

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:* Post Clinical Laboratory Survey Questionnaire and Supporting Regulations in 42 CFR 493.1771, 493.1773, and 493.1777; *Use:* To provide an opportunity and a mechanism for Clinical Laboratory Improvement Amendments of 1988 (CLIA) laboratories surveyed by CMS or CMS' agents to express their satisfaction and concerns about the CLIA survey process.; *Form Number:* CMS-668B (OMB #0938-0653); *Frequency:* Recordkeeping, Reporting—Biennially; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 21,000; *Total Annual Responses:* 10,500; *Total Annual Hours:* 2,625.

2. *Type of Information Collection Request:* New collection; *Title of Information Collection:* Enrolling Low-Income Beneficiaries into the Medicare Prescription Drug Program—Survey of State Agency Experiences; *Use:* The Centers for Medicare and Medicaid Services (CMS) will conduct a survey of State Medicaid agencies, State health insurance plans (SHIPs), and State pharmaceutical assistance programs (SPAPs) to identify best practices for the successful enrollment of all types of low-income Medicare beneficiaries into a low-income subsidy and the Medicare Part D Prescription Drug Benefit Program. The evaluation will assist in identifying the best practices, the factors that make them effective, and how the information can be disseminated in an effective manner. The information will be used to help CMS as it designs its outreach and communication campaigns in subsequent open enrollment periods.; *Form Number:* CMS-10181 (OMB #0938-NEW); *Frequency:* Reporting—Other, one-time; *Affected Public:* State, Local or Tribal governments, Federal government; *Number of Respondents:* 126; *Total Annual Responses:* 126; *Total Annual Hours:* 63.

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](mailto: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 May 2, 2006. CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—A, Attention: Melissa Musotto (CMS-668B), Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 22, 2006.

**Michelle Shortt,**

*Director, Regulations Development Group, 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-10110 and CMS-10170]

#### Agency Information Collection Activities: Submission for OMB Review; 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), 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:* 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 And Supporting Regulations in 42 CFR 414.804; *Form No.:* CMS-10110 (OMB #0938-0921); *Use:* In accordance with section 1847A of the Social Security Act (the Act), Medicare Part B covered drugs and biologicals not paid on a cost or prospective payment basis are paid based on the average sales price of the drug or biological, beginning in CY 2005. The ASP data reporting requirements are specified in section 1927 of the Act. The reported ASP data are used to establish the Medicare payment amounts. CMS will utilize the ASP data to determine the drug payment amounts for CY 2005 and beyond. In the interim final rule which published April 6, 2004 (69 FR 17935), the ASP reporting format, (Addendum A), was specified. In addition, we stated that, as we gain more experience with the ASP methodology, we may seek to modify the reporting requirements (data elements and format for submission) in the future. Based on our experience during the initial six reporting periods, we have found it necessary for carrying out section 1847A of the Act, to expand the ASP data collected from manufacturers.

We are proposing that, in addition to the original data elements (manufacturer name, National Drug Code (NDC), manufacturer's ASP, and number of units), the following data elements must be submitted quarterly by manufacturers:

- Name of drug or biological;
- Strength of the product;
- Volume per item;
- Number of items per NDC;
- Wholesale acquisition costs (applies to NDCs assigned to single source drug and biological billing codes and NDCs during the initial period under section 1847A(c)(4) of the Act);
- Expiration date of the last lot sold;
- Date NDC was first available for sale; and
- Date of first sale.

We are also proposing that manufacturers would no longer report ASP data for an NDC beginning the reporting period after the expiration date of the last lot sold. For NDCs first made available for sale or sold on or after October 1, 2005, we are also proposing to collect the date the NDC was first available for sale and the date of first sale. We are also proposing that manufacturers be required to submit these dates to us once with the first or second, if applicable, data submission for new NDCs. In addition, we are

proposing that the expiration date of the last lot sold must be reported to CMS once at the end of utilization of the NDC or when there are no sales for three consecutive quarters.

