

program payments for IME and GME are based upon an accurate number of FTE-IRs, determined in accordance with Medicare regulations. The IR data submitted by the hospitals are used by the FIs/MACs during their audits of the providers' cost reports. The audit procedures help assure that the information reported was correct, and that IRs who should not have been reported by the hospitals (or portions of the IRs' time) are not included in the FTE count. The FIs/MACs also use reports of duplicate IRs to prevent improper payment for IME and GME. *Form Number:* CMS-R-64 (OMB#: 0938-0456); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,190; *Total Annual Responses:* 1,190; *Total Annual Hours:* 2,380. (For policy questions regarding this collection contact Milton Jacobson at 410-786-7553. 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 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.

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 *February 8, 2010*.

OMB, Office of Information and Regulatory Affairs. Attention: CMS Desk Officer. *Fax Number:* 202-395-6974. *E-mail:* OIRA_submission@omb.eop.gov.

Dated: December 24, 2009.

Michelle Shortt,

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

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BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-906]

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:* Revision of a currently approved collection; *Title of Information Collection:* The Fiscal Soundness Reporting Requirements; *Use:* CMS is assigned responsibility for overseeing all Medicare Advantage Organizations (MAO), Prescription Drug Plan (PDP) sponsors, 1876 Cost Plans, Demonstration Plans and PACE organizations on-going financial performance. Specifically, CMS needs the requested collection of information to establish that contracting entities within those programs maintain fiscally sound organizations. Refer to the supporting documents for a list of changes to this collection. *Form Number:* CMS-906 (OMB#: 0938-0469); *Frequency:* Reporting—Yearly and Quarterly; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 514; *Total Annual Responses:* 1039; *Total Annual Hours:* 346. (For policy questions regarding this collection contact Robert Ahern at 410-786-0073. 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 *March 9, 2010*:

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: December 24, 2009.

Michelle Shortt,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-D-0568]

Draft Guidance for Industry on Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products." The draft guidance encourages manufacturers of medically necessary drug products (MNP) and components to develop contingency production plans in the event of an emergency that results in high absenteeism at one or more production