

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden (hours)
Phase II Mine Safety Personnel	Fatigue Risk Management Systems Assessment Tool.	50	1	1	50
Phase II Miners	Focus Groups	30	1	1	30
Phase III Miners	Experimental Research Studies	20	1	1	20
Total	295

Dated: September 14, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2012-23191 Filed 9-21-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the CDC announces the following meeting of the aforementioned committee:

Time and Date: 2 p.m.–4 p.m. (EDT), Thursday, October 25, 2012.

Place: Teleconference.

Status: Open to the public, limited only by the availability of telephone ports. The public is welcome to participate during the public comment period. The public comment period is tentatively scheduled for 3:50 p.m.–3:55 p.m. To participate in the teleconference, please dial (877) 930-8819 and enter code 1579739.

Purpose: The committee will provide advice to the CDC Director on policy and broad strategies that will enable CDC to fulfill its mission of protecting health through health promotion, prevention, and preparedness.

Matters To Be Discussed: Agenda items will include the following updates from the Global Workgroup; updates from the State, Tribal, Local and Territorial Workgroup; and Ethics Subcommittee, as well as an update from the CDC Director.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Carmen Villar, MSW, Designated Federal Officer, ACD, CDC, 1600 Clifton Road NE., M/S D-14, Atlanta, Georgia 30333, telephone (404) 639-7000, email: GHickman@cdc.gov. The deadline for notification of attendance is October 19, 2012. To register for this meeting, please send an email to ACDDirector@cdc.gov.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 14, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012-23455 Filed 9-21-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC)

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned board:

Times and Dates

8:30 a.m.–4:30 p.m., October 18, 2012.

8:30 a.m.–2 p.m., October 19, 2012.

Place: Centers for Disease Control and Prevention, 4770 Buford Highway, NE., Building 106, Atlanta, Georgia 30341.

Status: Open to the public, limited only by the space available.

Purpose: The Board will: (1) Conduct, encourage, cooperate with, and assist other appropriate public health authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases, and other impairments and (2) conduct and assist in research and control activities related to injury.

Matters To Be Discussed: The BSC, NCIPC will discuss the strategies and activities needed to guide the Center's research and program focus. Topics to be discussed include the Director's Update on the budget appropriation, reorganization and

partnerships; Science Update; health communication; global activities; Research to Practice Agenda; and increasing programmatic input to the BSC. There will be 15 minutes allotted for public comments at the end of the open session.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Gwendolyn H. Cattledge, Ph.D., M.S.E.H., Deputy Associate Director for Science, NCIPC, CDC, 4770 Buford Highway, NE., Mailstop F-63, Atlanta, Georgia 30341, Telephone (770) 488-1430.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 17, 2012.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2012-23452 Filed 9-21-12; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-846-849, 10125 and 10126]

Agency Information Collection Activities: Proposed Collection; 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) 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:* Extension of a currently approved collection;

Title: Durable Medical Equipment Medicare Administrative Contractor Certificate of Medical Necessity and Supporting Documentation Requirements; *Use:* The certificates of medical necessity (CMNs) collect 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. This clearance request is for CMNs with the form numbers, CMS 846-849, 10125 and 10126. *Form Numbers:* CMS-846, 847, 848, 849, 10125, 10126 (OCN: 0938-0679); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 462,000; *Total Annual Responses:* 462,000; *Total Annual Hours:* 92,400. (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 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.

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 *November 23, 2012*:

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: September 18, 2012.

Martique Jones,

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

[FR Doc. 2012-23367 Filed 9-21-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0966]

Prescription Drug User Fee Act V Patient-Focused Drug Development; Consultation Meetings; Request for Notification of Patient Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meetings; request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA) is issuing this notice to request that patient stakeholders notify FDA of their intention to participate in periodic consultation meetings on process issues related to FDA's patient-focused drug development initiative. This initiative is being conducted to fulfill FDA performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). These periodic consultation meetings will address important considerations and challenges in establishing a process for conducting a

series of patient-focused drug development meetings that will be useful to both the patient community and FDA. The purpose of this request for notification is to ensure continuity and progress in these discussions by establishing consistent patient stakeholder representation.

DATES: Submit notification of intention to participate in this series of meetings by October 3, 2012. The first stakeholder meeting on process issues will be held on October 10, 2012, from 2 p.m. to 3:30 p.m. These discussions will continue on an approximately bimonthly basis as needed during PDUFA V.

ADDRESSES: Submit notification of intention to participate in this series of meetings by email to PatientFocused@fda.hhs.gov. The first meeting with patient stakeholders will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 51, Rm. 1300, Silver Spring, MD 20993-0002. Entrance for the consultation meetings' participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT:

Andrea Tan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 1168, Silver Spring, MD 20993-0002, 301-796-7641, FAX: 301-847-8443, Andrea.Tan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the President signed into law the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA). Title I of FDASIA reauthorizes the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary user fee resources to maintain a predictable and efficient review process for human drug and biologic products. The reauthorization of PDUFA includes performance goals and procedures that represent FDA's commitments during fiscal years 2013-2017. These commitments are referred to in section 101 of FDASIA and are available on the FDA Web site at <http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf>.

Section X of these commitments relates to enhancing benefit-risk assessments in regulatory