

Dated: May 27, 2005.

Alvin Hall,

*Director, Management Analysis and Services
Office, Centers for Disease Control and
Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10014]

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:* Informatics, Telemedicine, and Education Demonstration Project; *Form No.:* CMS-10014 (OMB# 0938-0806); *Use:* The Informatics, Telemedicine and Education Demonstration Project studies the use of advanced computer and telecommunication technology in the collection of data for diabetes management. It aims to demonstrate the feasibility of a large-scale web-based system for electronic delivery of health care services that complies with the data security requirements of the Health Insurance Portability and Accountability Act (HIPAA); assesses impacts of telemedicine on the process of care for Medicare beneficiaries with diabetes; assesses impacts on diabetes related health outcomes; and assesses

the cost-effectiveness of the telemedicine intervention. The information collection seeks approval for an extension as the demonstration project enters Phase 2. Phase 2 of the project employs new advanced technologies to reduce the public burden associated with the information collection, while maintaining, to the extent possible, continuity of design, eligibility criteria, recruitment and enrollment, intervention, and data collection procedures already established in Phase 1. *Frequency:* Semi-Annually; *Affected Public:* Business or other not-for-profit, Individuals or households; *Number of Respondents:* 4,100; *Total Annual Responses:* 7,094; *Total Annual Hours:* 12,379.

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.

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: Christopher Martin, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: May 27, 2005.

Michelle Shortt,

*Acting 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-838 and CMS-10148]

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:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Credit Balance Reporting Requirements and Supporting Regulations in 42 CFR 405.371, 405.378, and 413.20; *Form Nos.:* CMS-838 (OMB # 0938-0600); *Use:* Section 1815(a) of the Social Security Act authorizes the Secretary to request information from providers which is necessary to properly administer the Medicare program. Quarterly credit balance reporting is needed to monitor and control the identification and timely collection of improper payments. The reporting requirements provide CMS with the authority to impose sanctions such as the suspension of program payments in accordance with 42 CFR 413.20(e) and 405.371 if providers do not report credit balances on a timely basis. Furthermore, once a credit balance has been identified on an 838 and demand for payment is made, CMS has the authority to charge interest if the amount is not repaid within 30 days in accordance with 42 CFR 405.378. The collection of credit balance information is needed to ensure that millions of dollars in improper program payments are collected. Approximately 48,300 health care providers will be required to submit a quarterly credit balance report that identifies the amount of improper payments they received that are due to Medicare. The intermediaries will monitor the reports to ensure these funds are collected; *Frequency:* Quarterly; *Affected Public:* Not-for-profit institutions, Business or other for-profit; *Number of Respondents:* 48,300; *Total Annual Responses:* 193,200; *Total Annual Hours:* 579,600.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* HIPAA Administrative Simplification Non-Privacy Enforcement; *Form Nos.:* CMS-10148 (OMB # 0938-0948); *Use:* The

Health Insurance Portability and Accountability Act (HIPAA) became law in 1996 (Pub. L. 104-191). Subtitle F of Title II of HIPAA, entitled "Administrative Simplification," (A.S.) requires the Secretary of Health and Human Services to adopt national standards for certain information-related activities of the health care industry. The HIPAA provisions, by statute, apply only to "covered entities" referred to in section 1320d-2(a)(1) of this title. Responsibility for administering and enforcing the HIPAA A.S. Transactions, Code Sets, Identifiers and Security Rules has been delegated to the Centers for Medicare & Medicaid Services; *Frequency*: Reporting—On occasion; *Affected Public*: Business or other for-profit, Individuals or Households; Not-for-profit institutions, Federal Government, and State, Local or Tribal Government; *Number of Respondents*: 500; *Total Annual Responses*: 500; *Total Annual Hours*: 500.

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/prs/>, 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.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice to the address below: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: William N. Parham, III, PRA Analyst, Room C5-13-27, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: May 27, 2005.

Michelle Shortt,

Acting 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-10156]

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

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 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. We cannot reasonably comply with the normal clearance procedures because the normal procedures are likely to cause a statutory deadline to be missed. It is critical that the Medicare Retiree Drug Subsidy (RDS) applications be available to plan sponsors on August 1, 2005 in order for there to be enough time for the RDS Center to process the applications.

Under Section 1860D-22 of the Social Security Act, added by the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and implementing regulations at 42 CFR

423.880 plan sponsors (employers, unions etc.) who offer prescription drug coverage to their qualified covered retirees are eligible to receive a 28% tax-free subsidy for allowable drug costs. Plan sponsors must submit a complete application to CMS in order to be considered for the RDS program.

CMS is requesting OMB review and approval of this collection by July 4, 2005, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below by July 3, 2005.

Type of Information Collection

Request: New Collection.

Title of Information Collection:

Retiree Drug Subsidy (RDS) Application and Instructions.

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% tax-free 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.

Form Number: CMS-10156 (OMB#: 0938-NEW).

Frequency: Quarterly, Monthly, Annually.

Affected Public: Business or other for-profit, Not-for-profit institutions, Federal Government, and State, Local 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 the proposed paperwork collections referenced above, access CMS' Web Site address at <http://www.cms.hhs.gov/regulations/prs/> 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 July 3, 2005:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Room C5-13-27, 7500 Security Boulevard, Baltimore, MD 21244-1850. Fax Number: (410) 786-