

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:* 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/regulations/pral/>, 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 February 21, 2006. CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development—C, Attention: Bonnie L Harkless, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: December 13, 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 R-193 and CMS-2567]**

#### Agency Information Collection Activities: Submission for OMB Review; 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), 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:* Important Message from Medicare Title XVII Section 1866(a)(1)(M), 42 CFR Sections 466.78, 489.20, and 489.27; *Form Number:* CMS-R-193 (OMB#: 0938-0692); *Use:* Hospitals participating in the Medicare program are required to distribute the "Important Message From Medicare" to all Medicare beneficiaries (including those enrolled in a Medicare

managed care health plan). Hospitals must distribute this notice at or about the same time of a Medicare beneficiary's admission or during the course of his or her hospital stay. Receiving this information will provide all Medicare beneficiaries with some ability to participate and/or initiate discussions concerning actions that may affect their Medicare coverage, payment, and appeal rights in response to a hospital's or Medicare managed care plan's notification that their care will no longer continue; *Frequency:* Recordkeeping and Reporting—Other: Distribution; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit institutions, Federal, State, Local or Tribal Government; *Number of Respondents:* 6,051; *Total Annual Responses:* 12,500,000; *Total Annual Hours:* 208,333.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Statement of Deficiencies and Plan of Correction contained under 42 CFR 488.18, 488.26, and 488.28; *Form Number:* CMS-2567 (OMB#: 0938-0391); *Use:* Section 1864(a) of the Social Security Act requires that the Secretary use State survey agencies to conduct surveys. The surveys are used to determine if health care facilities meet Medicare, Medicaid, and Clinical Laboratory Improvement Amendments (CLIA) participation requirements. The Statement of Deficiencies and Plan of Correction form, is used to record each deficiency discovered during an inspection. Providers, suppliers and CLIA laboratories also utilize this form to outline a corrective action plan for each deficiency. The States and CMS regional offices use this form to document and certify compliance, and to disclose information to the public; *Frequency:* Recordkeeping, Third party disclosure and Reporting—Annually and Biennially; *Affected Public:* Business or other for-profit, Not-for-profit institutions, Federal, State, Local or Tribal Government; *Number of Respondents:* 60,000; *Total Annual Responses:* 60,000; *Total Annual Hours:* 120,000.

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/pral/>, 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 by the OMB Desk Officer at the address below, no later than 5 p.m. on January 23, 2006. OMB Human Resources and Housing Branch, Attention: Carolyn Lovett, CMS Desk Officer, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: December 14, 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

[CMS-9033-N]

#### Medicare and Medicaid Programs; Quarterly Listing of Program Issuances—July Through September 2005

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice lists CMS manual instructions, substantive and interpretive regulations, and other **Federal Register** notices that were published from July 2005 through September 2005, relating to the Medicare and Medicaid programs. This notice provides information on national coverage determinations (NCDs) affecting specific medical and health care services under Medicare. Additionally, this notice identifies certain devices with investigational device exemption (IDE) numbers approved by the Food and Drug Administration (FDA) that potentially may be covered under Medicare. This notice also includes listings of all approval numbers from the Office of Management and Budget for collections of information in CMS regulations. Finally, this notice includes a list of Medicare-approved carotid stent facilities.

Section 1871(c) of the Social Security Act requires that we publish a list of Medicare issuances in the **Federal Register** at least every 3 months. Although we are not mandated to do so by statute, for the sake of completeness of the listing, and to foster more open and transparent collaboration efforts, we are also including all Medicaid issuances and Medicare and Medicaid

substantive and interpretive regulations (proposed and final) published during this 3-month time frame.

**FOR FURTHER INFORMATION CONTACT:** It is possible that an interested party may have a specific information need and not be able to determine from the listed information whether the issuance or regulation would fulfill that need. Consequently, we are providing information contact persons to answer general questions concerning these items. Copies are not available through the contact persons. (See Section III of this notice for how to obtain listed material.)

Questions concerning items in Addendum III may be addressed to Timothy Jennings, Office of Strategic Operations and Regulatory Affairs, Centers for Medicare & Medicaid Services, C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-2134.

Questions concerning Medicare NCDs in Addendum V may be addressed to Patricia Brocato-Simons, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-0261.

Questions concerning FDA-approved Category B IDE numbers listed in Addendum VI may be addressed to John Manlove, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1-13-04, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-6877.

Questions concerning approval numbers for collections of information in Addendum VII may be addressed to Bonnie Harkless, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Centers for Medicare & Medicaid Services, C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-5666.

Questions concerning Medicare-approved carotid stent facilities may be addressed to Sarah J. McClain, Office of Clinical Standards and Quality, Centers for Medicare & Medicaid Services, C1-09-06, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-2994.

Questions concerning all other information may be addressed to Gwendolyn Johnson, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Centers for Medicare & Medicaid Services, C5-14-03, 7500 Security Boulevard, Baltimore, MD 21244-1850, or you can call (410) 786-6954.

## SUPPLEMENTARY INFORMATION:

### I. Program Issuances

The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the Medicare and Medicaid programs. These programs pay for health care and related services for 39 million Medicare beneficiaries and 35 million Medicaid recipients. Administration of the two programs involves (1) furnishing information to Medicare beneficiaries and Medicaid recipients, health care providers, and the public and (2) maintaining effective communications with regional offices, State governments, State Medicaid agencies, State survey agencies, various providers of health care, all Medicare contractors that process claims and pay bills, and others. To implement the various statutes on which the programs are based, we issue regulations under the authority granted to the Secretary of the Department of Health and Human Services under sections 1102, 1871, 1902, and related provisions of the Social Security Act (the Act). We also issue various manuals, memoranda, and statements necessary to administer the programs efficiently.

Section 1871(c)(1) of the Act requires that we publish a list of all Medicare manual instructions, interpretive rules, statements of policy, and guidelines of general applicability not issued as regulations at least every 3 months in the **Federal Register**. We published our first notice June 9, 1988 (53 FR 21730). Although we are not mandated to do so by statute, for the sake of completeness of the listing of operational and policy statements, and to foster more open and transparent collaboration, we are continuing our practice of including Medicare substantive and interpretive regulations (proposed and final) published during the respective 3-month time frame.

### II. How To Use the Addenda

This notice is organized so that a reader may review the subjects of manual issuances, memoranda, substantive and interpretive regulations, NCDs, and FDA-approved IDEs published during the subject quarter to determine whether any are of particular interest. We expect this notice to be used in concert with previously published notices. Those unfamiliar with a description of our Medicare manuals may wish to review Table I of our first three notices (53 FR 21730, 53 FR 36891, and 53 FR 50577) published in 1988, and the notice published March 31, 1993 (58 FR 16837). Those desiring information on the Medicare NCD Manual (NCDM, formerly the Medicare