment System (IPPS)

Sections 1886(d)(5)(K) and (L) of the Social Security Act (the Act) require the Secretary to establish a process of identifying and ensuring adequate payments to acute care hospitals for new medical services and technologies under Medicare. Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the inpatient hospital prospective payment system (IPPS). In addition, section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered ''new'' if it meets criteria established by the Secretary (after notice and opportunity for public comment). (See the FY 2002 proposed rule (66 FR 22693), May 4, 2001) and final rule (66 FR 46912), September 7, 2001) for a more detailed discussion.)

In the FY 2002 IPPS final rule (66 FR 46914), we noted that we evaluate a request for special payment for a new medical service or technology against the following criteria in order to determine if the new technology meets the substantial clinical improvement requirement:

- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:

++ Reduced mortality rate with use of the device.

++ Reduced rate of device-related complications.

++ Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).

++ Decreased number of future hospitalizations or physician visits.

++ More rapid beneficial resolution of the disease process treatment because of the use of the device.

++ Decreased pain, bleeding, or other quantifiable symptoms.

++ Reduced recovery time.