DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS 1880/1882, CMS 10142 and CMS 10036]

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:* Extension of a currently approved collection; *Title of Information Collection:* The Request for Certification as a Supplier of Portable X–Ray Services and Portable X–Ray Survey Report Form under the Medicare and Medicaid Program—Portable X–Ray Survey Report and Supporting Regulations under 42 CFR 486.100–486.110; *Form Number:* CMS–1880/1882 (OMB#: 0938–0027); *Use:* The Medicare program requires portable X-ray suppliers to be surveyed for health and safety standards. The CMS–1882 is the survey form that records survey results. The CMS–1880 is used by the surveyor to determine if a portable X-ray applicant meets the eligibility requirements. This information serves as a screen for the State survey agency to determine if the portable X-ray supplier has the basic capabilities to participate in the Medicare program. CMS will use this information to make certification decisions; *Frequency:* Reporting—On occasion; *Affected Public:* Business or other for-profit; *Number of Respondents:* 655; *Total Annual Responses:* 98; *Total Annual Hours:* 172.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Bid Pricing Tool (BPT) for Medicare Advantage and Prescription Drug Plans (PDP) contained in 42 Code of Federal Regulation (CFR): 422.250, 422.252, 422.254, 422.256, 422.258, 422.262, 422.264, 422.266, 422.270, 422.300, 422.304, 422.306, 422.308, 422.310, 422.312, 422.314, 422.316, 422.318, 422.320, 422.322, 422.324, 423.251, 423.258, 423.265, 423.272, 423.279, 423.286, 423.293, 423.301, 423.308, 423.315, 423.322, 423.329, 423.336, 423.343, 423.346, 423.350; *Form Number:* CMS–10142 (OMB#: 0938–0944); *Use:* Under the Medicare Modernization Act, Medicare Advantage Organizations (MAO) and Prescription Drug Plans (PDP) are required to submit an actuarial pricing bid to CMS for approval. The BPT software is used by MAOs and PDPs to price their plan benefit package. The BPT software is used by CMS to review and approve the plan pricing proposed by each organization; *Frequency:* Reporting—On occasion, Annually and As required by new legislation; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 350; *Total Annual Responses:* 350; *Total Annual Hours:* 12,050.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Inpatient Rehabilitation Assessment Instrument and Data Set for Prospective Payment System for Inpatient Rehabilitation Facilities and Supporting Regulations in 42 CFR Sections 412.23, 412.604, 412.606, 412.610, 412.614, 412.618, 412.626, 413.64; *Form Number:* CMS–10036 (OMB#: 0938–0842); *Use:* This is a request to use the Inpatient Rehabilitation Facilities-Patient Assessment Instrument (IRF–PAI) and its supporting manual for the implementation phase of the Inpatient Rehabilitation) Prospective Payment System (PPS). This payment system is to cover both operating and capital costs for inpatient rehabilitation hospital services. It will apply to rehabilitation units of acute care hospitals as well as to rehabilitation hospitals, both of which are exempt from the current Inpatient PPS which is generally applicable for inpatient hospital services. Use of this instrument will enable CMS to implement a classification and payment system for the legislatively mandated inpatient rehabilitation hospital and the aforementioned exempt units. *Frequency:* Recordkeeping, Third party disclosure and Reporting—On occasion; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,165; *Total Annual Responses:* 390,000; *Total Annual Hours:* 421,939.

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/regulations/pra/,* 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 January 17, 2006.

OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 9, 2005.

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. 2003N–0273]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Research Study Complaint Form

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 January 17, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being