Information Collection: CY 2010 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 (PDP) 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. *Form Number:* CMS–10142 (OMB# 0938–0944); *Frequency:* Yearly; *Affected Public:* Business or other for-profits b. Not-for-profit institutions; *Number of Respondents:* 550; *Total Annual Responses:* 6050; *Total Annual Hours:* 42,350.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Internal Revenue Service (IRS)/Social Security Administration (SSA)/Centers for Medicare and Medicaid Services (CMS) Data Match and Supporting Regulations in 42 CFR 411.20–491.206 *Use:* Medicare Secondary Payer (MSP) is essentially the same concept known in the private insurance industry as coordination of benefits; it refers to those situations where Medicare assumes a secondary payer role to certain types of private insurance for covered services provided to a Medicare beneficiary.

Congress sought to reduce the losses to the Medicare program by requiring in 42 U.S.C. 1395y(b)(5) that the Internal Revenue Service (IRS), the Social Security Administration (SSA), and CMS perform an annual data match (the IRS/SSA/CMS Data Match, or ''Data Match'' for short). CMS uses the information obtained through Data Match to contact employers concerning possible application of the MSP provisions by requesting information about specifically identified employees (either a Medicare beneficiary or the working spouse of a Medicare beneficiary). This statutory data match and employer information collection activity enhances CMS's ability to identify both past and present MSP situations. *Form Number:* CMS–R–137 (OMB# 0938–0763); *Frequency:* Annually; *Affected Public:* Business or other for-profit, not-for-profit institutions, farms, State, Local or Tribal Governments; *Number of Respondents:* 326,597; *Total Annual Responses:* 326,597; *Total Annual Hours:* 1,900,795.

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 9, 2009: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503, Fax Number: (202) 395–6974.

Dated: December 28, 2008.

Michelle Shortt,

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

[FR Doc. E9–52 Filed 1–8–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10062, CMS–10275, and CMS–10137]

Agency Information Collection Activities: Proposed Collection; 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) 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 of Information Collection:* Collection of Diagnostic Data from Medicare Advantage Organizations for Risk Adjusted Payments: *Use:* CMS requires hospital inpatient, hospital outpatient and physician diagnostic data from Medicare Advantage (MA) organizations to continue making payment under the risk adjustment methodology as required by the Social Security Act, as amended by the Balanced Budget Act; the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act; and the Medicare Prescription Drug Benefit, Improvement and Modernization Act. CMS will use the data to make risk adjusted payment under Parts C. MA and MA–PD plans will use the data to develop their Parts C bids. As required by law, CMS also annually publishes the risk adjustment factors for plans and other interested entities in the Advance Notice of Methodological Changes for MA Payment Rates (every February) and the Announcement of Medicare Advantage Payment Rates (every April). Lastly, CMS issues monthly reports to each individual plan that contains the CMS-Hierarchical Condition Category (HCC) and RxHCC models' output and the risk scores and reimbursements for each beneficiary that is enrolled in their plan. *Form Number:* CMS–10062 (OMB# 0938–0878); *Frequency:* Quarterly; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 852; *Total Annual Responses:* 22,097,070; *Total Annual Hours:* 10,826.1.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* CAHPS Home Health Care Survey: *Use:* As part of the Department of Health and Human Services (DHHS) Transparency Initiative on Quality Reporting, CMS plans to implement a process to measure and publicly report home health care patient experiences through the CAHPS (Consumer Assessment of Healthcare

Providers and Systems) Home Health Care Survey. The Home Health Care CAHPS survey, as initially discussed in the May 4, 2007 **Federal Register** (72 FR 25356, 25452), is part of a family of CAHPS® surveys that ask patients about their health care experiences. The Home Health Care CAHPS survey, developed by the Agency for Healthcare Research and Quality (AHRQ), creates a standardized survey for home health patients to assess their home health care providers and the quality of their home health care. Prior to this survey, there was no national standard for collecting such information that would allow comparisons across all home health agencies.

AHRQ conducted a field test to determine the length and content of the Home Health Care CAHPS Survey. CMS has submitted the survey to the National Quality Forum (NQF) for consideration and approval in their consensus process. NQF endorsement represents the consensus opinion of many healthcare providers, consumer groups, professional organizations, purchasers, federal agencies, and research and quality organizations. The final survey has also been submitted to the Office of Management and Budget (OMB) for their approval under the Paperwork Reduction Act (PRA) process.

The survey captures topics such as patients' interactions with the agency, access to care, interactions with home health staff, provider care and communication, and patient characteristics. The survey allows the patient to give an overall rating of the agency, and asks if the patient would recommend the agency to family and friends.

CMS is beginning plans for implementation of Home Health Care CAHPS Survey. Administration of the survey will be conducted by multiple, independent survey vendors working under contract with home health agencies to facilitate data collection and reporting. Recruitment and training of vendors who wish to be approved to collect Home Health Care CAHPS data will begin in 2009. Home health agencies interested in learning about the survey and/or voluntarily participating in the survey are encouraged to view the Home Health Care CAHPS Web site: *http://www.homehealthCAHPS.org*. Information about the project can also be obtained by sending an e-mail to *HHCAHPS@rti.org*.

Home health agency participation in the Home Health Care CAHPS Survey is currently voluntary. *Form Number:* CMS–10275 (OMB# 0938–New); *Frequency:* Semi-annually, once and occasionally; *Affected Public:* Individuals or households; *Number of Respondents:* 2,706,000; *Total Annual Responses:* 2,706,000; *Total Annual Hours:* 541,200.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Application for Prescription Drug Plans (PDP); Application for Medicare Advantage Prescription Drug (MA–PD); Application for Cost Plans to Offer Qualified Prescription Drug Coverage; Application for Employer Group Waiver Plans to Offer Prescription Drug Coverage; Service Area Expansion Application for Prescription Drug Coverage; *Use* Collection of this information is mandated in Part D of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and under supporting regulations Subpart K of 42 CFR 423 entitled ''Application Procedures and Contracts with PDP Sponsors.''

Coverage for the prescription drug benefit is provided through contracted prescription drug plans (PDPs) or through Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA–PD plans). Cost Plans that are regulated under Section 1876 of the Social Security Act, and Employer Group Waiver Plans (EGWP) may also provide a Part D benefit. Organizations wishing to provide services under the Prescription Drug Benefit Program must complete an application, negotiate rates and receive final approval from CMS. Existing Part D Sponsors may also expand their contracted service area by completing the Service Area Expansion (SAE) application. The information will be collected under the solicitation of proposals from PDP, MA–PD, Cost Plan, PACE, and EGWP Plan applicants. The collected information will be used by CMS to: (1) Ensure that applicants meet CMS requirements, (2) support the determination of contract awards. *Form Number:* CMS–10137(OMB#: 0938–0936); *Frequency:* Reporting–Once; *Affected Public:* Business or other for-profit and not-for-profit institutions; *Number of Respondents:* 455; *Total Annual Responses:* 455; *Total Annual Hours:* 11,890.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's 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 10, 2009:

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 30, 2008.

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–2008–N–0500]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 9, 2009.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: