

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10167, CMS-10009, CMS-10001, and CMS-10079]

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: New collection; **Title of Information Collection:** Competitive Acquisition Program (CAP) for Medicare Part B Drugs: CAP Physician Election Agreement; **Form Number:** CMS-10167 (OMB#: 0938-NEW); **Use:** Beginning in 2006, physicians will have a choice between acquiring and billing for Part B covered drugs under the Average Sales Price (ASP) drug payment methodology or electing to receive these drugs from vendors/suppliers selected for the CAP through a competitive bidding process. The provisions for this new payment system are described in the proposed rule (42 CFR Part 414 Subpart K) published March 4, 2005 (70 FR 10746), the interim final rule published July 6, 2005 (70 FR 39022), and a final rule (CMS-1502-FC) that published on November 21, 2005. Competitive bidding is seen as a means of using the dynamics of the marketplace to provide incentives for suppliers to provide reasonably priced products and services of high quality in an efficient manner. The CAP's objectives include the following: (1) To provide an alternative method for physicians to obtain Part B drugs to administer to Medicare

beneficiaries; and (2) to reduce drug acquisition and billing burdens for physicians.; **Frequency:** Reporting—Annually; **Affected Public:** Business or other-for-profit; **Number of Respondents:** 10,000; **Total Annual Responses:** 10,000; **Total Annual Hours:** 20,000.

2. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** HIPAA Nondiscrimination Provisions (Regulation HCFA 2078-P); **Form Number:** CMS-10009 (OMB#: 0938-819); **Use:** The provisions of Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are designed to make it easier for people to get access to health care coverage, to reduce the limitations that can be put on the coverage, and to make it more difficult for issuers to terminate the coverage. Title I provisions are divided into group and individual market protections. The group provisions apply to employment-related group health plans and to the issuers who sell insurance in connection with group health plans. Section 2702 of the Public Health Service Act (PHS Act—the HIPAA nondiscrimination provisions) establish rules generally prohibiting group health plans and group health insurance issuers from discriminating against individual participants or beneficiaries based on any health factor of such participants or beneficiaries; **Frequency:** Third party disclosure, Reporting—Annually; **Affected Public:** Business or other-for-profit, Individuals or Households, Not-for-profit institutions, Federal government, and State, Local, or Tribal Government; **Number of Respondents:** 2600; **Total Annual Responses:** 2600; **Total Annual Hours:** 100.

3. Type of Information Collection Request: Extension of a currently approved collection; **Title of Information Collection:** HIPAA Nondiscrimination Provisions (Regulation HCFA 2022-IFC); **Form Number:** CMS-10001 (OMB#: 0938-827); **Use:** The provisions of Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) are designed to make it easier for people to access health care coverage; to reduce the limitations that can be put on the coverage; and to make it more difficult for issuers to terminate the coverage. Title I provisions are divided into group and individual market protections. The group provisions apply to employment-related group health plans and to the issuers who sell insurance in connection with group health plans. Section 2702 of the Public Health

Service Act (PHS Act) (the HIPAA nondiscrimination provisions) establish rules generally prohibiting group health plans and group health insurance issuers from discriminating against individual participants or beneficiaries based on any health factor of such participants or beneficiaries; **Frequency:** Third party disclosure, Reporting—Annually; **Affected Public:** Business or other-for-profit, Individuals or Households, Not-for-profit institutions, Federal government, and State, Local, or Tribal Government; **Number of Respondents:** 18; **Total Annual Responses:** 18; **Total Annual Hours:** 194.

4. Type of Information Collection Request: Revision of a currently approved collection; **Title of Information Collection:** Hospital Wage Index—Occupational Mix Survey and Supporting Regulations in 42 CFR 412.230, 412.304, and 413.65; **Form Number:** CMS-10079 (OMB#: 0938-0907); **Use:** Section 304 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Benefits Improvement and Protection Act of 2000 requires CMS to collect wage data on hospital employees by occupational category, at least once every 3 years in order to construct an occupational mix adjustment to the wage index. CMS first collected occupational mix survey data in 2003 for the FY 2005 wage index. The next data collection is occurring in 2006 for the FY 2008 wage index. In response to industry comments suggesting ways to improve the occupational mix survey, CMS has revised the survey. The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor. Each of the approximately 3,800 acute care hospital inpatient prospective payment system (IPPS) providers participating in the Medicare program will be required to complete the 2006 Medicare Wage Index Occupational Mix Survey. The initial survey will be forwarded via email to all of CMS's fiscal intermediaries; **Frequency:** Reporting—Other, Triennially; **Affected Public:** Business or other for-profit and Not-for-profit institutions; **Number of Respondents:**

3,800; *Total Annual Responses*: 3,800; *Total Annual Hours*: 608,000.

To obtain copies of the supporting statement and any related forms for these 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 *March 13, 2006*. OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 3, 2006.

Michelle Shortt,

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

[FR Doc. E6-1819 Filed 2-9-06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-359, 360, R-55; CMS-368, R-144; and CMS-643]

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 of Information Collection:* Comprehensive Outpatient Rehabilitation Facility (CORF) Eligibility and Survey Forms and Information Collection Requirements at 42 CFR 485.56, 485.58, 485.60, 485.64, 485.66 and 410.105; *Use:* In order for a provider to participate in the Medicare program as a CORF, a provider must meet the Federal conditions of participation. The form CMS-359 is utilized as an application for facilities wishing to participate in the Medicare/Medicaid program as CORFs. This form initiates the process of obtaining a decision as to whether the conditions of participation are met. The form CMS-360 is an instrument used by the State survey agency to record data collected in order to determine the provider compliance with individual conditions of participation and to report it to the Federal government; *Form Numbers:* CMS-359, 360, R-55 (OMB#: 0938-0267); *Frequency:* Reporting—On occasion; *Affected Public:* State, Local, or Tribal government and Business or other for-profit; *Number of Respondents:* 630; *Total Annual Responses:* 630; *Total Annual Hours:* 300,046.

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* State Medicaid Drug Rebate; *Use:* Section 1927 of the Social Security Act requires each State Medicaid agency to report quarterly prescription drug utilization information to drug manufacturers and to the Centers for Medicare and Medicaid Services. As part of this information, the State Medicaid agencies are required to report the total Medicaid rebate amount they claim they are owed by each drug manufacturer for each covered prescription drug product each quarter; *Form Numbers:* CMS-368, R-144 (OMB#: 0938-0582); *Frequency:* Reporting—Quarterly; *Affected Public:* State, Local, or Tribal government; *Number of Respondents:* 51; *Total Annual Responses:* 204; *Total Annual Hours:* 9,389.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Hospice Survey and Deficiencies Report Form and Supporting Regulations at 42 CFR 442.30 and 488.26; *Use:* In order to participate in the Medicare program, a hospice must meet certain Federal health and safety conditions of

participation. This form is used by State surveyors to record data about a hospice's compliance with these conditions of participation in order to initiate the certification or recertification process; *Form Number:* CMS-643 (OMB#: 0938-0379); *Frequency:* Reporting—Annually; *Affected Public:* Not-for-profit institutions and Business or other for-profit; *Number of Respondents:* 2,293; *Total Annual Responses:* 475; *Total Annual Hours:* 238.

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 at the address below, no later than 5 p.m. on April 11, 2006. CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto (CMS-359, 360, R-55; CMS-368, R-144; and CMS-643) Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: January 31, 2006.

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. 2004D-0369]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommendations for the Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of