DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10142, CMS–R–262, CMS–R–0282 and CMS–R–64]

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:* Revision of a currently approved collection; *Title of Information Collection:* CY 2011 Bid Pricing Tool (BPT) for Medicare Advantage (MA) Plans and Prescription Drug Plans (PDP); *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), and implementing regulations at 42 CFR, Medicare Advantage organizations (MAO) and Prescription Drug Plans are required to submit an actuarial pricing "bid" for each plan offered to Medicare beneficiaries for approval by CMS. MAOs and PDPs use the Bid Pricing Tool (BPT) software to develop their actuarial pricing bid. The information provided in the BPT is the basis for the plan's enrollee premiums and CMS payments for each contract year. The tool collects data such as medical expense development (from claims data and/or manual rating), administrative expenses, profit levels, and projected plan enrollment information. By statute, completed BPTs are due to CMS by the first Monday of June each year. CMS reviews and analyzes the information provided on the Bid Pricing Tool. Ultimately, CMS decides whether to approve the plan pricing (*i.e.,* payment and premium) proposed by each organization. Refer to the supporting document attachment "C" for a list of changes. *Form Number:* CMS–10142 (OMB#: 0938–0944); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 550; *Total Annual Responses:* 6,050; *Total Annual Hours:* 42,350. (For policy questions regarding this collection contact Diane Spitalnic at 410–786–5745. For all other issues call 410–786–1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* CY 2011 Plan Benefit Package (PBP) Software and Formulary Submission; *Use:* Under the Medicare Modernization Act (MMA), Medicare Advantage (MA) and Prescription Drug Plan (PDP) organizations are required to submit plan benefit packages for all Medicare beneficiaries residing in their service area. The plan benefit package submission consists of the PBP software, formulary file, and supporting documentation, as necessary. MA and PDP organizations use the PBP software to describe their organization's plan benefit packages, including information on premiums, cost sharing, authorization rules, and supplemental benefits. They also generate a formulary to describe their list of drugs, including information on prior authorization, step therapy, tiering, and quantity limits. Additionally, CMS uses the PBP and formulary data to review and approve the plan benefit packages proposed by each MA and PDP organization.

CMS requires that MA and PDP organizations submit a completed PBP and formulary as part of the annual bidding process. During this process, organizations prepare their proposed plan benefit packages for the upcoming contract year and submit them to CMS for review and approval. Based on operational changes and policy clarifications to the Medicare program and continued input and feedback by the industry, CMS has made the necessary changes to the plan benefit package submission. Refer to the supporting document "Appendix B" for a list of changes. *Form Number:* CMS–R–262 (OMB#: 0938–0763); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 475; *Total Annual Responses:* 4988; *Total Annual Hours:* 12,113. (For policy questions regarding this collection contact Sara Walters at 410–786–3330. For all other issues call 410–786–1326.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Advantage Appeals and Grievance Data Disclosure Requirements (42 CFR § 422.111); *Use:* Medicare Advantage (MA) organizations must disclose information pertaining to the number of disputes, and their disposition in the aggregate, with the categories of grievances and appeals to any individual eligible to elect an MA organization who requests this information. Medicare demonstrations also are required to conform to MA appeals regulations and thus are included in the count of organizations affected by this requirement. MA organizations also are required by the statute and the MA regulation to provide aggregate grievance data to MA eligible beneficiaries upon request. MA eligible individuals will use this information to help them make informed decisions about their organization's performance in the area of appeals and grievances. *Form Number:* CMS–R–0282 (OMB#: 0938–0778); *Frequency:* Reporting—Semi-annually and Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 629; *Total Annual Responses:* 47,175; *Total Annual Hours:* 4,931.36. (For policy questions regarding this collection contact Stephanie Simons at 206–615–2420. For all other issues call 410–786–1326.)

4. *Type of Information Collection Request:* Extension of the currently approved collection; *Title of Information Collection:* Indirect Medical Education (IME) and Supporting Regulations at 42 CFR 412.105; Direct Graduate Medical Education (GME) and Supporting Regulations at 42 CFR 413.75 through 413.83; *Use:* The information collected on interns and residents (IRs) is used by the Medicare Part A fiscal intermediaries (FI) and Part A Medicare Administrative Contractors (MAC) to verify the number of IRs used in the calculation of Medicare program payments for indirect medical education (IME) as well as direct graduate medical education (GME). The IR data collected from the hospitals is processed through computers at FIs/MACs to identify any duplicated time based upon the accumulated time of each individual that worked at one or more hospitals. The identification of duplicate IRs is necessary to ensure that no IR is counted more than once.

The FIs/MACs use the information collected on IRs to help ensure that all

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.

[FR Doc. E9–31299 Filed 1–7–10; 8:45 am]

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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 (MNPs) and components to develop contingency production plans in the event of an emergency that results in high absenteeism at one or more production