

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 *November 15, 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: *October 8, 2010*.

Martique Jones,

Director, Regulations Development Division—B, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-153 and CMS-10152]

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:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Medicaid Drug Utilization Review (DUR) Annual Report; *Use:* The DUR program is required to assure that prescriptions are appropriate, medically necessary and are not likely to result in adverse medical results. Each State DUR program must consist of prospective drug use review, retrospective drug use review, data assessment of drug use

against predetermined standards, and ongoing educational outreach activities. In addition, States are required to submit an annual DUR program report that includes a description of the nature and scope of State DUR activities as outlined in the statute and regulations. Over the years, technology has changed as has the practice of the pharmacy. Therefore, CMS has revised the old survey vehicle to more fully address the current practices and areas of concern with the Medicaid Pharmacy Programs. *Form Number:* CMS-R-153 (OMB#: 0938-0659); *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 51; *Total Annual Hours:* 20,298. (For policy questions regarding this collection contact Madlyn Kruh at 410-786-3239. For all other issues call 410-786-1326.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection for Medicare Beneficiaries Using NaF-18 Positron Emission Tomography (PET) to Identify Bone Metastasis in Cancer; *Use:* In Decision Memorandum # CAG-00065R, issued on February 26, 2010, the Centers for Medicare and Medicaid Services (CMS) determined that the evidence is sufficient to conclude that for Medicare beneficiaries receiving NaF-18 PET scan to identify bone metastasis in cancer is reasonable and necessary only when the provider is participating in and patients are enrolled in a clinical study designed to assist in initial antitumor treatment planning or to guide subsequent treatment strategy by the identification, location and quantification of bone metastases in beneficiaries in whom bone metastases are strongly suspected based on clinical symptoms or the results of other diagnostic studies. Qualifying clinical studies must ensure that specific hypotheses are addressed; appropriate data elements are collected; hospitals and providers are qualified to provide the PET scan and interpret the results; participating hospitals and providers accurately report data on all Medicare enrolled patients; and all patient confidentiality, privacy, and other Federal laws must be followed. Consistent with section 1142 of the Social Security Act, the Agency for Healthcare Research and Quality (AHRQ) supports clinical research studies that the CMS determines meet specified standards and address the specified research questions.

To qualify for payment, providers must prescribe certain NaF-18 PET scans for beneficiaries with a set of

clinical criteria specific to each solid tumor. The statutory authority for this policy is section 1862(a)(1)(E) of the Social Security Act. The need to prospectively collect information at the time of the scan is to assist the provider in decision making for patient management. To qualify for payment, providers must prescribe certain NaF-18 PET scans for beneficiaries with a set of clinical criteria specific to each solid tumor. Data elements will be transmitted to CMS for evaluation of the short and long-term benefits of NaF-18 PET to beneficiaries and for use in future clinical decision making. *Form Number:* CMS-10152 (OMB#: 0938-0968); *Frequency:* Annually; *Affected Public:* Individuals or Households; *Number of Respondents:* 25,000; *Total Annual Responses:* 25,000; *Total Annual Hours:* 2,084. (For policy questions regarding this collection contact Stuart Caplan at 410-786-9564. 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 *December 14, 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: October 8, 2010.

Michelle Shortt,

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

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