

the address below, no later than 5 p.m. on *January 14, 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.

Date: *December 5, 2008*.

**Michelle Shortt,**

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

[FR Doc. E8-29542 Filed 12-12-08; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10110, CMS-R-250 and CMS-668B]

#### 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:* Manufacturer Submission of Average Sales Price (ASP) data for Medicare Part B Drugs and Biologicals; *Use:* Section 1847A of the Social Security Act requires that the Medicare Part B payment amounts for covered drugs and biologicals not paid on a cost or prospective payment basis be based upon manufacturers' average sales price data submitted to CMS. CMS will utilize the ASP data to determine

the Medicare Part B drug payment amounts. *Form Number:* CMS-10110 (OMB# 0938-0921); *Frequency:* Quarterly; *Affected Public:* Business or other for-profits; *Number of Respondents:* 180; *Total Annual Responses:* 720; *Total Annual Hours:* 28,800.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* MPAF Data and Supporting Regulations in 42 CFR 413.337, 413.343, 424.32 and 483.20; *Use:* Resident assessment information that Skilled Nursing Facilities (SNFs) are required to submit is described under section 42 CFR 413.343 and 483.20. The manner necessary to administer the payment rate methodology is described under section 42 CFR 413.337. An assessment form comprised of a subset of resident assessment information has been developed for use by SNFs to satisfy Medicare payment requirements, in lieu of a full Minimum Data Set. The associated burden is the time the SNF staff is required to complete the Medicare PPS Assessment Form (MPAF), SNF staff time to encode, and SNF staff time spent in transmitting the data. *Form Number:* CMS-R-250 (OMB# 0938-0739); *Frequency:* Occasionally; *Affected Public:* Business or other for-profits and Not-for-profit institutions, State, Local, or Tribal Governments, and Federal Governments; *Number of Respondents:* 15,039; *Total Annual Responses:* 3,834,945; *Total Annual Hours:* 2,704,764.

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Post Clinical Laboratory Survey Questionnaire and Supporting Regulations in 42 CFR 493.1771, 493.1773, and 493.1777; *Use:* This form is used by the State agency to determine a laboratory's compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This information is needed for a laboratory's CLIA certification and recertification. *Form Number:* CMS-668B (OMB# 0938-0653); *Frequency:* Biennially; *Affected Public:* Business or other for-profits and Not-for-profit institutions, State, Local, or Tribal Government, Federal Government; *Number of Respondents:* 21,000; *Total Annual Responses:* 10,500; *Total Annual Hours:* 2,625.

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/>

*Paperwork Reduction Act of 1995*, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto: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 *February 13, 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 5, 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-0602]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Experimental Study of the Impact of Coupons Embedded in Direct-to-Consumer Prescription Drug Print Advertisements on Consumer Perceptions of Product Risks and Benefits

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for