

(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. We cannot reasonably comply with the normal clearance procedures because the regular clearance process will exceed the MMA mandated prescription drug benefit effective date and thereby result in public harm to enrolled Medicare prescription drug beneficiaries.

The Social Security Act as amended by the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) mandates that the prescription drug benefit be available to beneficiaries on January 1, 2006. The conditions under which Medicare Advantage prescription drug plans (MA-PD), private prescription drug plans (PDP) and Fallout Plans/Sponsors receive payment for the Part D drug benefit upon collection of Prescription Drug Event (PDE) data are specified in sections 1860D-15(c)(1)(C), 1860D-15(d)(2) and 1860D-15(f) of the MMA and 42 CFR sections 423.322 and 422.310.

1. Type of Information Collection Request: New Collection; **Title of Information Collection:** Collection of Prescription Drug Data from MA-PD, PDP and Fallout Plans/Sponsors for Medicare Part D Payments and Supporting Regulations in 42 CFR 423.301, 423.322, 423.875, 423.888 and 422.310; **Use:** The MMA requires Medicare payment to Medicare Advantage (MA) organizations, PDP sponsors, Fallbacks and other plan sponsors offering coverage of outpatient prescription drugs under the new Medicare Part D benefit. The Act provided four summary mechanisms for paying plans: Direct subsidies, subsidized coverage for qualifying low-income individuals, Federal reinsurance subsidies and risk corridor payments. In

order to make payment in accordance with these provisions, CMS has determined to collect a limited set of data elements for 100 percent of prescription drug claims or events from plans offering Part D coverage. The transmission of the statutorily required data will be in an electronic format. The information users will be Pharmacy Benefit Managers (PBM), third party administrators and pharmacies and the PDPs, MA-PDs, Fallbacks and other plan sponsors that offer coverage of outpatient prescription drugs under the new Medicare Part D benefit to Medicare beneficiaries. The statutorily required data will be used primarily for payment, claims validation, quality monitoring, program integrity and oversight; **Form Number:** CMS-10174 (OMB#: 0938-NEW); **Frequency:** Monthly, Quarterly and Annually **Affected Public:** Business or other for-profit, and Not-for-profit institutions; **Number of Respondents:** 455; **Total Annual Responses:** 2,418,000,000; **Total Annual Hours:** 4,836.

CMS is requesting OMB review and approval of these collections by *December 19, 2005*, with a 180-day approval period. Written comments and recommendation will be considered from the public if received by the individuals designated below by *December 18, 2005*.

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/regulations/prd> 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.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be mailed and/or faxed to the designees referenced below by *December 18, 2005*: Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850. Fax Number: (410) 786-5267. Attn: Bonnie L Harkless; and, OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 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

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10130, CMS-10164 and CMS 10156]

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: Extension of a currently approved collection; **Title of Information Collection:** Federal Funding of Emergency Health Services (section 1011): Provider Payment Determination and Request for section 1011 On-Call Payments; **Form No.:** CMS-10130 (OMB # 0938-0952); **Use:** Section 1011 of MMA provides that the Secretary will establish a process for eligible providers to request payment. The Secretary must directly pay hospitals, physicians, and ambulance providers (including Indian Health Service, Indian tribe and tribal organizations) for their otherwise unreimbursed costs of providing services required by Section 1867 of the Social Security Act (EMTALA) and related hospital inpatient, outpatient and ambulance services. Payments may be made only for services furnished to

certain individuals described in the statute as: (1) Undocumented aliens; (2) aliens who have been paroled into the United States at a United States port of entry for the purpose of receiving eligible services; and (3) Mexican citizens permitted to enter the United States for not more than 30 days under the authority of a biometric machine readable border crossing identification card (also referred to as a "laser visa") issued in accordance with the requirements of regulations prescribed under a specific section of the Immigration and Nationality Act as published in the Bureau of Customs and Border Protection's interim final rule dated August 13, 2004.; *Frequency*: Other—as needed; *Affected Public*: Business or other for-profit, Not-for-profit institutions, and State, Local or Tribal Governments; *Number of Respondents*: 7,503,000; *Total Annual Responses*: 7,512,000; *Total Annual Hours*: 634,000.

2. *Type of Information Collection Request*: New Collection; *Title of Information Collection*: Electronic Data Interchange (EDI) Enrollment Form and Centers for Medicare and Medicaid Services EDI Registration Form; *Form No.*: CMS-10164 (OMB # 0938-NEW); *Use*: CMS is requiring that providers who wish to conduct Electronic Data Interchange (EDI) transactions, specifically the HIPAA Eligibility Inquiry and Response (270/271) directly with CMS at the Baltimore data center, provide certain information related to their organization and/or organizations conducting EDI business on their behalf. Health care providers, clearinghouses, and health plans that wish to access the Medicare system for the purposes of conducting other EDI business transactions are also required to complete this form. Furthermore, CMS has incorporated changes to the collection as a result of public comments. One specific comment resulted in the combining of the information collected related to Medicare Modernization Act (MMA) section 1011 and Medicare Fee-For Service Part A and Part B. Both programs collect similar information for the purposes of provider enrollment and trading partner profile information related to the exchange of EDI transactions. To further reduce the burden on providers enrolling in either the MMA section 1011 and/or the Medicare Fee-For Service program the CMS-10164 collection will change terms from "Carrier/FI" to "Medicare contractor". The purpose is to generically refer to the organization that CMS contracts with to operate the

specific program function such as MMA section 1011 or Medicare Part A, Medicare Part B for a specific jurisdiction. The information will be used to assure that profile data for those entities that access the section 1011 and/or Medicare system are entered appropriately. *Frequency*: Recordkeeping and Reporting—Other (As-Needed); *Affected Public*: Business or other for-profit, Not-for-profit institutions; *Number of Respondents*: 1,220,000; *Total Annual Responses*: 1,220,000; *Total Annual Hours*: 400,000.

3. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Retiree Drug Subsidy (RDS) Application and Instructions; *Form Number*: CMS'10156 (OMB#: 0938" 0957); *Use*: Under the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 and implementing regulations at 42 CFR subpart R plan sponsors (employers, unions) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% taxfree subsidy for allowable drug costs. In order to qualify, plan sponsors must submit a complete application to CMS with a list of retirees for whom it intends to collect the subsidy; *Frequency*: Quarterly, Monthly, Annually; *Affected Public*: Business or other for-profit, Not-for-profit institutions, Federal, State, local and/or tribal Government; *Number of Respondents*: 50,000; *Total Annual Responses*: 50,000; *Total Annual Hours*: 2,025,000.

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/regulations/prra/>, 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 December 19, 2005. OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: November 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

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10173, CMS-437A and CMS-437B]

Agency Information Collection Activities: Proposed Collection; 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) 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*: New Collection; *Title of Information Collection*: Individuals Authorized Access to the CMS Computer Services; *Form Number*: CMS-10173 (OMB#: 0938-NEW); *Use*: The Centers for Medicare and Medicaid Services (CMS) is requesting the Office of Management and Budget (OMB) approval of the Individuals Authorized to Customer Service Application for Access to CMS Computer Systems. CMS has planned to provide a centralized user provisioning and administration service that supports the creation, deletion, and lifecycle management of enterprise identities. This service creates accounts, supports Role Based Access Control (RBAC), the form flow approval process and enterprise identity audit and recertification, and provides business application integration points. An application integration point allows