On November 21, 2005, we published an interim final rule (70 FR 70478) stating that, during the first three years of the Part B Drug Competitive Acquisition Program (CAP), sales and price concessions associated with units administered to a beneficiary by a participating CAP vendor are excluded from the ASP units and price. We propose to collect the number of CAP units excluded from the ASP calculation. *Frequency*: Recordkeeping and Reporting—Quarterly; *Affected Public*: Business or other for-profit; *Number of Respondents*: 120; *Total Annual Responses*: 480; *Total Annual Hours*: 17,760.

## 2. Type of Information Collection

*Request*: Extension of a currently approved collection; *Title of Information Collection*: Retiree Drug Subsidy (RDS) Payment Request and Instructions; *Form Number*: CMS-10170 (OMB #0938-0977); *Use*: Under section 1860D-22 of the Social Security Act (Act), added by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, plan sponsors (employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28 percent tax-free subsidy for allowable drug costs. To receive the subsidy, plan sponsors must submit required prescription cost data. CMS has contracted with an outside vendor (ViPS) to assist in the administration of the retiree drug subsidy (RDS) program; this effort is called the RDS Center. Plan sponsors will request subsidy payments on-line by logging on to the RDS secure Web site. Cost data required for each payment request may be entered into the RDS secure Web site, or uploaded to the RDS Center mainframe. Once the plan sponsor submits the payment request, the RDS Center will process the request to determine if payment is due and the amount of the payment; *Frequency*: Recordkeeping and Reporting—Monthly, Quarterly and Annually; *Affected Public*: Not-for-profit institutions, Business or other for-profit, Federal Government, State, Local, or Tribal Government; *Number of Respondents*: 6,000; *Total Annual Responses*: 6,000; *Total Annual Hours*: 222,000.

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](mailto:Paperwork@cms.hhs.gov), or call the Reports Clearance Office on (410) 786-1326.

Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: February 23, 2006.

**Michelle Shortt**,

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

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare and Medicaid Services

[Document Identifier: CMS-10185]

### Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

**AGENCY**: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and 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 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.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management

and Budget (OMB) the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320. This is necessary to ensure compliance with an initiative of the Administration. CMS does not have sufficient time to complete the normal PRA clearance process. We request this Paperwork Reduction Act clearance under an emergency approval process to meet the statutorily-mandated reporting requirement under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) and to accommodate the operational schedule for the bidding process for prospective and renewing Part D Sponsors. In order to uphold the MMA reporting requirement in conjunction with the bid deadline for contract year 2007, key preceding events must occur. If these events do not occur, prospective and renewing Part D Sponsors will be unable to adjust their bids to reflect compliance with these reporting requirements. Inaccuracies in Part D bids will cause many adverse consequences to Part D Sponsors, their enrolled Medicare beneficiaries, and CMS.

1. *Type of Information Collection Request*: New Collection; *Title of Information Collection*: Medicare Part D Reporting Requirements; *Use*: Data collected via Medicare Part D Reporting Requirements will be an integral resource for oversight, monitoring, compliance and auditing activities necessary to ensure quality provision of the Medicare Prescription Drug Benefit to beneficiaries. Data will be validated, analyzed, and utilized for trend reporting by CMS. If outliers or other data anomalies are detected, CMS will work in collaboration with other CMS divisions for follow-up and resolution. *Form Number*: CMS-10185 (OMB #0938-New); *Frequency*: Reporting: Quarterly and Semi-annually; *Affected Public*: Business or other for-profit; *Number of Respondents*: 3,203; *Total Annual Responses*: 12,812; *Total Annual Hours*: 102,496.

CMS is requesting OMB review and approval of these collections by April 14, 2006, with a 180-day approval period. Written comments and recommendations will be considered from the public if received by the individuals designated below by April 3, 2006.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site